

Indo-US Bilateral Collaborative Research Grants on Human Immune Phenotyping and Infectious Disease

Key Dates

Release Date: November 20, 2017

Letter of Intent Receipt Date: December 20, 2017

Application Receipt Date: **March 23, 2018 (by 5pm local time for the submitting HIPC site)**

Primary Review Completed: **April 16, 2018**

Rebuttal Receipt Date: **May 4, 2018**

Secondary Review Completed: **May 18, 2018**

Earliest Anticipated Award Date: June 1, 2018

Purpose

The purpose of this renewal program is to promote U.S.-India collaborative research on human immunophenotyping studies (see definition under “Research Objectives” section), in collaboration with investigators of the NIAID Human Immunology Project Consortium (HIPC, www.immuneprofiling.org). HIPC was established in 2010 and renewed in 2015 and 2016 by the NIAID Division of Allergy, Immunology, and Transplantation (DAIT) as part of the overall NIAID focus on human immunology. The current HIPC program is co-sponsored by the NIAID Division of AIDS (DAIDS) and the Division of Microbiology and Infectious Diseases (DMID), and is composed of nine cooperative agreement awards to investigators throughout the U.S. (see list below of Eligible HIPC Investigators).

Introduction

This program is being conducted under the auspices of the Indo-U.S. Vaccine Action Program (VAP) – a bilateral program of the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) within the Department of Health and Human Services, United States (U.S.); and the Department of Biotechnology (DBT), Ministry of Science and Technology, Government of India; in conjunction with HIPC. **Applications are invited from HIPC investigators to work together with investigators in India to perform collaborative research projects in the area of human immunophenotyping. U.S. investigators not currently supported under HIPC also are eligible to apply to this funding opportunity by establishing a collaboration with a HIPC investigator.** Awards will be funded jointly, by NIAID *via* the HIPC Infrastructure and Opportunities Fund, and by the Government of India *via* DBT.

Background

In the broad scheme of global health, infectious diseases continue to plague various communities around the world, claiming numerous lives and significantly compromising the well-being of many others. Understanding basic immunological principles and the human immune response to various infectious agents, or to vaccines developed to prevent infectious diseases, can create knowledge to develop new vaccines, diagnostics and therapeutics. India, with its large and genetically diverse population, provides an opportunity to study human immunology in relation to a number of communicable diseases that are either uniquely tropical or global health threats. Moreover,

preliminary epidemiological data generated by researchers in India suggest that the Indian population may have a wide variation of susceptibility or resistance to infectious pathogens due to diverse exposure conditions. Recent studies also suggest that early life exposures may profoundly impact the developing immune system of infants and shape the nature of their immune responses to pathogenic infections and vaccines in the long term. The physiologic changes that occur during aging also can impact an individual's ability to resist pathogenic infections or response well to vaccines. Therefore, the study of human immune phenotypes in Indian populations, and comparisons with U.S. populations, is of interest to scientists in both India and the U.S., and is in line with the current research goals and previous undertakings of the DBT and NIAID, NIH, as well as the HIPC program.

The NIH supports international collaborative biomedical research to advance science and expand biomedical knowledge. Scientific cooperation between the U.S. and India has taken place for over forty years under a variety of bilateral agreements. Recognizing that enhanced cooperative research would be of mutual benefit to both countries, the Governments of the United States and India signed an umbrella Agreement on Science and Technology (S&T) Cooperation (<https://energy.gov/sites/prod/files/US-India%20ST%20Agreement.pdf>), which has been extended until March 2019.

However, even prior to the signing of this historic S&T Agreement, the Indo-U.S. Vaccine Action Program (VAP; <https://www.niaid.nih.gov/research/indo-us-vaccine-action-program>) was implemented between the U.S. and India in 1987. The lead U.S. agency to implement activities under the VAP is NIAID and the lead Indian Government agency is the DBT.

Eligibility

All applications MUST include at least one HIPC investigator from the U.S. (see list at end of announcement) AND one investigator from India. In addition, non-HIPC investigators are invited to contact a HIPC Project Leader or Indian Project Leader to initiate a collaboration on an application; thus, multiple investigators may partner with the HIPC Project Leader or the Indian Project Leader within any one application, and within the budget constraints.

Funds Available

Both NIAID (through HIPC) and DBT have allocated funds to support joint activities pursued under this program, and each plans to contribute funding for every collaborative project selected under this joint program. Based on the scientific merit of the applications as evaluated by peer review in both countries, and on the availability of funds, HIPC may award up to \$1,000,000 in FY 2018 to support the U.S. components of meritorious applications received in response to this funding opportunity. The Government of India has agreed to provide financial support to implement the projects in India after completion of requisite documentary requirements by project Investigator (as per DBT norms) .

Budget Issues

Funds will be awarded for 2 years, with the possibility for a third year based upon scientific progress. Each award will be limited to \$200,000 total costs per year (total costs = direct plus indirect costs) for

the U.S.-led component of the project, and a comparable amount per year(not exceeding Rs. 100.00 lakhs including both Recuring and Non- Recurring budget) for the Indian-led component of the project . Two months before the end of the second year of funding, a progress report will be submitted by the grantees for review by the HIPC Steering Committee and appointed Indian scientists, to determine if a requested third year of funding will be awarded.

Research Objectives

The intent of this program is to foster, stimulate, or expand research describing human immune phenotypes after vaccination or infection by supporting collaborative projects between Indian researchers and current recipients of HIPC (<https://www.immuneprofiling.org/>) grant funds. The objective is to characterize the diverse states of the human immune system (1) prior to and following infection, (2) prior to and following vaccination against an infectious disease, or (3) prior to and following administration of an adjuvanted versus non-adjuvanted vaccine to assess the effects of the adjuvant. This effort relies on the analysis of well-characterized human cohorts for immunophenotyping studies, which are defined as studies that apply a variety of systems biology approaches or other multiparameter phenotyping methods to discover and begin to define molecular signatures characteristic of the specific immune status induced by a particular infection or vaccine, or characteristic of the resting immune status in a particular population. The goal of the HIPC program and of this collaborative effort is to generate research results leading to improved human vaccines and immunotherapeutics for infectious disease.

NOTE that HIV/AIDS research is excluded from this program.

Examples of areas of research interest include:

-) Discovery of longitudinal immune signatures of pathogen infection or vaccination in ethnically-diverse or immunocompromised populations, such as infants, neonates, elderly, transplant recipients, patients with autoimmune disease, or malnourished individuals.
-) Comparisons of immune responses to natural infections or vaccines between ethnically similar populations who are exposed to drastically diverse environments (e.g. urban vs rural, Indian; urban vs Indian population born raised in urban US environments).
-) Identification of immune profiles that correlate with vaccine immunogenicity or efficacy.
-) Dissociation of markers of protective immunity from markers of vaccine or adjuvant toxicity/reactogenicity.
-) Identification of immune profiles that correlate with adjuvant function.

Eligibility Requirements

-) All applications MUST include at least one HIPC investigator from the U.S. AND one investigator from India. The list of investigators from the 9 HIPC centers, who might serve as potential collaborators, is provided at the end of this document with their contact information, and a link to a description of their project. Additional investigators in the U.S. or other countries may join a proposed project through partnership with the HIPC investigator or the Indian investigator prior to submission of the application. A HIPC investigator who wishes to submit an application will decide which collaborators to include in the application.

-) All applications **MUST** be geared toward research focused on human immune phenotyping in response to one or more non-HIV/AIDS infectious disease or vaccine, and/or characterize baseline human immune phenotypes, and thus, must be conducted with samples from human subjects; the use of human cell lines is not sufficient.
-) Each application will have a HIPC Project Leader (PL) and an Indian PL, and will be submitted as a **SINGLE JOINT APPLICATION** written in English.
-) **NO MORE** than 2 joint applications may be submitted from each HIPC center.
-) Each joint application may not exceed 8 pages for the research plan (see instructions under “Format of Applications” below).
-) The Principal Investigator (PI) of a HIPC grant **MUST** agree to submit the application, because the U.S. award to the HIPC investigator will be managed through the parent HIPC grant.
-) All applications **MUST** be submitted by the HIPC PI through the HIPC website at www.immuneprofiling.org.
-) Applications may propose the development of data management or data analysis tools, as long as the proposed work includes studies with human samples to validate the usefulness of the proposed methods. The use of human cell lines is not sufficient.

This initiative will NOT fund:

-) HIV/AIDS research
-) Animal studies
-) Clinical trials, as defined below

Clinical Trial Definition

For the purpose of this initiative, the NIH definition of a clinical trial will be applied:

A clinical trial is a research study in which one or more human subjects are prospectively assigned¹ to one or more interventions² (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.³

¹The term “*prospectively assigned*” refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

²An *intervention* is defined as a manipulation of the subject or subject’s environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

³*Health-related biomedical or behavioral outcome* is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects’ biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention

for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

Examples:

-) **Study of a licensed vaccine, if the vaccine is administered in accordance to approved indication (given at the appropriate time for immunization and to approved populations, as indicated in the product label), WOULD NOT be considered a clinical trial as long as the vaccination is done for medically indicated purposes OUTSIDE THE STUDY PROTOCOL** (*there is no prospective assignment to an intervention*).
-) Study of a licensed vaccine, if the vaccine is administered in accordance to approved indication (given at the appropriate time for immunization, and given to approved populations, as indicated in the product label), WOULD be considered a clinical trial if the vaccination is done AS PART OF THE STUDY PROTOCOL (i.e., it is incorporated as a procedure in the protocol and the informed consent form).
-) Study of a licensed seasonal vaccine that is given either at a time different than what indicated in the product label or given to subjects outside of the approved indication age range, WOULD be considered a clinical trial.
-) Study of an investigational/candidate vaccine in any age group WOULD be considered a clinical trial.

Peer Review of Applications

Both Indian and U.S. scientists will be extensively involved in all stages of the review process. Review will follow the standard two-step HIPC procedure, with a primary critique focused on scientific merit and conducted by an ad hoc panel of extramural experts from the scientific community, including prominent Indian scientists. A secondary review will be conducted by the HIPC Steering Committee and the VAP Leadership.

Following the primary review, applicants will have a brief opportunity to provide rebuttal information to be evaluated in the secondary review together with the comments from the primary review panel. Rebuttal instructions will be provided to the applicants upon communication of the primary review results.

The following review criteria will be used, and each application will receive an overall score based on a

1 (best) - 9 (worst) numerical scoring system:

-) Overall Impact: likelihood for the project to exert a sustained, powerful influence on the research field.
-) Significance: importance of the project in terms of advancing concepts or technologies that drive the field.
-) Investigators: appropriateness of the proposed investigators for the project, with well-integrated and complementary expertise, and evidence of ongoing records of accomplishment.
-) Innovation: potential to change paradigms in the field.

-) Approach: clear presentation of well-reasoned and appropriate strategies, methods, and analyses; and potential problems and alternative approaches.
-) Environment: appropriate institutional support, equipment, and other physical resources.

Letter of Intent

All applicants are strongly encouraged to provide a Letter of Intent (LOI) prior to submission of full proposals, to facilitate the selection of appropriate reviewers in preparation for the incoming proposals. However, LOIs are not required, are not binding, and do not enter into the review of a subsequent application.

A letter of intent should be submitted no later than December 20, 2017, by email to Alison Augustine (augustine@niaid.nih.gov), Halonna Kelly (kellyhr@mail.nih.gov) and Jyoti Logani (jyoti.logani@nic.in). The letter of intent (2-page maximum) should include the following:

-) Name and institution of the HIPC investigator serving as Project Leader (see list of eligible HIPC investigators at end of this document);
-) Name and institution of the Indian investigator serving as Project Leader;
-) Grant number and name of the Principal Investigator of the parent HIPC grant;
-) Name and institution of any additional key collaborators;
-) Working title of the project; and
-) Very brief description (1 page maximum) of the overall research objectives and scientific components to be proposed from each of the HIPC and Indian collaborators.

Application Submission Procedure and Deadline

An application may ONLY be submitted by the Principal Investigator (PI) of a HIPC grant, for a project proposed by an investigator within that HIPC center in collaboration with the Indian investigator. The usual electronic application process will be employed by the HIPC PI using the HIPC website. Each HIPC center may submit up to 2 different applications. Applications must be submitted by 5:00 PM U.S. Eastern Standard Time on March 13, 2018. The applications will be shared with the DBT officer for funding consideration. After completion of review process, only selected applications will be submitted at the electronic project submission portal of DBT.

Format of Applications

Please submit a single PDF file that includes all of the following information, in the order given below.

Cover page for each institution involved in the project, to include the following:

-) HIPC U19 Grant #;
-) HIPC U19 Grant Principal Investigator's name;
-) Title of proposed project;
-) U.S. and Indian Project Leaders' names, institutions, email addresses, and phone numbers;
-) Requested total costs for each institution (direct and indirect costs); and
-) Project abstract (no more than ½ page).

Detailed budget and justification. Each project is limited to 2 years of initial funding, with the potential for a 3rd year (based on program progress) . The budget for the entire U.S. component is limited to \$200,000 total costs per year (total costs = direct plus indirect costs). Provide a separate detailed budget and justification for the U.S. and Indian components.. Each of these justifications also should include separate detailed budgets/justifications for any U.S. or Indian institution serving as a subcontractor or collaborator to the parent U.S. and Indian components, respectively.

The detailed U.S. budgets shall include:

-) Both the direct and indirect costs requested for each year;
-) List of personnel to be supported;
-) Salary plus fringe benefits requested for each person;
-) Proposed percent effort for each person;
-) Costs for research supplies;
-) Costs for equipment;
-) Other expenses; and
-) Travel costs for attendance of the Project Leader at an annual meeting of all grantees funded under this initiative, to be held in India one year and in the US in the other year. Justification for each budget category requested.

The Indian budget component should follow DBT guidance, using the format available at the eProMIS portal of DBT: <http://www.dbtepromis.nic.in/Login.aspx>. Please refer the to Section on Budget Particulars of **Proposal Submission form for R&D Projects**.

The proposed U.S. and Indian budgets shall include Nonrecurring (for equipment) and Recurring budget (for Overhead, Manpower, Consumables and Contingency) for a period of two years.

Biographical Information for proposed Project Leader and any other key personnel; include:

-) Name, degree, and current position title;
-) Education/training and field(s) of study;
-) Relevant research experience; and
-) Current research support including the % effort already committed for currently funded projects.

Description of proposed work (strict 8 page limit), to include:

-) Rationale: how the project will advance human immune phenotyping; include discussion of complementary expertise and/or resources brought by each Project Leader and other collaborators, as well as feasibility of completing the work within the timeline;
-) Each Project Leader's prior work in human immunology/phenotyping/informatics, etc.;
-) Background information;
-) Preliminary data;
-) Resources available to complete the work, including sources of human samples, and any samples to be obtained from an independent clinical study (if obtaining samples or other resources from an independent source, include a letter from the director of the independent study confirming the availability of the samples or resources);

-) Research strategy: a detailed description of the proposed work that includes the central hypothesis(es) or research question(s), specific aims , experimental approaches and sample size calculations offering adequate statistical power; Inclusion of workplan indicating work to be done in India and U.S. respectively to address the objectives proposed; and
-) Description of the statistical, bioinformatic, and/or systems biology methods to be employed for analysis of results.

Bibliography: limited to essential references.

Protection of human subjects: provide a detailed description of the procedures to be used with human subjects, the measures that will be employed to protect human subjects, and the total numbers of each definable population included in the study (3 page maximum).

Letter(s) of agreement: from independent sources of human samples or other resources, if applicable.

Biohazard descriptions: if applicable.

Data sharing statement: brief statement of agreement with the HIPC Data Sharing Plan (www.immuneprofiling.org).

Appendix: only 2 documents are allowed (e.g., in-press manuscript).

Terms of Award

Human Subjects: Before award, all U.S. studies with human subjects must conform to NIH policies on the protection of human subjects (<http://grants.nih.gov/grants/policy/hs/index.htm>).

Before any funds can be expended for in-country research activities in a foreign country, the grantee institution must show evidence of compliance with both U.S. and Indian regulations for the conduct of research involving human subjects. Additional information on U.S. requirements can be found at the HHS Office for Human Research Protections at <http://www.hhs.gov/ohrp>. Additional information on Indian requirements can be found in the Revised ICMR National Ethical Guidelines for biomedical and health research involving human participants: http://icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf.

Intellectual Property: The provisions of the Agreement on Science and Technology Cooperation between the Government of the United States of America and the Government of the Republic of India (<https://energy.gov/sites/prod/files/US-India%20ST%20Agreement.pdf>) will govern the allocation of intellectual property, copyright, and patent rights relevant to awards from this initiative.

Data Sharing Policy: In keeping with the NIH Data Sharing Policy (http://grants.nih.gov/grants/policy/data_sharing/) and the HIPC Data Sharing Policy

(<https://www.immuneprofiling.org/hipc/page/showPage?pg=dataShare>, applicants will be required to provide a data sharing plan within one month after award. Each data set will be determined in consultation with NIAID staff, using the HIPC definition of a data set as a “publishable unit” of data. For example, if an investigator wants to publish a manuscript to include only the antibody titers in association with B cell studies, these two units of data would constitute a “Data Set”. The ImmPort database (www.immport.org) is the preferred site for data submission, although other public databases may be used if more appropriate for a particular data type (e.g., Gene Expression Omnibus). To fulfill the HIPC data sharing objectives, funded investigators are strongly encouraged to enter all study data and meta-data into ImmPort as soon as they are available, with the understanding that data submitted to ImmPort will remain private until the appropriate public release date, which is the date of online publication in a scientific journal or, if no association with a manuscript, 9 to 12 months after submission to ImmPort. All public data sets generated through this funding opportunity will also be made available through ImmuneSpace (www.immunespace.org), the HIPC-supported data management and analysis engine where data sets can be easily explored and analyzed using state-of-the-art computational tools.

Inquiries

Direct inquiries regarding scientific, review or budgetary matters to:

For U.S.-based investigators:

Alison (Deckhut) Augustine, Ph.D.

Division of Allergy, Immunology and Transplantation National Institute of Allergy and Infectious Diseases, U.S. National Institutes of Health

Bethesda, MD 20892

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Email: augustine@niaid.nih.gov

For India-based investigators:

Jyoti Logani, Ph.D.

Department of Biotechnology

Ministry of Science and Technology

Government of India

Phone: 011-24362329

Email: jyoti.logani@nic.in

ELIGIBLE HIPC INVESTIGATOR COLLABORATORS

Highlighted names are the Principal Investigators of the HIPC centers. The names that follow are investigators supported under a particular center (project or core leaders). Collaborations can be with either the Principal Investigator or investigators supported by a particular HIPC center. Descriptions of the ongoing projects at each center can be found by selecting the NIH RePORT link below or by entering the grant number in the RePORT system (<http://report.nih.gov/>). In addition, project descriptions are available at the HIPC website: www.immuneprofiling.org

PRINCIPAL INVESTIGATOR/PROJECT LEADER/CORE LEADER (EMAIL)	INSTITUTION	HIPC GRANT NUMBER	RePORTER PROJECT INFORMATION
FARBER, DONNA L (df2396@cumc.columbia.edu)	COLUMBIA UNIVERSITY	AI128949	RePORTER Proj Info
FLORATOS, ARIS (af2202@columbia.edu)	Columbia University		
GOODRUM, FELICIA D (fgoodrum@email.arizona.edu)	Arizona Board of Regents, University of Arizona		
MERAD, MIRIAM (miriam.merad@mssm.edu)	Icahn School of Medicine at Mount Sinai		
REIZIS, BORIS (boris.reizis@nyumc.org)	New York University School of Medicine		
SIMS, PETER ALAN (pas2182@columbia.edu)	Columbia University		
FERNANDEZ-SESMA, ANA (ana.sesma@mssm.edu)	ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI	AI118610	RePORTER Proj Info
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KROGAN, NEVAN J (nevan.krogan@ucsf.edu)	University of California San Francisco (UCSF) /The J. David Gladstone Institutes		
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HAINING, WILLIAM NICHOLAS (nicholas_haining@dfci.harvard.edu)	Dana-Farber Cancer Institute		
MULLIGAN, MARK JOSEPH (mmulli2@emory.edu)	Emory University		
YU, TIANWEI (tianwei.yu@emory.edu)	Emory University		
REED, ELAINE F (ereed@mednet.ucla.edu)	UNIVERSITY OF CALIFORNIA, LOS ANGELES	AI128913	RePORTER Proj Info
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ROSSETTI, MAURA (mrossetti@mednet.ucla.edu)	University of California, Los Angeles		
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MCEL RATH, MARGARET JULIANA (jmcelrath@fhcrc.org)	Fred Hutchinson Cancer Research Center		
ZAK, DANIEL E (daniel.zak@cidresearch.org)	Center for Infectious Disease Research		