Promoting Academic Research Conversion to Enterprise (PACE)

Complete Scheme Document including Proposal Submission, Evaluation and Review Guidelines



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Promoting Academic Research Conversion to Enterprise (PACE)

1. **Introduction**

Biotechnological research and development in India is largely carried out by academic institutions (universities/research organizations) and to some extent by industry (mostly large companies). By virtue of their strong infrastructure & technical capability academic/research establishments are mandated to research on variety of problems of national importance and societal relevance. Also, unlike industry, research by academia is not governed by commercial gains alone thus allowing them to work on problems involving even high degree of risk.

To encourage/ support academia to develop and validate technology and/or IP into viable products or services, BIRAC has launched **PACE** (**Promoting Academic Research Conversion to Enterprise**).

2. PACE Scheme aims to

- To encourage/support academic collaborations
- For development of products and technologies up to proof of concept
- For validation of products /technologies towards commercialization
- stimulate technological innovation

The PACE scheme has two components as below:

(A) Academic Innovation Research (AIR):

The objective of Academic Innovation Research (AIR) scheme is to promote development of Proof-of-concept (PoC) for a process/ product by academia with or without the involvement of collaborator.

- > Types of projects to be supported: Projects with well-established proof-of-principle leading to development of prototype of a product /technology of national relevance or commercial potential. Basic/exploratory research, projects without well-established Proof of principle or with no or low commercial potential will not be supported)
- ➤ **Duration of project**: up to 18 months (BIRAC's Technical Expert Committee at its discretion may recommend for increased duration of the project depending upon the nature of the research study)
- Funding Support (Grant): Total cost of the project must not exceed Rs. 50 lakhs (Non-recurring cost must not exceed 10% of the total cost)
- ➤ **IPR**: IP rights may be with academia alone, or jointly shared between academia and industry (if academia establishes PoC with industry) as per the understanding between the two partners.

(B) Contract Research Scheme (CRS):

Contract Research Scheme (CRS) aims at validation of a process or prototype (developed by the academia) by the industrial partner

Principles of the Scheme:

- ➤ The Contract research gives opportunity for validating academic technologies would have the following principles. Applicants will provide the Proof-of-Concept (POC)/leads to the industry which in turn would validate it functionally.
- The study/validation proposed for the CRS scheme should provide sufficient data and evidence as its outcome and should be able to move forward towards scale up/validation/Product Development and may fall under the following categories but not limited to:
 - Exploratory validation of technology i.e. creation of a prototype or moving the lab scale level quantity to a batch level quantity for validation.
 - Small scale contract research, resulting in generating several batches of process or creation of multiple prototypes to engage in comparative evaluation and process refinement while fixing standard parameters.
 - Large scale validation, which augmenting the prototype to commercial design in case of design related research or moving the process parameters to optimized process efficiency that can be accomplished in commercial batch size in any of the biotech sector.
- The requirements of the Academic groups for some specific research assistance from the industry such as toxicology studies, gene sequencing, studies using specific industrial equipment etc. forming a part of validation of PoC could also be supported under this scheme.
- For the research support there should be a clear justification for services to be outsourced. The competence of the identified company in conducting such services should be highlighted along with the details of facilities available.
- ➤ These services should be undertaken after executing necessary Agreement/ MOU that will govern the scope including Non-Disclosure, Material Transfer, and Intellectual Property etc. as required between the academia and the Company
- **Duration of the project:** No time limit
- Funding Support (Grant): Funding in the form of grant is provided to both academic as well as industrial partners. While funding is provided to the academia for In-House research which forms a part of validation of the Proof of Concept, funds are provided to the industrial partner for validation. There is no ceiling to the funding.

- Non-recurring cost is not allowable for collaborator.(company)
- ➤ IPR: Although the IP rights reside with the academia, the industry partner has first right of refusal for commercial exploitation of the New IP. The first right of refusal will be accompanied with an undertaking that its business strategy encompasses possibility of commercialization of the present technology under validation.
- Applicant should be the owner of the background IP. The applicant cannot submit the proposal with in-licenses technology/ IP of the recognized incubation facility

How to apply?

Proposals under AIR or CRS are required to be submitted online only. For submission of proposals, Institutions need to register with BIRAC through "Institution User Registration". Additional information on user registration and proposal submission is available online at BIRAC website at www.birac.nic.in.

3. Eligibility

Academic Institute, University, NGO or Research Foundation, registered/accredited by a government body can apply either alone, or in partnership with academia or industry (while involvement of industry is optional for AIR Scheme, it is mandatory to have an industrial partner for CRS)

Under the scheme, academia (Public or Private Institute, University, NGO, Research Foundation or trust/society), National research laboratories having a well-established support system for research shall be the primary applicant. The PI has to be a permanent facility of the applicant entity. It applicant can apply either:

- 1. Individually, or
- 2. Jointly with academic and/or industrial partner

Eligibility Criteria for academia:

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.

Eligibility Criteria for Industrial partner can be following:

- 1. Company incorporated under the Companies Act, 2013 or
- 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. Participating companies should have adequate in-house facility to address the project implementation aspects (which shall be evaluated during the site visit) OR Incubated with any of the recognized Incubation Facility)

Ineligibility:

- Applicant 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 3 calls (1 year) unless the withdrawal was due to papers not being ready.
- Proposals submitted in collaboration with companies defaulting on repayment of loan or are irregular with regard to repayment of instalments to BIRAC would be considered ineligible

4. **Proposal Submission**

How and when to submit proposal?

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

- Log on the BIRAC website http://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 PACE link.
- Click on the PACE 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 PACE User Guide available on the website.

Academic User Registration is open when the call is active.

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 DBT and BIRAC websites)

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

5(A) Evaluation and Decision Making for AIR Scheme

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.
- The PI has to be a permanent facility of the applicant entity
- Presentation of technically sound projects recommended by the ARP to the Technical Expert Committee (TEC), comprising eminent scientists from all over the country
- Expert Review, wherever required
- Final review by TEC and the decision for funding will be taken by the Technical Expert Committee only.
- Role and Responsibility of the Reviewer and Expert Member

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

- Initial Peer Review- Area Review Panel (ARP)
- Technical Screening Committee
- There are different subject specific "Scientific/Technical Evaluation Panels" for each of the areas viz; Agriculture, (Field trails, Transgenics, Marker assisted Selection, Molecular Biology, RNAi and Tissue Culture) Healthcare, (clinical trials, molecular Biology preclinical Diagnostics, Oncology, vaccines biosimilars and biological), Bio medical devices and instruments, Bioenergy, Bioinformatics and computational, Environmental biotechnology, formulation development Industrial products and processes, New drug discovery, development and nutraceuticals.
- Reviewers are senior scientists/ experts in the relevant subject area and each reviewer signs a no- conflict and confidentiality certificate while accepting to be associated with the review process.
- The Reviewers 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:

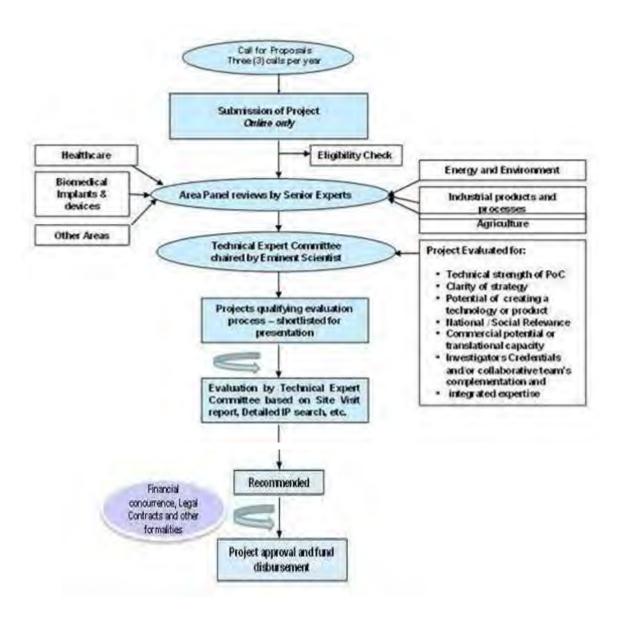
- a. Technical strength of PoC
- b. Clarity of Lead Present
- c. Potential of creating a technology or producer
- d. National / Social Relevance
- e. Commercial potential or translational capacity
- f. Investigators Credentials and collaborative teams' complementation.
- g. Integrated expertise

- 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 academia and partnering company to carrying out the proposed research
 - d. Relevance of project deliverable as commercially viable product/process
 - e. Any other relevant aspect

In addition to above parameters, following factors shall also be given due consideration:

Overall success of the earlier projects in terms of accomplishment of all the sanctioned milestones.

Operational mechanism-AIR



5(B) Evaluation and Decision Making for CRS Scheme

The process of evaluation under the CRS scheme broadly comprises the following steps:

- Peer Review by a Panel of area-specific experts called as Area Review Panels (ARPs) created for evaluation.
- The PI has to be a permanent facility of the applicant entity
- 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 in CRS comprising Senior Technical Experts of members from various ministries and Government departments.
- Role and Responsibility of the Reviewer and Expert Member

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

- Initial Peer Review- Area Review Panel (ARP)
- Technical Screening Committee
- Site visit and Due Diligence (Technical & Financial).
- Apex Committee
- There are different subject specific "Scientific/Technical Evaluation Panels" for each of the areas viz; Agriculture, (Field trails, Transgenics, Marker assisted Selection, Molecular Biology, RNAi and Tissue Culture) Healthcare, (clinical trials, molecular Biology preclinical Diagnostics, Oncology, vaccines biosimilars and biological), Bio medical devices and instruments, Bioenergy, Bioinformatics and computational, Environmental biotechnology, formulation development Industrial products and processes, New drug discovery, development and nutraceuticals. Reviewers are senior scientists / experts in the relevant subject area and each reviewer signs a no- conflict and confidentiality certificate while accepting to be associated with the review process.
- The Reviewers 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 Lead Present.
 - c. Potential of creating a technology or producer.
 - d. National / Social Relevance.
 - e. Commercial potential or translational capacity.
 - f. Investigators Credentials and collaborative teams' complementation
 - g. Integrated expertise
 - h. Adequacy of CRO infrastructure
- 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

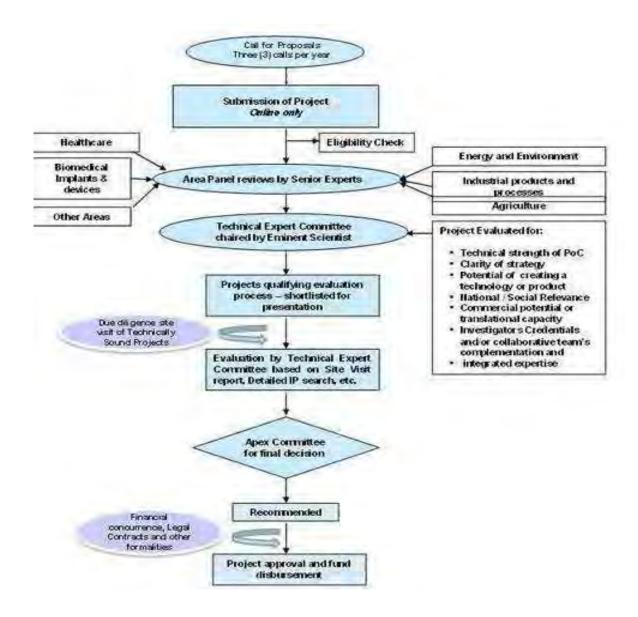
evaluations of the reviewers are then discussed by the Technical Expert Committee (TEC). The coordinator of each of the Review Panel would serve as the moderator for that area and would discuss and normalize scores for the proposals for which there is a significant variation in the scores allotted by 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 academia and partnering company to carrying out the proposed research
- d. Relevance of project deliverable as commercially viable product/process
- e. Adequacy of CRO infrastructure (for only CRS projects)
- f. Any other relevant aspect

In addition to above parameters, following factors shall also be given due consideration:

Overall success of the earlier projects in terms of accomplishment of all the sanctioned milestones.

Operational Mechanism-CRS



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.

Confidentiality and Transparency

• An effort has been made to ensure complete transparency in the proposal submission and evaluation. An important feature of the PACE 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 expert is clearly made aware of the following governing terms of the process;
- "BIRAC receives applications under PACE 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."
- **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—e.g. as an applicant for funding or as the supervisor of an applicant;
- membership/ Directorship of a Panel member in an organization 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 organization 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**

This scheme provides for BIRAC contribution of up to 100% of project cost. The support to the academia / public sector will be given as Grant-in-aid for the research.

- a. The approved funds would be released by BIRAC to the applicant academia and the proposed Collaborator (if any) in instalments.
- b. Non-recurring cost is not allowable for collaborating Industry partner under CRS.
- c. There would no provision for overheads under the Recurring Budget head.
- d. The manpower salaries should be strictly as per the prevailing DST norms for Academic organizations.
- e. The fund disbursement is milestone based and is released in 5 instalments.

The Applicant and the Proposed Partner can specify their quantum percentage and their corresponding milestones. The funds will be disbursed to them separately subject to the achievement of milestone and reporting of progress.

S.No.	Milestone	Quantum of fund release
1.	1st Instalment on signing of Contract	(30% of BIRAC contribution)
2.	2nd Instalment on completion of 1st Milestone	(20% of BIRAC contribution)
3.	3rd Instalment on completion of 2nd Milestone	(20% of BIRAC contribution)
4.	4th Instalment on completion of 3rd Milestone	(20% of BIRAC contribution)
5.	5th Instalment on Submission of Report	(10% of BIRAC contribution)

f. For duration less than 18 months the fund disbursement is released in 4 installments as per number of sanctioned milestones. Guidelines for Disbursement of Funds may also be seen at Fund Disbursement

S. No.	Milestone	Quantum of fund release
1.	1st Instalment on signing of Contract	(30% of BIRAC contribution)
2.	2nd Instalment on completion of 1st Milestone	(30% of BIRAC contribution)
3.	3rd Instalment on completion of 2nd Milestone	(30% of BIRAC contribution)
4.	4 th Installment on Submission of Report	(10% of BIRAC contribution)

7. Project Monitoring & Mentoring

The projects under PACE 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;

- 1. Monitor the progress of the Project in conformity with the outputs, milestones, targets and objectives is contained in the Agreement.
- 2. Based on the foregoing, to assess and recommend:
 - a. the release of next instalment or part release thereof by the BIRAC.
 - b. revision of project duration

- c. closing or dropping or modifying any of the components of the Project, within the overall approved objectives, budget and time-frame,
- d. inclusion of additional industrial/institutional partner(s), if the applicant requests involvement of such partner(s), in the overall interest of the Project,
- e. mentor(s) to overcome any technological problem faced in the Project implementation; and
- f. Revision of the financial assistance.
- 3. To advise on issues related to securing of IPR; and
- 4. 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 AIR Scheme.

ii. Reporting of Progress:

- 1. On Successful completion of each monitorable Milestone the primary Academic applicant and other Partners (including academia well as company) are required to submit a detailed Milestone Completion Report (MCR) as per prescribed format.
- 2. The MCR is assessed by the PMC for its completion. On recommendation of the PMC, the next Milestone budget is released.
- 3. Each partner has to submit a Statement of Expenditure for the Budget available for the specific milestone being reported upon.
- 4. Format for Milestone Completion Report (MCR), Utilization Certificate and Statement of Expenditure will be made available as per requirement.

9. Foreclosure and Termination

- In case, during the tenure of the Project, 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 Institute and the Company shall immediately refund any grant-in- aid unutilized out of BIRAC's disbursements, along with detailed accounts of funds received, utilized and unutilized. If the Institute and the Company like to continue the CRS-Proposal Submission, Evaluation and Review Guidelines
- Project at its own cost, it would be able to do so without restrictions from BIRAC after complying with these provisions. The Institute and/or the Company 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 to "the Institute and/or the Company" 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. The Institute and/or the Company shall be liable to return immediately the amount of grant-in-aid already availed of from BIRAC with simple interest at the rate of 12 (twelve) per cent per annum 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.

10. 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) or any other financial/technical document by the Institute/company 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.

11. 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.

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:
- A letter of authorization by the Head of the Academia for acceptance of the Grant-in-Aid under both AIR and CRS.
- Board Resolution form the Company for acceptance of the Grant-in-Aid under CRS. Opening up a No-Lien Account with a scheduled/ nationalized Bank for company under CRS

12 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. <u>Use of BIRAC logo is not permitted without written approval.</u>

All the above tools and instruments may be seen at:

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

Contact/ Query/Information

Further information can be obtained at

• BIRAC Website: <u>www.birac.nic.in</u>

• **Contact Person:** GM & Head - Investment, BIRAC;

Email: investment.birac@gov.in

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