ANNEXURE-I

Eligibility Criteria/Regulatory and Ethical Considerations

PARTICIPANTS FROM INDIA

The participating entities/organisations from India have to be a legal entity as per Indian law (Indian applicants).

The Indian entities eligible to participate include:

- Government of India supported or recognised (Public or Private) academia; research; organisations and urban or other local bodies;
- Government of India recognised not-for-profit, NGO(s)/ VO(s)/ Trust(s)/ Research foundations, having research as one of the imperative mandates;
- Indian Industry can be a partner in the consortium and are eligible for funding subject to fulfilment of DBT's technical, administrative and financial norms.

ELIGIBILITY CRITERIA

Academic/Research Partners:

- Public and/or private universities and research organisations must have a well established research support system, for basic or applied research; and
- Submission of proof of establishment under Indian statue; recognition documents and registration at Government of India's Public Finance Management System (PFMS) - https://pfms.nic.in shall be obligatory.

NGO(s)/VO(s)/Trust(s)/Research Foundations:

- The Indian private R&D performing institutions and Not-for-profit, NGO(s)/ VO(s)/ Trust(s)/ Research foundations should have experience of at least 3 years in scientific research, teaching, training and extension activities; and must follow research as one of the mandates;
- Proof of registration at 'NGO DARPAN' of NITI Aayog (http://ngodarpan.gov.in/), Certificate of registration under Society Registration Act, Firm's Memorandum of Association, Registration at Government of India's Public Finance Management System (PFMS) (https://pfms.nic.in), Valid SIRO certificate for firm's in-house R&D recognition and audited account statements for the past three years shall be obligatory.

Industry Partners:

- Should be an Indian Company registered under the Companies Act, wherein 51% (or more) of the ownership/shareholding/partnerships shall be held by resident Indian citizen(s); should be complying with General Financial Rules (GFR), 2017; and
- Submission of Certificate of Incorporation issued under Companies Act, Valid SIRO certificate for firm's in-house R&D recognition, Exemption Certificate (as applicable), Firm's Memorandum of Association, registration at Government of India's Public Finance Management System (PFMS) (https://pfms.nic.in) and Audited Account Statements for the past three years shall be obligatory.

Ineligible Organisations:

- Companies headquartered and owned outside India and their subsidiaries in India, or vice versa, are not eligible to receive funding from DBT under this action; and
- Research centres and academic organisations headquartered and owned outside India and their subsidiaries in India, or vice versa, are not eligible to receive funding from DBT under this programme.

Consortium:

- The number of Indian project partners should be optimum and correspond to the objectives of the project. Each project should clearly demonstrate the partner's essentiality, complementarities, and added value in jointly addressing the topic.
- In case there is more than one Indian participant in a given project it is advised that the Indian participants appoint among them a **'Lead Scientific Coordinator'**, who can represent the Indian participants in the consortium vis-à-vis DBT.

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http://www.dsir.gov.in/#files/tpdup/irdpp/SIRO-revised-guidelines.html

1The Department of Scientific and Industrial Research (DSIR), Government of India is the nodal government department for granting recognition to non-commercial Scientific & Industrial Research Organisations (SIROs). The functional SIROs having clearly stated objectives of undertaking scientific research, broad based Governing Council, Research Advisory Committee, research personnel, infrastructure facilities for research, well defined, time bound research programs and clearly stated objectives of undertaking scientific research are considered eligible for recognition by DSIR.

FUNDING SUPPORT BY DBT

DBT will fund the Indian consortium members as per requirement of the project, for the project duration, up to 3 years. Budget should be commensurate with the essentiality of participation, workload and objectives of the project and cost of participation.

Eligibility for Funding:

Budgeted cost of the project to legal entities subject to obligatory fulfilment of eligibility criteria.

1. **DBT will support (Grant-in-aid) 100% of the approved budget costs to the following two categories of organizations:**
   a) Government of India supported or recognised public or private academic institutions or research organisation, and urban or other local bodies;
   b) Indian private R&D performing institutions and Not-for-profit, NGO(s)/ VO(s)/ Trust(s)/ Research Foundations, having research as one of the imperative mandates.

Eligible costs for funding are: Capital expenditure (equipment's) || Manpower || Consumables || Travel (local and international travel) || Contingency || Overheads || Outsourcing || Others. (*Academia can factor in additional sub heads (in other category) such as; workshops; publications; review meetings, etc. under expenditure based on the requirement of the project).*

Funding Instruments/Items ***(Rs. in lakhs)***

Head	**Year 1**	**Year 2**	**Year 3**	**Total**
A. Non-recurring				
1. Equipment				
Total A				
B. Recurring				
1. Consumables				
2. Manpower (JRF/SRF/ RA/ TA)				
3. Travel (both Domestic and International for project purpose)				
4. Contingency				
5. Overheads – as per DBT norms				
6. Outsourcing				
7. Others				
TOTAL B				
TOTAL (A+B)				

Important Notice: *This budget table should be made for each Indian participating/applicant partner. Details and Justification should be provided for each head. Equipment cost should not exceed 30 per cent of total project cost.*

2. Grant-in-aid to Industry:

a) Support to Industry shall not exceed 50% of the total cost (up to maximum of Rs. 1.5 Crore) proposed by the Industry participant, 50% of the contribution shall mandatorily come from the Industry;

b) The cost breakup for the DBT component of the proposal shall be: Capital (equipment) and Manpower costs each not exceeding 30% of the DBT supported project cost; and balance will cover consumables and travel costs. Contingency & overhead costs will not be permissible.

Funding instruments/items: ***(Rs. in lakhs)***

	Contribution from Industry				**Contribution from DBT**			
Head	**Year 1**	**Year 2**	**Year 3**	**Total**	**Year 1**	**Year 2**	**Year 3**	**Total**
A. Non-recurring								
1. Equipment								
Total A								
B. Recurring								
1. Consumables								
2. Manpower (JRF/ SRF/ RA/ TA)								
3. Travel								
TOTAL B								
TOTAL (A+B)								

Non-Admissible Cost from DBT:

i. Regulatory approval fees;
ii. Prosecution/litigation costs;
iii. Insurance coverage;
iv. Salary of investigators;
v. Capital expenditure for the purchase of assets such as office furniture, motor vehicles, Office equipment viz. desktops, laptops, tablets, cell phones, scanners, printers, photocopy machines, and renovation or extension of facilities such as buildings and laboratories;
vi. Capital expenditure toward technology(ies), demonstration plants and associated field equipment(s), hardware, software etc. for test and analysis from consortium partner(s) from abroad;
vii. Expenditure toward rental and utilities;
viii. International travel to countries other than the one participating within the consortia in a particular call;
ix. Mere attendance at conferences/ symposiums/ congresses

REGULATORY, ETHICAL, SAFETY & STATUTORY CONSIDERATIONS (IF APPLICABLE)

i) Research Using Hazardous Microorganisms, Genetically Engineered (GE) Organisms & Products thereof for R&D Purpose:

In India, research using hazardous microorganisms, genetically engineered (GE) organisms & products thereof are governed under Rules, 1989 (Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/ Genetically Engineered Organisms or Cells) of Environment (Protection) Act, 1986, according to which, necessary intimation/ recommendation/ authorization from concerned Institutional Biosafety Committee (IBSC), Review Committee on Genetic Manipulation (RCGM) & Genetic Engineering Appraisal Committee (GEAC) is obligatory based on type & scale of research operations.

Further guidance on regulatory considerations can be obtained from:

- Guidelines and Handbook for IBSCs, 2011 http://www.dbtindia.nic.in/wp-content/uploads/9.-Guidelines-_Handbook_2011.pdf
- Regulations and Guidelines on Biosafety of Recombinant DNA Research & Biocontainment, 2017 http://www.dbtindia.nic.in/wp-content/uploads/Draft-Biosafety-Regulations-andBiocontainment-Guidelines-2017-FF.pdf
- Recommendations for Streamlining the Current Regulatory Framework, 2005 http://www.moef.nic.in/divisions/csurv/geac/draftreport_rpharma.pdf

ii) Human and Animal Subjects Research:

DBT and DLT-PT are committed to ensure that projects involving human or animal subjects are protected from research risks in compliance with the rules and policies in respective countries (ICMR/DBT policies).

All projects recommended for award that involve human or animal subjects will undergo review by the Indian Bioethics Committees prior to award request. For information on ICMR policies, please consult

- National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf

- India PIs of the consortium should apply to their institutional review boards (IRBs)/ institutional ethics committees (IECs) at the time of submission of proposal to obtain necessary bioethics approvals from all involved institutions. If selected, Indian PIs are required to submit proof of their institution's IRB/IECs approval to DBT by before start of project.

iii) Authorizations for Pre-Clinical and/or Human Clinical Trials:

While exploring pre-clinical and/or human clinical trial studies in India, Investigators must satisfy regulatory and ethical provisions adopted under:

- Drugs and Cosmetics Rules, 1945 (as amended from time to time) of Drugs and Cosmetics Act, 1940
- Committee for the purpose of Control and Supervision of Experiments on Animals. (http://cpcsea.nic.in/Auth/index.aspx)
- Schedule 'Y' of Drugs and Cosmetics Rules, 1945 || Requirements and Guidelines for Permission to Import and/or Manufacture of New Drugs for Sale or to undertake Clinical Trials: (http://cdsco.nic.in/html/D&C_Rules_Schedule_Y.pdf)
- Guidance for Industry on Preparation of Common Technical Document for import/Manufacture and Marketing Approval of New Drugs for Human Use (New Drug Application-NDA): (http://www.cdsco.nic.in/writereaddata/CDSCO-Guidance For Industry.pdf)
- Handbook: Good Laboratory Practice (GLP). Quality practices for regulated non-clinical research and development, 2nd ed. Geneva, World Health Organization, 2009 || (http://www.who.int/tdr/publications/documents/glp-handbook.pdf)
- Clinical Trials Registry of India (CTRI) – India (http://ctri.nic.in/Clinicaltrials/login.php)

Other Documents:

PI, whose project is recommended by Expert Committee after peer review for funding, will have to submit necessary documents such as detail check list, IPR arrangement, approvals of necessary authority such as ICMR, National Biodiversity authority, DBT, NBPGR etc as the case may be, and any other documents required by DBT.