Department of Biotechnology
Government of India

India-U.S. Collaborative Vision Research Program
Funding Opportunity Announcement-2023

National Eye Institute

Part 1. Overview Information

Participating Organization(s)	Department of Biotechnology & NEI-NIH
Funding Opportunity Title	India-U.S. Collaborative Vision Research Program (R01 Clinical Trial Not Allowed)
Activity Code	R01 Research Project Grant (for DBT)
Funding Opportunity Purpose	This Funding Opportunity Announcement (FOA) encourages Multiple Principal Investigator (Multi-PD/PI) applications from United States (U.S.) and Indian institution as bilateral collaborations that will advance science and technology important to understanding, preventing, and treating blinding eye diseases, visual disorders, and their complications. Areas of Research Collaboration: Applications are encouraged from organization/institutions that propose to conduct research on the basic biology and/or genetics of ophthalmic diseases through collaborations with Indian investigators on the following: diabetic retinopathy, glaucoma, age-related macular degeneration, retinitis pigmentosa, including rare and genetic diseases such as congenital cataracts, as well as other eye conditions such as ocular inflammation/uveitis, refractive error, low vision, and corneal injury. Basic, translational, or epidemiological research maybe proposed. Clinical trials will not be supported under this FOA.
Open Date (Earliest Submission Date)	**October 08, 2023**
Application Due Date(s) for submission to DBT	**November 08, 2023 by 5:00 pm IST.**
NIH weblink for application form	**https://grants.nih.gov/grants/guide/pa-files/PAR-21-249.html**
DBT weblink for application form	**https://dbtepromis.nic.in/Login.aspx**

Background

Scientific collaborations between India and the U.S. have been successfully conducted for several years under a variety of bilateral agreements. Recognizing that continuing collaborative research focused on eye diseases and visual disorders would be of mutual benefit to India and the U.S.,

the Indian Department of Biotechnology (DBT), the U.S. National Eye Institute (NEI), and a Joint Working Group (JWG) developed a strategic plan for collaborations and to facilitate the expedited review and clearance of proposed bilateral projects. Both the DBT and the NEI have pledged funds to support joint activities pursued under this bilateral program.

Several eye diseases such as diabetic retinopathy, Acute Macular Degeneration (AMD), and glaucoma are complex and influenced by multiple genetic, epigenetic, and environmental factors including family, nutrition, and exposure to toxins. During the past decade progress has been made identifying these factors. In AMD, for example, environmental factors include smoking and sunlight have been shown to increase risk, and a diet rich in fatty acids has been shown to decrease risk. There are likely other unknown factors that are involved in precipitating AMD and other ocular diseases. Large scale genomic, proteomic, metabolomic, and informatic methods using emergent or current technologies to study unique populations are encouraged to identify new factors that can affect susceptibility to these diseases and/or ocular infections, as well as biomarkers that will provide the basis for accurate diagnostic test and predict treatment outcome.

There are also many eye conditions and complications such as inflammation that affect some intracommunity populations to a much greater extent, providing a valuable resource for learning more about visual restoration as well as the pathogenesis and physiology of a disorder. For instance, the impact of environmental pollutants, including those generated by cooking stoves, on the development of cataracts, as well as the susceptibility of toxins to cause infections, such as ocular TB and trachoma, are not well understood. Research on these populations that will further our understanding of neural plasticity including neurogenesis, cognition, and processing after treatment of visual disorders and injury are also of interest to the DBT and NEI.

Research Objectives

This FOA is intended to support collaborations between India and the U.S. that focus on the basic biology, epigenetic, and/or genetics of ophthalmic diseases and visual disorders.

Applications may include, but are not limited to collaborations addressing the following areas:

- Family based genome wide association studies (GWAS) on available cohorts from India to identify genetic variants that predispose to both Mendelian and complex forms of eye disease;
- Validation of novel GWAS findings in appropriate animal models;
- Identification of biomarkers that predict and/or assess risk and response to interventions;
- Study of environment on factors that predict risk of eye diseases such as imprinting and other epigenetic effects;
- Studies to determine the underlying biology of ocular diseases including, AMD, diabetic retinopathy, glaucoma, retinitis pigmentosa, cataracts, myopia and presbyopia;
- Studies focusing on the basic science of neuroplasticity of vision including perceptual learning and adaptation after eye injury;
- Studies of the mechanisms through which environmental pollutants/toxins contribute to ocular diseases and their complications including infection and inflammation;
- Identification of factors that influence the success of corneal transplantation and recovery after surgery.

Collaborations

The FOA requires that the collaboration between the U.S. and Indian research teams be submitted as a Multiple Principal Investigator (Multi-PD/PI) application with both of the lead scientists from each country as the PD/PI. Applications may be derived from existing collaborations with an established history of interaction, or from new partnerships developed in response to this FOA. The collaboration must be based on interactive relationships that maximize the expertise of the individual U.S. and Indian research teams.

Through this FOA, U.S. and Indian collaborating investigators should work together to develop and submit an application to National Institutes of Health (NIH) and the India Ministry of Science and Technology's Department of Biotechnology (DBT). The Indian application should follow DBT guidance using the 'Proposal Submission form for R&D Projects' format available at the DBT eProMIS portal: http://www.dbtepromis.nic.in/sample_forms.htm (http://www.dbtepromis.nic.in/sample_forms.htm). In addition to a detailed research plan, the application must include a leadership plan that describes the roles, responsibilities, and working relationship of the PD/PIs, as well as information about performance sites, the proposed work to be accomplished at each site, and a complete budget for the collaboration. Only those applications that are determined to be meritorious will be considered for joint funding and will be supported by the DBT and NIH under this program. The DBT will provide funds for the Indian component and NIH will fund the US component.

The NIH Research Project Grant will directly support salaries of U.S. personnel and research activities within the U.S. It is anticipated that the Indian award will fund the Indian component and will support research activities within India, salaries of Indian research personnel, and other research cost as per DBT norms. All research in India will be conducted in accordance with both U.S. and Government of India regulations for the protection of human subjects.

Note:

1. Organizations must register and apply with their eRA Commons.
2. All U.S. and Indian applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration.

Applications Not Responsive to this FOA

The following applications will be considered non-responsive and will not be reviewed for this FOA:

- Applications that include clinical trials
- Applications that include the diagnosis and treatment of ocular cancers

1. Eligibility

India - Entities eligible to participate: Please refer Annexure I for submission of proposal to DBT.

U.S - Entities eligible to participate:

- Any natural or legal person /entity (e.g. any company, big or small, research organisations, universities, non-governmental organisations, etc.) regardless of their place of residence or establishment in U.S.
- They must possess the operational and financial viability to carry out the research tasks that they propose.

Required Registrations

Applicant organizations must complete and maintain several registrations as described in the NIH SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the US application being submitted. **Registration can take 6 weeks or more, so applicant organizations should begin the registration process as soon as possible**. In addition, all PD(s)/PI(s) must have an NIH eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. The processes and timelines for applicant organization and PD/PI registrations are detailed at: https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and- register/register.htm.

- Dun and Bradstreet Universal Numbering System (DUNS) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.

- System for Award Management (SAM) (formerly CCR) — Applicants must complete and maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.

    - NATO Commercial and Government Entity (NCAGE) Code — Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.

- eRA Commons - Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.

- Grants.gov – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s)

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. **Obtaining an eRA Commons account can take up to 2 weeks.**

Eligible Individuals (Program Director (PD) /Principal Investigator (PI)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for DBT/NIH support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

Additional Information on Eligibility

a. Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The DBT& NIH will not accept duplicate or highly overlapping applications

under review at the same time.

2. Application and Submission Information

Each application needs to be submitted to both DBT & NIH otherwise will be disqualified.

Requesting an Application Package

Buttons to access the online ASSIST system or to download application forms are available in Part 1 of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

Content and Form of Application Submission

The Indian and US participants should formulate a joint proposal according to the requirements and templates provided by the DBT and NIH for support to Indian and US components respectively. It is critical that US applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

For information on Application Submission and Receipt, visit Frequently Asked Questions — Application Guide, Electronic Submission of Grant Applications

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits must be followed

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

A. For NIH submission:

SF424(R&R) Cover

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Other Project Information

All instructions in the SF424 (R&R) Application Guide must be followed.

Other Attachments: Applications are required to include a Collaborative Strategy. The Collaborative Strategy should include a description of how the

proposed collaboration will be maintained throughout the duration of the award. The following areas should be addressed:

- Organizational structure
- Management plan detailing how existing resources will be utilized
- Planned interaction and responsibilities of key personnel
- Description of how research teams will communicate (e.g., video/teleconference, web meeting)
- Plans for making decisions and procedures for resolving conflicts
- Available resources (e.g. patient samples, data, and reagents) and details of how these resources will be shared as appropriate.
- How the collaboration brings complementary or unique expertise to the project that will enhance the research and stimulates collaborative basic, translational, or applied research between Indian researchersand U.S.-based researchers.

Provide the information as a single PDF file with the name "Collaboration.pdf."

SF424(R&R) Senior/Key Person Profile

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R Modular Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R Subaward Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Cover Page Supplement

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Research Plan

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

B. For DBT submission: Please refer **Annexure I** for submission of proposal to DBT.

Letters of Support: Applicants must include a Letter of Support co-written and co-signed by the PD(s)/PI(s) of the NIH application and the Indian collaborating partner and co-signed by the authorizing institutional officials confirming the new or existing collaboration and confirming that the U.S. awardee organization will provide a copy of the NIH submitted application to the DBT through their Indian collaborating partner.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide.

The following modifications also apply:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing plan.

Appendix:

Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the SF424(R&R) Application Guide.

PHS Human Subjects and Clinical Trials Information

When involving NIH-defined human subjects research, clinical research, and/or clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the SF424 (R&R) Application Guide must be followed with the following additional instructions.

3. Funding

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement.

Pre-award costs are allowable only as described in the NIH Grants Policy Statement

All DBT awards are subject to the terms and conditions, cost principles, and other considerations described in the Annexure I.

Preparation of Budget

The "Project Coordinator" must ensure that the financial budget in the joint proposal to the US is presented in DOLLAR ($), while the Indian PI" must ensure that the proposal submitted to DBT is presented in Indian Rupees (₹).

Budget should be commensurate with the workload, objectives of the project and cost of participation.

Eligible costs for Indian funding are: Capital expenditure (Equipments) || Manpower || Consumables || Travel (local and international travel) || Contingency || Overheads || as per DBT format) **Please refer Annexure I for submission of proposal to DBT.**

4. Other Submission Requirements and Information

For a NIH submission: Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section 1. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically. If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Guidelines for Applicants Experiencing System Issues. For assistance with application submission, contact the Application Submission Contacts in Section VII.

For a DBT submission: the joint project proposal must be submitted online via **https://dbtepromis.nic.in/Login.aspx** along with all supporting documentation required by the funding organization. All documents and forms required for the application are accessible online. **Please refer Annexure I for submission of proposal**.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to DBT and NIH. See Section 1 of this FOA for information on registration requirements.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

See more tips for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review, NIH& DBT respectively. Applications that are incomplete or non-compliant will not be reviewed.

In order to expedite review, applicants are requested to notify the NEI Referral Office by email at ellenliberman@nei.nih.gov when the application has been submitted. Please include the FOA number and title, PD/PI name, and title of the application.

5. a. Application Review Information:

a) Criteria

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the NIH mission (//grants.nih.gov/grants/guide/url_redirect.htm?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
Is the proposed project likely to stimulate collaborative basic, translational, or applied research between U.S.- based researchers and Indian researchers?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?
Do the U.S. and Indian collaborators bring complementarity or unique expertise to the project that will enhance the research project?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
Does the U.S.-Indian collaboration enhance the existing research capacity at each site?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the

proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

Does the application provide appropriate plans for the collaborative research, demonstrating the integration of the
U.S. and Indian collaborator efforts, including communication plans, process for making decision on scientific direction, and procedures for resolving conflicts? Does the application provide appropriate contingency plans and/or solutions for addressing setbacks and delays?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?
Is the collaboration plan well-defined with clearly identified responsibilities for the U.S. and Indian collaborators, and does it take advantage of the strengths of each collaborator?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects (//grants.nih.gov/grants/guide/url_redirect.htm?id=11225).

5.b. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the Center for Scientific Review, in accordance with NIH peer review policy and procedures, using the stated review criteria & by DBT as per GOI norms.

As part of the scientific peer review, all applications:

- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.

- Will receive a written critique.

Appeals of initial peer review will not be accepted for applications submitted in response to this FOA.

Applications will compete for available funds with all other recommended applications. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- Demonstrated collaboration with Indian and US partner(s)

6. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons.
On Indian side recommendations/Comments will be communicated by email.

Information regarding the disposition of applications is available in the NIH Grants Policy Statement.

7. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award

costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

On Indian side award notification will be issued by the DBT Programme Officer.

8. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement as part of the NoA. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities. More information is provided at Award Conditions and Information for NIH Grants.

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA. HHS provides general guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please

http://www.hhs.gov/ocr/civilrights/resources/laws/revisedlep.html. The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html; and http://www.hhs.gov/ocr/civilrights/understanding/index.html. Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html. Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.html or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.

Cooperative Agreement Terms and Conditions of Award Biohazard descriptions: if applicable.

Regulatory and Ethical Considerations

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, 2017http://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

Human and Animal Subjects Research in India:

DBT and the US Commission are committed to ensure that projects involving human or animal subjects are protected from research risks in compliance with the rules and policies in respectivelythe NIH and India (ICMR/DBT policies).

All projects recommended for award that involve human or animal subjects will undergo review by the Indian institute Bioethics Committees prior to funding. 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

Indian PIs are required to submit proof of their institution's Institutional Review Board(IRB)/ Instituional Ethical Committee (IEC) approval to DBT prior to funding.

Authorizations for pre-clinical studies:

For 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
- 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

9. Submission of Application to DBT:

Please apply through this link; https://dbtepromis.nic.in/Login.aspx

Steps for submission:

a. Please login to eProMIS account (https://dbtepromis.nic.in/Login.aspx)
b. Go to International Cooperation-Bilateral Programs area
c. Open Call link for Indo-US Joint Call on Vision Research
d. Submit proposal

For any query, please contact **Dr. Vinita Chaudhary, Scientist – E at vinita.chaudhary@nic.in**

IN CASE OF NON-SUBMISSION TO DBT THE PROPOSAL WILL NOT BE CONSIDERED FOR FURTHER PROCESSING.

ANNEXURE-I

MODALITIES OF PARTICIPATION AND FUNDING

PARTICIPANTS FROM INDIA

The participating entities/organizations 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 recognized (Public or Private) academia; research; organizations and urban or other local bodies;
- Government of India recognized not- for profit NGO(s)/VO(s) Trust(s)/Research foundations, having research as on the imperative mandates

ELIGIBILITY CRITERIA

❖ **Academic/Research Partners:**

- Public and/or private universities and research organizations 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[1].

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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 SIRO sharing 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.

❖ **Ineligible Organizations:**

- 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 proposal 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.
- In case there is only one Indian participant in a given proposal it is advised that the Indian participant should include one Co-Principal Investigator in the proposal.

FUNDING SUPPORT BY DBT

DBT will fund the Indian consortium as per the requirement of the project, for the project duration, upto 3 years. Budget should be commensurate with the essentiality of participation, work load and objectives of the project and cost of participation.

Eligibility for Funding:

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

DBT will support (Grant-in-aid) 100% of the approved budget cost 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	Year1	Year2	Year3	Total
A.Non-recurring				
1.Equipment				
TotalA				
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				
TOTALB				
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.*

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 there off or R&D Purpose:

In India, research using hazardous microorganisms, genetically engineered (GE) organisms & products there of 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 Hand book forIBSCs,2011 http://www.dbtindia.nic.in/wp-content/uploads/9.-Guidelines-_Handbook_2011.pdf
- Regulations and Guidelines on Biosafety of Recombinant DNAResearch&Biocontainment,2017http://www.dbtindia.nic.in/wp-content/uploads/Draft-Biosafety-Regulations-andBiocontainment-Guidelines-2017-FF.pdf
- Recommendations for Streamlining the Current Regulatory Framework, 2005http://www.moef.nic.in/divisions/csurv/geac/draftreport_rpharma.pdf

***ii)* Human and Animal Subjects Research:**

DBT is 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 InvolvingHumanParticipants,2017http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf

- Indian 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.

CONSORTIUM AGREEMENT

The participants shall enter into a Project Agreement. The Project Agreement shall include the Participants mutual commitments, conditions concerning rights to foreground and background information and other issues of significance to the cooperation. The project Agreement shall be consistent with each funding organizations terms and conditions for grants for funding (foreground and background information refer to IPR).

INTELLECTUAL PROPERTY RIGHTS

The IPR arising from cooperative activities under this working Programme shall be regulated in accordance with the relevant laws of the two countries.

With respect to any invention or discovery made or conceived in a joint venture in the course of the execution of the cooperation, the Parties agree that ownership, title and patent rights as well as other rights accruing shall be handled according to the agreement signed by the participants in that specific joint venture.

All details shall be settled amicably by consultation or negotiation between the participants in each specific case of joint venture.

OTHER DOCUMENTS:

PI, whose project is recommended by Expert Committee after peer review for funding, will have to submit necessary documents such as detailed checklist, 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.

HOW TO APPLY:
For the submission to DBT:
Please apply through this link; https://dbtepromis.nic.in/Login.aspx

Steps for submission:

a. Please login to eProMIS account (https://dbtepromis.nic.in/Login.aspx)
b. Go to International Cooperation-Bilateral Programs area
c. Open Call link for Indo-US Joint Call on Vision Research
d. Submit proposal