

Biotechnology Industry Research Assistance Council (BIRAC) A Government of India Enterprise Announces

'All Children Thriving' A Third Grand Challenges India Grant Opportunity

With Funding Support from Department of Biotechnology (DBT), Ministry of Science and Technology, Government of India, Bill & Melinda Gates Foundation (BMGF)

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United States Agency for International Development (USAID)

Table of Content

Ι.	Grand Challenges India Background	2
П.	Program Goal	3
III.	Program Objectives	3
IV.	What we are looking for	4
٧.	Examples of what we are looking for	4
VI.	Examples of what we are NOT looking for	5
VII.	Application instructions	6
VIII.	Letter of Interest	7
IX.	How we evaluate proposals	7
Х.	Collaborations	7
XI.	Eligibility criteria of target groups	8
XII.	Application Procedure	8
XIII.	Allowable Costs	9
XIV.	Timelines	9
XV.	Contact	9

Creating and Measuring Integrated Solutions for Healthy Birth, Growth, and Development Grand Challenges India: All Children Thriving

Grand Challenges India Background

On June 2012, the Bill & Melinda Gates Foundation (BMGF) and the Department of Biotechnology (DBT) signed an umbrella Memorandum of Understanding (MOU) to collaborate on mission-directed research and build a **Grand Challenges India** to support health research and innovation. The MOU aims to support initiatives that could dramatically change the health and development landscape in India and other countries facing similar challenges. Specifically, it identifies the following priorities for cooperation:

- 1) Reduction of maternal and child mortality and morbidity;
- 2) Scientific and technical solutions for infectious diseases;
- 3) Strengthening India's scientific translation capacity;
- 4) Scientific and technical advances related to agriculture,
- 5) Scientific advancement in food and nutrition;
- 6) Other joint interests that may arise.

Grand Challenges initiatives would follow these core principles:

- 1. Strategic and well-articulated grand challenges serve both to focus research efforts and to capture the imagination and engage the world's best researchers.
- 2. Projects are selected based on national and societal need and transparent calls for proposals seeking the best ideas.
- 3. Funders, investigators and other stakeholders actively collaborate to accelerate progress and integrate advances to ensure these advanced technologies reach to developing countries masses
- 4. Projects are selected not only for scientific excellence, but also for their likelihood to achieve the desired impact, and they are milestone-driven and actively managed to that end.
- 5. Projects and investigators will have to follow global access commitments to ensure the fruits of their research are available to those most in need.

Creating and Measuring Integrated Solutions for Healthy Birth, Growth, and Development Background

BIRAC is pleased to announce the All Children Thriving Grand Challenge as the third Grand Challenges grant program to be launched in India, in collaboration with Department of Biotechnology (DBT), U.S. Agency for International Development (USAID) and Bill & Melinda Gates Foundation (BMGF). Globally, over 6 million children under the age of five die each year, and approximately 165 million (26%) of the world's children have stunted growth jeopardizing subsequent physical as well as cognitive development. India has among the highest prevalence of stunting in the world, and represents 38% of the global burden of chronic under nutrition. Much remains unknown about the root causes of unhealthy birth, growth, and development. Current evidence suggests that the causes – whether based on malnutrition, infectious disease, social or other factors – are interwoven, and that addressing them one at a time can solve only

a small fraction of the problem. Furthermore, stunted growth and development can reduce human productivity and perpetuate poverty.

Please review the background paper prior to applying for this Grand Challenge.

Program Goal

We need to know how and when to most effectively intervene to ensure all children thrive – that they not only survive, but also have the chance to live healthy productive lives. The ultimate goal of this challenge is to determine what packages of interventions should be delivered to which group of individuals at what point in their life cycle to reduce the burden of fetal growth impairment and preterm birth, stunted postnatal growth, and impaired cognitive development.

Program Objectives

We are looking for projects that – by piloting new approaches – will determine:

1) What combinations of interventions from any sector—health, agriculture, education, social protection etc.—are most effective for prevention and treatment of unhealthy birth, growth, and development;

2) When in the human lifecycle they are most effectively applied;

3) How they are most effectively and practically integrated into a continuum of care, encompassing preconception, conception to birth, birth to two years, childhood, adolescence, and adulthood.

Interventions of interest include – but are not limited to – those focused on preconception and maternal nutrition (e.g., adequate micronutrient intake); exclusive breastfeeding to 6 months of age; complementary feeding from 6 to 24 months of age; food security and dietary diversity (e.g., accommodating seasonality); farm productivity and women farmers' income generation; prevention of moderate or severe acute malnutrition (to reduce the relapse rate); infection control (e.g., vaccines, drugs, clean water access, sanitation, food hygiene, hand washing); reduced toxin exposure (e.g., indoor air pollution, aflatoxin, pesticides); reducing the burden of unhealthy pregnancy, including fetal growth delays (e.g., maternal stress, preeclampsia, gestational diabetes); reducing the burden of preterm birth; birth assistance; fostering newborn care (e.g., immediate initiation of breastfeeding, kangaroo care); family planning and birth spacing; infant nurturing and early child stimulation; addressing violence and abuse; and addressing the role of socioeconomic status and gender norms.

What we are looking for

To reach these objectives, we are looking for projects that propose innovation in the following areas:

• **Measurement tools**: Pilot tests of new measurement tools, such as those based on a new technology or new biomarkers of linear growth, cognitive function, or gestational age, including rapid response indicators of intervention success or failure

- Intervention packages: Tests of new interventions especially combinations of interventions –that 1) develop a new human cohort with unique advantages over existing cohorts, such as the potential for developing a unique biorepository; or 2) add an activity, such as a prospective pilot trial of an intervention or new measurement tool, to ongoing work with a human cohort, including at sites of intervention trials and sites for public health surveillance
- **Analytical tools**: Pilot tests of new analytical tools that use existing biorepositories or existing health and development databases for retrospective analysis

We will give highest priority to those projects that:

- Build on ongoing work in some way, especially by building on clinical trial sites where the sustained availability of descriptive data has had demonstrable success in helping design interventions, stratifying populations by risk factor, and enabling an understanding of the community that includes barriers and constraints to delivery of interventions and to implementation of government programs
- Incorporate multiple of the areas of innovation listed above, e.g., testing multiple interventions, especially sets of interventions targeting combinations of outcomes spanning healthy birth, growth, and development; combining a new measurement tool with a new intervention; or combining retrospective analysis of a database with the design and piloting of a new intervention
- Clearly incorporate progress indicators against each objective and timelines within the timespan of the grant, such as a series of measurements to monitor trends or an early measurement useful to predict success at the end of the grant period
- Have a project plan whereby after two years the end of the seed grant period and the halfway point for the full grant period grantees will be in a position to participate in initial collaborative meetings to explore how the results from their project could inform the design of more extensive intervention packages for testing in single large cohorts
- Could contribute to a portfolio of funded projects that addresses a country's regional diversity and the need to provide health equity for diverse vulnerable populations
- Explain how proposed interventions will be tested in communities so that they have the highest likelihood of being relevant for implementation more broadly in the country's public health system

Examples of what we are looking for

- Approaches to clinical trial design that allow testing combinations of interventions and relatively rapidly determining which subsets of interventions are yielding impact
- Approaches that help determine how to effectively and efficiently deliver all necessary interventions together as a package to promote children thriving and health equity
- Approaches that reveal the interplay of biological pathways associated with stress, inflammation, and nutrition, and how such pathways might be targeted to simultaneously prevent multiple pathologies, such as intrauterine growth retardation and preterm birth, stunted postnatal growth, and impaired cognitive development

- Approaches that specifically combine interventions focused on improving child survival with those focused on improving healthy child development, including cognitive function
- Approaches, tools, and biomarkers for stratifying populations to determine who would benefit from a preventive intervention package, and who is at higher risk and warrants a therapeutic intervention package, including determining what is the optimal duration of treatment to prevent relapse
- Approaches, tools, and biomarkers for stratifying populations to reduce the risk of interventions causing unintended harm (e.g., metabolic disease, including obesity)
- Approaches for 1) rapid measurement of physical growth velocity and body composition; 2) measuring brain function and development, with a focus on tests that are simple, reliable, non-invasive, objective, universally applicable, and include those appropriate for fetal life, newborns, or early infancy; 3) measuring gestational age, with a focus on tests that are simple, reliable, non-invasive, universally applicable, and include those that can be applied to pregnant women or to the newborn or infant; 4) predicting or identifying metabolic complications or diseases in pregnancy that affect birth or postnatal outcomes; 5) measuring individual food intake, including validated and simple markers to assess exclusive breastfeeding practices; 6) developing integrated markers of systemic inflammation; and 7) developing combinations of tests either new or preexisting tests that when evaluated in combination provide better predictors of the outcomes of interest than any single test
- Approaches that specifically address the roles of women as perceived by society from adolescence to motherhood creating new or better opportunities to improve children's health and development (e.g., new uses of women's self-help groups)
- Food-based approaches that seek to identify the key ways in which agriculture interventions can improve nutrition outcomes
- Approaches that determine how to shift the emphasis to earlier prevention within the first 1,000 days of life, including determining the value of intervening in the first 100 days and preconception
- Approaches that yield actionable knowledge by characterizing populations for which there has been striking progress in children thriving

Examples of what we are NOT looking for

- Basic research that does not provide a clear path to development and testing of prevention and treatment strategies
- Studies that lead to solutions applicable to only a small fraction of the population (e.g., because of a focus on a specific disease or condition with limited incidence)
- Projects without the potential to expand in scale to provide solutions to a greater number or diversity of people
- Studies that propose interventions that detract from favorable family practices (e.g., studies that would lead to inappropriate early cessation of breast feeding, deter skin-to-skin care, or disrupt routine immunizations)

- Projects lacking metrics to determine success or failure and to allow decisions about the appropriateness of follow-on funding
- Solutions that are only slight improvements over existing approaches (e.g., replication of an approach in a new geography in the absence of added innovation)

Application instructions

Within this context, we are looking for applicants to apply to one of two categories:

- 1. Seed grants
- 2. Full grants

Details	Seed grants	Full grants
Funding amount	Up to INR 250 Lakhs	Between INR 12.5 Cr
	(USD \$500,000)	(USD \$2.5 million)
Duration of grant	Up to two years	Up to four years
Prerequisite data	Do not require preliminary data	Require data that demonstrate feasibility and effective application in a controlled or limited setting
Objective	To demonstrate proof of concept of an intervention or combination of approaches that has the potential to transform nutritional status for women and/or children in India	an intervention or combination of approaches that has the potential to transform nutritional status for women and/or children in India
Impact	within the timeframe and b) must be on the causal	be directly related to the goal statement (to reduce the burden of fetal growth impairment and preterm birth, stunted postnatal growth, and impaired cognitive

Partner requirements	None	None required. However, a
		consortium approach is strongly encouraged, including a partner organization that is currently implementing a program upon
		which the intervention or approach will be layered

In order to apply, please submit a 5 page, Letter of Interest that includes the following:

- Executive Summary (1/2 Page)
 - Must clearly define and describe key idea or hypothesis that motivates project
- Goals and Outcome (1 Page)
 - Must clearly define the potential outcome of the project if the goal is achieved (assuming subsequent work might be needed to take the project to scale).
 - Must clearly describe the key idea or hypothesis and how this idea or hypothesis is to be tested
- Project Plan (1 Page)
 - Must define critical experiments to prove/disprove idea or hypothesis
 - It is anticipated that the project plan will be organized by the Objectives needed to accomplish the goal of the Project. <u>The project plan must be organized by</u> <u>these objectives.</u>
- Organization Capabilities (1 Page)
 - Includes preliminary data of relevance
 - Includes partners and past experience
- Budget (1/2 Page)
 - Summary by objective
- *Submissions that exceed 5 pages will not be reviewed.

How we evaluate proposals

We seek proposals that clearly demonstrate the attributes below:

- Potential to lead to solutions with substantial impact related to the specific topic
- Scientific and technical excellence & innovation
 - including creativity of the project's approach and clear differentiation from existing approaches
 - o including a clear and rigorous conceptual framework for the activities
- Project Plan including:
 - o investigator and organization capabilities and potential for collaboration
 - Value in terms of appropriateness of the budget and timeline relative to project complexity, risk, and potential impact

Collaborations

This request for proposals seeks to create a consortium of individually funded projects that will benefit from sharing information between projects. We expect that such sharing will help to ensure that the goals of the innovative approaches in individual projects are ultimately integrated with each other, thereby increasing the chances that the programs will be greater than the sum of their parts. Furthermore we expect that sharing experimental methods, data, and resources will ultimately improve the ability to compare and validate local research findings and to develop interventions and products that can have impact at a greater scale. The specific terms of the collaborative activities will be negotiated prior to the grant award. Collaborative efforts include:

- **Cohort harmonization** When collaborating with projects with existing cohorts or establishing new cohorts, investigators will be expected to participate, whenever possible, in cohort harmonization. Study sites will be expected to develop and follow standard operating procedures and quality control protocols for specimen collections and participate in the establishment of a minimum common set of data and specimens to be collected across the program.
- **Data sharing** A data sharing plan will be developed that is equitable, ethical, and efficient. It will include a policy covering 1) sharing data for confidential and strictly internal use at the Gates Foundation, and 2) sharing data with the broader scientific community.

Eligibility criteria of target groups: This RFA is India-led; the programme is open to academics, research institutions, medical research institutions, for-profit companies, not-for-profit organizations, trusts and foundations. Grants will be made to researchers and innovators who are Indian individual or Indian entities *, we also encourage partnerships with researchers of national/international expertise. Experts of the relevant discipline as mentors should be a part of proposal such as agriculturist, nutritionist, agronomist, biotechnologist, clinicians, pediatricians, dieticians, ethnographers, biochemist, microbiologist, market analyst etc.

- * An Individual should be a Citizen of India
- * Indian entities are defined as those established under any relevant statute, agreement, rule or regulation in India.

Through national and international collaboration we expect that sharing experimental methods, data, and resources will ultimately improve the ability to compare and validate local research findings and to develop interventions and products that can have impact at a greater scale.

Application Procedure:

- 1. Review panels established under the Grand Challenges India partnership will evaluate the LOIs.
- 2. Post LOI Review, shortlisted LOIs will be invited for online full proposal submission.
- 3. Instructions on the submission of full proposals will be provided to shortlisted applicants through proposal development workshops.
- 4. Post full proposal review, the applicants will be invited to present their proposals in detail to TAG.
- 5. Awards certificate will be awarded to GCI applicants who are selected through the due process.
- 6. BIRAC will enter into a separate funding agreement with successful GCI grantee(s) to govern the project terms and conditions and fund disbursement modalities.

* We will not be able to provide individual feedback to applicants those who are not selected for submission of full proposals.

Allowable Costs:

- Non-Recurring Budget: **Equipment and Accessories** (Upto 20% of proposed cost) list of equipment's, if required and justification in relevance to the project activities (Quotations supporting proposed equipment and accessories).
- Recurring Budget (commensurate with project activities): Manpower (Upto 30% of proposed cost); Consumables (Upto 20% of proposed cost); Travel (Inclusive of International travel, in case of International Cost Recipient(s)); Research Contingency (On case to case basis); Outsourcing (In case any activity to be outsourced); Training / Awareness Campaigns to the primary beneficiaries; Overhead of each Primary & other Cost Recipients(s) (Upto 10% of the Recurring Cost).
- International Cost Recipient(s) if any will be supported by BMGF directly, for operational cost excluding honorarium and travel expenses which will be reimbursed by the Indian Applicant.

<u>*Note:</u> Justifications to be provided for roles of each manpower involved, consumables proposed, travel (Local and International in case if any), research contingency and trainings.

RFP Timeline:

Launch of RFP
Start of LOI submission
LOI submissions due at 11 p.m. IST
Finalists notified and invited to a proposal development workshop
Final proposals due
Award Announcement

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