

Contract Research and Services Scheme
*(A scheme to take forward the research lead of Academia through validation
and translation by Industry)*

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



CRS-Proposal Submission, Evaluation and Review Guidelines

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1. Introduction

Contract Research/Service Scheme (CRS) in the Biotechnology Sector would facilitate the academia-industry interaction and to take forward the research leads of Academic Universities and Research Institutes through validation and translation by industry. This scheme would enable the lab scale technology of the academia to reach the commercial scale along with the industry under a specific contract and fee structure

i. What is CRS

Numerous lab scale research leads have been/are being generated in the academic sector through funding from various agencies like DBT, CSIR, DST, DRDO etc., which have the potential for validation and translation into products. Currently the academia is capable of limited translational research; however, product development is generally not a part of their mandate. Moreover, they may not have the required infrastructure to take on product development and commercialization activity. It is, therefore, important to take the industry on board to validate such research leads for pilot studies through Contract Research Agreements.

- a. The scheme specifically involves supporting the Proof of Concept with translational attributes. Exploratory Research or fundamental discovery not having commercial potential will be discouraged. In many cases, if the Academic group requires some specific services from the industry which form a part of validation of the PoC could also be supported under this scheme.
- b. For all purposes, the term academia refers to the eligible applicants from academic sector (research institutes, universities, public funded research laboratories, governmental organizations, research foundations involved in research and education).

ii. Principles of the Scheme

The contract research and service opportunity for validating academic technologies would have the following principles.

a. Contract Research

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.

b. Contract Service

The requirements of the Academic groups for some specific services 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 contract service 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.

c. Parameters for Evaluation

- Data analysis and data generation approaches with detailed description of the ability in generating reliable data
- Facilities for carrying out contract research in detailed description and key resources available or accessible
- Nature and form of contract research results that will be provided as tangible output as well as analytical results
- Competency of research team, in addition to the core researchers, technicians and process specialists.
- Reflection of cost structure with associated deliverables.

2. Eligibility

Public and/or Private Universities and Research Institutes can apply under the Contract Research Scheme with pre-determined company partner having a DSIR recognized R&D unit.

i. Eligibility for Participating Academia

Any Public and/or Private Institute or University having a well-established research support system, for basic or applied research and education is eligible under this scheme. A registration/recognition/ accreditation/ certification from a government body is mandatory.

ii. Eligibility for Collaborating Company

Only Indian Company (ies), registered under the Indian Companies Act 1956 with at least 51% Indian shareholding and having DSIR* recognised in-house R&D unit, which is interested to perform such a contract research service with academic partner.

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

iii. Eligibility of Leads

The proposal from academia should come with pre-existing scientifically established *proof of concept* and should propose the specific research and validation/translation process to be performed by a company partner within a specific time frame.

3. Proposal Submission

i. 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 2 calls are advertised each year. Process for submitting the proposals online is detailed below:

- Log on the BIRAC website www.birac.nic.in)
- If you are a registered user, log-in using the credentials, else you need to register your institution with by clicking on New User Registration.
- In case of new user registration, a computer generated password would be sent to the email-id provided at the time of registration. The password can be changed later.
- Once you login, you would be navigated to the page displaying CRS link.
- Click on the CRS 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 CRS User Guide available on the website.

Academic 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 DBT and BIRAC websites)

ii. Details on How to submit a proposal are available in the CRS User Guide (Annexure I)

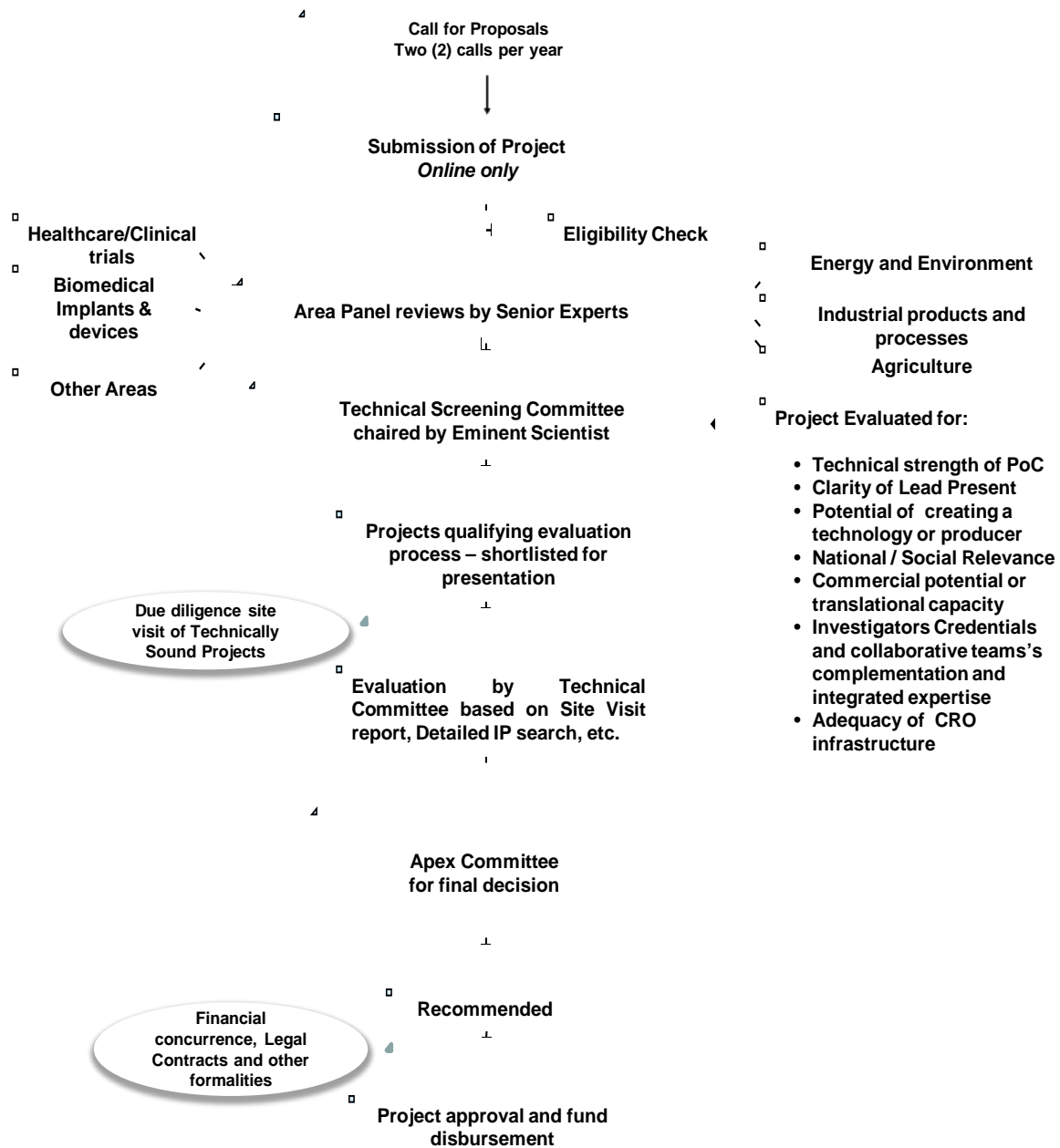
Information can also be obtained on

http://birac.nic.in/uploads/new_crs_guide.pdf

iii. Performa for Submission of Proposal may be seen at

http://birac.nic.in/uploads/new_crs_prof.pdf

CRS – Operational Mechanism



Process of Evaluation / Decision Making takes 4-6 months. Decision is conveyed at each stage.

4. Evaluation and Decision Making

- *Process of Evaluation*

The process of evaluation broadly comprises the following steps:

- Peer Review by a Panel of area-specific experts called as Area Review Panels (ARPs) created for evaluation.
- Presentation of technically sound projects recommended by the ARP to the Technical Screening Committee (TSC), comprising eminent scientists from all over the country
- Site Visit for the projects shortlisted by the TSC
- Expert Review, wherever required
- Final review by TSC and scrutiny and decision by the Apex Committee comprising Senior Technical Experts of members from various ministries and Government departments

- Role and Responsibility of the Reviewer and Expert Member

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

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

- Guidelines for Reviewers and Panel Members

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

- Initial Peer Review- Area Review Panel (ARP)
- Technical 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 trials, Transgenics, Marker assisted Selection, Molecular Biology, RNAi and Tissue Culture) Healthcare, (clinical trials, molecular Biology preclinical Diagnostics,Oncology, vaccines biosimilars and biologicals), Bio medical devices and instruments, Bioenergy, Bioinformatics and computational, Environmental biotechnology, formulational 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's complementation and
- 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 Screening Committee (TSC). 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 Screening Committee (TSC) 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
- f. Any other relevant aspect

Each is ranked as high, medium and low.

Evaluation Formats are at Annexure II

These may also be seen at

http://birac.nic.in/uploads/tech_eval.pdf

5. 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 CRS 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 CRS 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.

No Conflict of Interest and Confidentiality form is at Annexure III

These may also be seen at

http://birac.nic.in/uploads/Cond_conf.pdf

6. Funding, Cost Sharing & IP Management

This scheme provides for BIRAC contribution of up to 100% of project cost. The grant-in-aid by BIRAC to the academia / public sector will be given as Grant-in-aid for the research, if any required to be done. The validation and contract research and service component to be conducted by Company Partner will be funded as Grant-in-aid. The project will be assessed as per defined set of criteria mentioned below and ranked as high, medium or low by the Technical Committee.

The Apex Committee recommendations will be based on the Technical Committee's Evaluation and more specific scrutiny of the following aspects:

- a. National importance/societal relevance of the problem being addressed by the present proposal.
- b. Clarity of the proof-of-concept/ lead and its sufficiency to support the project
- c. Potential for creation of a product/ technology/ Commercial potential / translational capability
- d. Presence of complementary and integrated expertise between the Applicant and the proposed Partner.

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- e. Adequacy of equipment and other resources available in-house with the Applicant and the proposed Partner.
- f. Level of risk and the strategy to mitigate and manage them.
- g. The approved funds would be released by BIRAC to the applicant academia and the participating industry in instalments.
- h. 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.

Guidelines for Disbursement of Funds may also be seen at

<http://birac.nic.in/uploads/Disbursement.pdf>

S.No.	Milestone	Quantum of fund release
1.	1st Instalment on signing of Contract	shall not exceed 30% of the approved funds to the Applicant and the proposed Partner cumulatively.
2.	2nd Instalment on completion of 1st Milestone	shall not exceed up to 50% of the approved funds (including the 1st instalment) to the Applicant and the proposed Partner cumulatively.
3.	3rd Instalment on completion of 2nd Milestone	shall not exceed up to 70% of the approved funds (including the previous two instalments) to the Applicant and the proposed Partner cumulatively.
4.	4th Instalment on completion of 3rd Milestone	shall not exceed up to 90% of the approved funds (including the previous three instalments) to the Applicant and the proposed Partner cumulatively.
5.	5th Instalment on Submission of Report	Remaining of the funding% or remaining 10% of the approved funds to the Applicant and the proposed Partner cumulatively.

7. Foreclosure and Termination

- i. 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 Project at its own cost, it would be able to do so without restrictions from BIRAC after complying with these provisions.

- ii. 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.

8. Sharing of benefits (IP)

i. Background IP Rights:

All rights, title and interest in or to any information, data, reports, documents, procedures, forecasts, technology, know-how, and inventions, including any patents, designs, copyrights, trademarks and any applications for patents, designs, copyrights or trademarks, in India and anywhere else in the world, that are owned by or vest in any Party before execution of this Agreement ("Background IP") shall remain the property of such Party.

ii. New IP:

For the purpose of CRS, New IP means intellectual property generated during the conduct of the Project by the Institute and the Company excluding the intellectual property generated by the Institute before execution of this Agreement and any New IP generated by the Institute and the Company outside the scope of this Agreement even during the term of this Agreement. All rights, title and interest in New IP in India and anywhere else in the world, shall be owned by or vest in the applicant academia.

- i. The collaborating Company will have the first right of refusal with regard to the commercial exploitation of the New IP unless agreed otherwise between the parties.
- ii. Any other governing terms related to aspects of New IP, Technology transfer, licensing arrangements and/or profit sharing shall be determined by the Institute and the Company after BIRAC approval and will be in the manner as set out in the Memorandum of Understanding/ Agreement between the Academia and the Company.
- iii. The fund recipients will not publish in any manner with regard to the results of the Project which will be in derogation to the creation and protection of IP and related rights as stated above.

- iv. The BIRAC through its IP cell will work closely with Academic and Industry Partners to assist in the FTO analysis and to ensure that all necessary patents of the background and new IP are well protected.

9. Project Monitoring & Mentoring

i. Project Monitoring Committee (PMC)

The projects under CRS 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 CRS Scheme.

ii. Reporting of Progress:

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

10. 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.

11. Terms & Conditions and Requisites for Fund Disbursement

i. Agreement of funding

On announcement of Award, all concerned applicants need to sign an Agreement for Funding with BIRAC.

Agreement Templates:

a. Template for Grant (BIRAC +Institute+ Company)

b. Confidentiality Disclosure Conflict Interest Agreement

c. Material Transfer Agreement

ii. 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 and A Board Resolution form the Company Partner for acceptance of the Grant-in-Aid under CRS. **Opening up a No-Lien Account with a scheduled/nationalized Bank**

All the above tools and instruments will be made available as per requirement:

Contact Information

Further information can be obtained at

BIRAC Website: www.birac.nic.in

Contact Person

Dr Amita Joshi

Programme Manager

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BIRAC

Email: ajoshi.birac@nic.in; biraccrs.dbt@nic.in