

Food Systems for Improved Nutrition Research Program: Request for Applications

Application Deadline: May 7, 2018 GMT

Overview

Introduction

The UK Department for International Development (DFID) and the Bill & Melinda Gates Foundation are seeking applications to address a broad set of robust and large-scale research priorities to guide program and policy efforts to **improve food safety in sustainable, nutritious food systems in low- and middle-income countries (LMICs).**

Background

Undernutrition remains one of the world's greatest human and economic development challenges. Undernutrition comes in many forms and is not always visible. One in four children under 5 years of age suffers from stunting, or chronic undernutrition, which is caused by diets of insufficient quality and quantity, inappropriate care and feeding practices in early life, and high rates of infectious disease. Wasting, or acute undernutrition, can be the result of seasonal changes in diets or infectious diseases. Micronutrient deficiencies are associated with a multitude of poor health and development outcomes.

Improving nutrition requires a multi-sectoral approach that brings together the health, agriculture, education, environment, water, sanitation and hygiene and social protection sectors. Food systems--defined as the production, transportation, storage, processing, marketing, purchase, and consumption of food--play an integral role in multiple nutritional outcomes. A functioning, healthy food system should deliver equitable consumption of a safe, affordable, and nutritious diet year-round. It should do so sustainably, with respect to both environmental considerations and food systems viability over the long-term, especially in the face of changing environments and the demand for foods from increasingly urban populations. A well-developed food system can deliver increased and diversified outputs (crops, livestock, fish) that may enhance nutrition and health directly through increased access to and consumption of diverse foods, or indirectly through greater incomes to food systems actors and increased national wealth. Furthermore, the links between the food system and health work in both directions in that better nutrition and health of farmers, traders, processors, and retailers can increase their economic productivity. Food systems that interface with both rural and urban populations provide key opportunities for improving nutrition and health outcomes.

Food systems can carry risks to nutrition and health outcomes, particularly through food-borne diseases (FBD), zoonotic infections and other agriculture-related impacts on health such as exposure to pesticides and antimicrobial resistance (AMR). According to the 2015 WHO Foodborne Disease Burden Epidemiology Reference Group (FERG 2015) report, which examined 31 food-borne hazards, FBD resulted in the loss of 33 million disability-adjusted life years (DALYs) in 2010. Seventy percent of global cases of FBD are concentrated in Sub-Saharan Africa and South/South East Asia, and 40% of the burden falls on children under 5 years of age. Biological hazards (viruses, bacteria, and parasites) cause 97% of the total FBD burden LMICs. While fresh foods such as fruits, vegetables and animal-source foods (ASFs) are among the most nutrient-rich foods, mounting evidence suggests that they are often the most contaminated foods (Hoffmann 2017). As rising incomes increase the demand for fresh foods, and urbanization increases the volume of food being transported between food producers and consumers, the burden of FBDs is expected to increase in LMICs. This trend is counter to the trend of other infectious disease incidence that generally declines as nations develop.

Ensuring food safety is important for several outcomes including population health, national economies and gender equality:

- **Health:** FBD currently results in substantial morbidity and mortality globally. The FERG estimates that FBD resulted in the loss of 33 million DALYs in 2010. A conservative estimate places the annual cost of treating

illness due to FBD in Africa at \$10.5 billion (Grace 2018). Food safety challenges in LMICs seem set to increase in the future as growing populations access increasingly diverse foods from new and largely unregulated markets. The impacts on nutrition and health of these changing diets may further compound negative impacts. Tackling FBD can also help tackle AMR, since reservoirs of AMR within the food supply can contribute to the spread of AMR as well as transmit resistance to other pathogenic organisms.

- *Economy:* Sourcing safe food has been a challenge for companies seeking to operate both in domestic and export markets in LMICs. In parallel, the inability to consistently provide safe, quality food is often a barrier to smallholder farmers participating in more lucrative value chain activities. An estimated \$15 billion annual loss to GDP in sub-Saharan Africa results from FBD and worker ill-health. Trends also show that informal markets, where low income consumers currently purchase over 90% of their food, will continue to serve as the main point of purchase in Africa and South Asia for some time to come, but a lack of infrastructure, awareness, and capacity make them especially important sources of contaminated foods (Grace 2015, 2018).
- *Gender:* Food safety has both health and economic implications that have particular impacts on women. FBD can be particularly damaging to the health of pregnant and lactating women and interfere with their ability to care for young children. In smallholder agricultural and informal market systems, women play significant roles in production, processing, and food preparation. As such, they are on the frontline both in terms of risks for FBDs and as actors for reducing contamination within the food supply.

Despite their adverse impacts on health and economies especially in LMICs, understanding and mitigating FBD has received relatively little attention. Furthermore, investments in food safety have often been built around **perceptions** of a hazard's impact on health rather than on **evidence** of its contribution to the burden of disease. For example, the 2015 FERG study reports that chemicals such as pesticides and natural toxins such as mycotoxins are collectively responsible for 3% of global burden of FBD. Conversely in public and in policy circles there is often a perception that pesticides and toxins carry the greatest FBD risk, compared to bacterial pathogens. This perception has also translated into research funding: in sub-Saharan Africa aflatoxin consumption is attributed to 14% of the food-borne health burden and research on aflatoxins receives 60% of hazard-specific funding.

FBD is not a priority in many LMICS and the global community lacks evidence on the efficacy, costs, and benefits of possible solutions. Limited evidence does exist in the following areas:

- *Agricultural practices:* Small-scale studies in several countries suggest that following Good Agricultural Practices (GAP) leads to improvements in practices, hygiene, reduced pesticide use and improved yield. There is no evidence on the sustainability or scalability of such interventions. Some small farmers adopt GAP in order to comply with standards for export markets, but frequently exit these markets as standards increase. Little information exists on whether and how the adoption of GAP impacts the safety of the food supply for domestic markets.
- *Training of informal value chain actors:* A meta-analysis of findings from intervention studies that trained food processors and vendors on safe handling practices identified that after training compared with non-trained control participants, 30% more trained actors demonstrated improved knowledge and 70% more improved practices (Grace 2015). Recent evidence from Robinson and Yoshida (2016) demonstrates that where consumers demand safe food, targeting actors in the middle of the value chain—traders, processors, retailers—with a “facilitative approach” that includes incentives and light training can yield moderate improvements, but results are also inconsistent. Targeting actors in the middle of the value chain may also prove to be a relatively cost-effective approach because there are fewer of them compared to either producers or consumers.
- *Technologies:* Innovations to enhance food safety in LMICs exist but are not commonly used and are often not cost-effective or practical to roll out on a large scale. These innovations include technologies to diagnose, prevent, and treat food contamination. For example, food-grade containers and treated water can prevent growth and spread of biological pathogens. Other potential technological solutions that have been tested at small scale include vinegar sprays for animal carcasses and off-grid cold storage designed for small-scale producers and traders.
- *Governance:* LMIC governments often struggle to implement strong regulatory systems that protect domestic consumers from risk of FBD and to enforce sanitary, phytosanitary, and quality standards. Implemented in low capacity systems with infrastructural challenges, common food safety regulatory approaches include raising standards, issuing fines, and shutting vendors down. These approaches have largely been ineffective and can push unsafe food to markets where poorer consumers shop. More effective food safety governance systems include: harmonized and appropriate regulatory standards accounting for informal sector realities, an enforcement structure with capacity and delegated authority that works with food systems actors to improve food safety practices, and robust consumer engagement.

The FERG report highlights the growing evidence base on the health and economic impacts of FBD and provides estimates of FBD at a regional level based on best available evidence and expert opinion. However, the FERG expert

group identifies that there are significant gaps in the current knowledge base thus making it difficult for program designers and policy makers to design and implement effective solutions. Based on the clear health burden, there is a need for a broader set of robust evidence to identify and control food-borne hazards. Of particular interest, and **the focus of this call, is to characterize and address FBD and biological hazards related to food systems:**

- **in fresh food supply chains, i.e. animal-source foods, fruits, and vegetables;**
- **along the food system continuum, i.e. from production to consumption and from rural to urban environments; and**
- **in informal, domestic points of sale where low-income consumers generally purchase their food and meals.**

This research program will complement support currently provided by DFID and the Gates Foundation to deliver high-quality evidence on the links between food systems, nutrition and health to multiple initiatives including: the prior four RFAs; the Leveraging Agriculture for Nutrition in South Asia (LANSA) research program consortium; Advancing Research on Nutrition and Agriculture (ARENA); and Innovative Metrics and Methods for Agriculture and Nutrition Actions (IMMANA). The program will be expected to contribute significantly to ongoing international efforts to improve evidence and policies related to the intersection of food systems, nutrition and health, such as those underway at the CGIAR Agriculture for Nutrition and Health (A4NH) initiative, Partnership for Aflatoxin Control in Africa (PACA), and Global Food Safety Partnership (GFSP). It will build on a portfolio of investments seeking to build evidence on how to reduce FBD, including the International Livestock Research Institute's MoreMilk trial, the USAID Feed the Future Livestock System Innovation Lab's Campylobacter Genomics and Environmental Enteric Dysfunction (CAGED) trial, and the University of Michigan's Invisible Fishers formative research.

Goal

The goal of this program is to deliver high-quality evidence on **innovations, interventions and approaches to characterize and mitigate FBD and biological hazards related to food systems at large scale in LMIC food systems**. The outcome will be a portfolio of research investments that fill the gaps in evidence related to the nature of the problem, incentives and barriers to reducing the presence of hazards in the food supply, and appropriate policies, regulations, and standards.

Scope and Approach

This partnership between DFID and the Bill & Melinda Gates Foundation has been designed to select and support multiple research studies through a Request for Applications (RFA) announced annually. This is the fourth open call for applications. Three earlier rounds requested research to understand how the agricultural sector can more effectively improve nutrition outcomes in women and children. There was also a competitively commissioned research program on [Drivers of Food Choice](#). This is the first call focused on food safety.

Research questions and topics

This research agenda on FBD and biological hazards (bacteria, viruses, and parasites) related to food systems is open for exploration both at the household level and in single value chains as well as toward a more holistic exploration of systems-level interventions at the production through market levels. A deep focus on both programmatic and environmental sustainability is needed to ensure lasting impact. Proposed studies should also demonstrate grounding in the current reality of the systems of focus, for example, stakeholder awareness, feasible partnerships to ensure uptake, existing infrastructure and capacities, and cost implications.

Based on a review of evidence and expert consultations, the following research categories with illustrative questions have been prioritized:

1. Understanding the scale and nature of the problem:

- *What standardized tools, methods, and metrics can be developed and applied to diagnose and evaluate FBD and biological hazards related to food systems and their impact on human health?*
- *How does the health burden of FBD translate into economic costs?*
- *What is the business case to invest in improving food safety in terms of both economic impact and health costs?*
- *Given that FBD surveillance is the foundation of an effective food safety system, how can the data collection and analysis capabilities of governments and businesses to assess risk be improved?*

2. Approaches to mitigate the impact of FBD:

- *How can effective interventions to reduce the risk of FBD and biological hazards related to food systems be adapted and implemented at large scale in LMIC settings? What are the barriers to uptake of these interventions?*

and how can uptake be incentivized? Interventions with proven effectiveness in LMIC settings to-date include raising awareness and training among private and public sector actors, provision of an enabling regulatory environment, and technologies to diagnose, prevent, and treat the problem.

- *What are the costs associated with interventions to improve food production, transport, storage, processing, retail, and preparation practices? What is the cost-effectiveness of these interventions?*
- *How can behavior change to reduce the risk of FBD be incentivized at the market and consumer levels? What role can different value chain actors play in improving food safety practices, e.g. aggregation services, marketing, etc.? What is effective communication on food safety risks and what is the impact of raising awareness of these risks on the practices of various food systems actors?*
- *What are gendered considerations for the above questions? How do time constraints, financial burdens, and roles in the value chain affect women's ability to respond to food safety issues as food producers, traders, and consumers?*

3. Food safety governance:

- *What are the appropriate policies, regulations, and standards to improve food safety in informal markets for fresh, perishable foods?*
- *What documented and effective approaches from export markets, other LMICs, and global food safety standards (e.g. Global Food Safety Initiative) can realistically be applied and adapted to fresh food value chains in informal markets?*
- *How can the public sector build food safety systems and standards that do not negatively impact low-income producers, traders, and consumers, such as concentrating unsafe food in markets used by the lowest-income consumers and pushing smallholder farmers and traders out of markets?*
- *How can standards be affordable and manageable to smallholder farmers and small and medium enterprises in the value chain?*
- *How might public sector approaches differ across urban, peri-urban, and rural markets?*

Research methods

We are open to a wide variety of research methods for this call. Experimental designs, such as randomized controlled trials, may work well to assess the impact of single interventions, but more complex market-level interventions can be difficult to randomize with a clean control group, and furthermore it can be particularly hard to identify net impacts. It is also likely that experimental designs may be unable to address many of the research questions, and therefore the field must be innovative in the types of methods used to advance the proposed research agenda. Multi-disciplinary research teams are strongly encouraged for this call.

In order to address the prioritized research questions, this RFA is open to methods that address the complexities of food systems. These methods include:

- Secondary data analysis that would, for example, utilize existing data to investigate linkages between policies or interventions and health impacts and draw out potential applications for new environments. Systematic reviews of specific interventions to address FBD would be another example of appropriate secondary data analysis.
- Comparative analysis, exploring outcomes across countries with a standardized approach, that allows for attribution and comparison and compares multiple country experiences to identify successes, failures, and entry points for a strong pro-equity food safety system.
- Qualitative policy analysis and case studies that would, for example, investigate the impact of specific food safety policies or standards on FBD hazards or risk in specific value chains or across the food system.
- Modeling studies, for example, risk assessments examining the impact of biological hazards in the food system on human health or cost-effectiveness studies that analyze the economic and health costs of FBD.
- Formative, feasibility, and validation research that is critical for developing effective interventions. This would include studies designed to explain the interests, behaviors and practices of target populations and the testing and validation of existing tools and interventions. Effective behavior change communication, one category of potential interventions, is crucial to drive changes necessary to mitigate the presence of hazards and risks.
- Quasi-experimental approaches that investigate the impact of real-world policies or programs and are potentially more conducive to measuring market-level interventions. We welcome studies that examine the long-term impact of programs that seek to change behaviors or practices to understand what changes were sustained over time, including ex-post assessments of existing or closed programs. (See note in the following bullet on acceptable outcome measures for quasi-experimental studies.)
- Experimental approaches, including randomized controlled trials where appropriate, feasible, and cost-effective. A lack of validated metrics and common approaches to measurement has been a challenge for researchers working in food systems, and is a particular problem when it comes to understanding food safety issues. While

experts emphasize that a focus on risk is preferable to a focus on hazards, documenting attribution of specific foods and the production system to a human health outcome is challenging. Thus, for studies proposing to test interventions to specifically improve the safety of a value chain, we will accept “presence of hazard” as an acceptable outcome measure. For research focused on changing behaviors of food system actors, acceptable outcome indicators include changes in practices that impact the safety of food and “presence of hazard”. We welcome studies that examine the long-term impact of programs that seek to change behaviors or practices to understand what changes were sustained over time, including ex-post assessments of existing or closed programs.

Focus geographies

The focus geographies for this call include countries with high burdens of undernutrition and DFID and Gates Foundation priority countries. They are: Burkina Faso, Ethiopia, Ghana, Nigeria, Mozambique, Rwanda, Tanzania, Uganda, Zambia, Bangladesh, Myanmar, Pakistan, and the Indian states of Andhra Pradesh, Bihar, Odisha, and Uttar Pradesh. We will accept studies drawing on work from other LMICs that have direct application to the countries in this list and demonstrate clear additional value to those countries.

We will NOT accept applications on the following topics:

- Physical or chemical hazards, including pesticides, metals, and mycotoxins
- Export value chains
- Anti-microbial resistance (whilst recognizing there are links with FBD, e.g. ingestion of AMR organisms via food can, if they are pathogenic, result in human illnesses)
- Development of new technologies (application of existing technologies proven to be effective is allowed)
- Infrastructure development, such as roads, electrification, and laboratory construction

Rules & Guidelines

Eligibility

Funding Criteria

Proposals are expected from an organization or consortia that can demonstrate specific competencies relevant to this program. In particular, they must demonstrate:

- Excellent past performance in the delivery of high-quality research in agriculture, nutrition, health, or food systems
- Multidisciplinary expertise across relevant sectors
- A track record of publication of research findings in peer-reviewed academic journals
- Significant experience of conducting research in LMIC settings
- Evidence of successful capacity strengthening of LMIC research institutions
- An ability to transfer research findings to policy and program dialogue for evidence-based decision making and action

Applicants may include academic institutions, research institutions, non-governmental organizations (NGOs), governments, U.N. agencies, and for-profit companies.

Exclusion Criteria

We will NOT consider funding for:

- Applications that do not include the strong participation of a LMIC research institution
- Organizations unable to demonstrate proven success in implementing large-scale, rigorous research studies
- Studies that do not sufficiently demonstrate expertise in food systems and food safety
- Study designs that will result in findings unlikely to fill a gap in the existing research evidence base
- Study designs that are not methodologically robust and adequately powered for primary outcomes
- Applications from individuals
- Studies not focused on the geographies specified above
- Submissions that exceed the page limit of 7 pages

Evaluation Criteria

Proposals will be selected for funding in a two-phase process of short concept memos followed by longer full proposals.

We are expecting the following outputs to be delivered:

1. High quality evidence structured to address the research questions, methods, and outcomes outlined above
2. Publications in international peer-reviewed journals
3. Increased capacity of researchers, evaluators, and practitioners working on agriculture, nutrition and health linkages, particularly those based in the priority countries for this call which are mentioned above.

Submissions received after the deadline will not be reviewed. Submissions received by the deadline will be evaluated on the following criteria:

- Alignment with the goals of this RFA and with DFID and the Gates Foundation's strategies in agriculture and nutrition (links provided below)
- Potential to fill, or contribute to filling, a major gap in global or country evidence on food safety outcomes, including continued relevance of the research question over time
- Capability and commitment of the lead principal investigator (PI) and the lead institution
- Strong participation of institutions based in the country or countries of work
- Excellence and rigor of the research design and implementation plan
- Articulation of the final outcome of the program following the conclusion of the research study, including dissemination and research uptake plan and link with key policy makers
- A commitment to the translation of research findings into use, and the proactive sharing of open data to make information about agriculture and nutrition more widely accessible. Please refer to the Global Open Data for Agriculture and Nutrition (www.godan.info) for more information on global efforts to make relevant data available. Please also see the Gates Foundation's Open Access Policy [here](#).
- Complementarity with existing research studies on food systems globally and within projects supported by DFID and Gates Foundation
- Overall value for money

Activities & Timeline

March 28, 2018: RFA released
May 7, 2018: Concept memos due 5 pm GMT
May 30, 2018: Invitations for proposals
July 23 2018: Final proposals due

How to Apply

Response Requirements

To apply, please submit a concept note in the required format of up to 7 pages, including references and the budget, that includes the following:

Study Design, Scope, and Approach

- Clear articulation of the primary and secondary research questions
- Description of the proposed research study, including study design, methods, and outcomes to be measured
- Summary of environmental and gender considerations that are relevant to the study design and their potential implications

Relevance and Uptake

- Description of the gap in knowledge in food safety that the proposed study will fill and how the findings will be relevant at the end of the proposed study timeline
- Description of how and where the findings from the research study would be applicable at a program and/or policy level
- Brief communications plan that describes the approach for publication, research uptake and policy linkage

Organizational Fit

- Summary of the lead PI's and applicant organization's previous experience and expertise that is relevant to this call
- Description of any potential collaborative partners (letters of support are not expected)

Budget

- Justification of overall value for money
- If the method is selected is to layer on an existing research study, a description of the specific added value of requested funds on top of existing funding
- Summary budget for the proposed activities in format provided (see template in concept memo)

Submissions that exceed 7 pages total will not be reviewed.

If the concept memo is selected to move forward, we will request a full proposal of up to 25 pages that includes details on the above components plus the following:

- A project implementation plan with timeline
- A full monitoring and evaluation plan
- A results framework that specifies project outputs and outcomes
- Summary of partners with whom the lead organization will work and their corresponding roles
- Biographical information for the PI and key project staff
- Signed Global Access Policy documents
- Detailed budget as an annex

Submission Instructions

1. Fill out the concept note form.
2. Once you have finished filling out the concept note form, attach it to an email addressed to FoodSafetyRFA@gatesfoundation.org.
3. In the subject line, please include the name of the applicant organization.

Submissions are due no later than 5 pm GMT on May 7, 2018.

More Information

Reference

Please reference the following for further information:

DFID 2017 [Saving Lives, investing in future generations and building prosperity: the UK's Global Nutrition position paper](#)

[DFID, 2015 DFID's Conceptual Framework on Agriculture](#)

Foodborne Disease Burden Epidemiology Reference Group (FERG). 2015. *WHO Estimates of the Global Burden of Foodborne Disease*. Geneva: World Health Organization.

[Gates Foundation Nutrition Strategy](#) and [Gates Foundation Agricultural Development Strategy](#)

Grace D., S. Alonso, F. Mutua, et al. 2018. [Food Safety Investment Expert Advice: Burkina Faso, Ethiopia, Nigeria](#). Report commissioned by Gates Foundation from International Livestock Research Institute.

Grace, D. 2017. [Food Safety in developing countries: research gaps and opportunities](#). White Paper commissioned by USAID/Feed the Future/Bureau for Food Security.

Grace, D. 2015. Food Safety in Low and Middle Income Countries. *International Journal of Environmental Research and Public Health*, 12(9), 10490–10507. <http://doi.org/10.3390/ijerph120910490>

Hoffmann S, Devleesschauwer B, Aspinnall, W, Cooke R, Corrigan T, Havelaar A, et al. 2017. "Attribution of global foodborne disease to specific foods: Findings from a World Health Organization structured expert elicitation. *PLoS ONE* 12(9): e0183641. <https://doi.org/10.1371/journal.pone.0183641>

Robinson, E. and Yoshida, N. 2016. *Improving the Nutritional Quality of Food Markets through the Informal Sector: Lessons from Case Studies in Other Sectors*, IDS Evidence Report 171, Brighton: IDS

[Roessel, K. and Grace, D. 2014. Food safety and informal markets: Animal products in sub-Saharan Africa. London, UK:](#)

Ruel, M, A. Quisumbing, M. Balagamwala. 2018. Nutrition-Sensitive Agriculture: What Have We Learned So Far? *Global Food Security*. <https://doi.org/10.1016/j.gfs.2018.01.002>

FAQ

Who can participate? This is an open solicitation. We welcome submissions from organizations in all sectors (NGO, government, academic, UN, and private). Submissions cannot come from individuals without organizational affiliation.

When are concept notes due? Concept notes must be submitted by 5 pm GMT on May 7, 2018.

When will applications be selected? Finalists will be notified that they are invited to submit a full proposal by May 30, 2018.

Will I receive any compensation for submitting? You will not receive any compensation for your submission even if it is used by the Gates Foundation or third parties in any way.

What will the Gates Foundation and DFID do with my submission? The Gates Foundation and DFID will review all submissions. We may also share your submission, or ideas contained within it, with the public or partners to ensure that good ideas and new innovations are broadly disseminated and available for use. With this in mind, please ensure that any materials you provide under this solicitation are your own, and understand that the Gates Foundation and others will have a right to use your submission freely, upon delivery, for non-commercial purposes.

What are the focus countries for this RFA? The focus geographies for application of work include countries with high burdens of undernutrition and DFID and Gates Foundation priority countries. They are: Burkina Faso, Ethiopia, Ghana, Nigeria, Mozambique, Rwanda, Tanzania, Uganda, Zambia, Bangladesh, Myanmar, Pakistan, and the Indian states of Andhra Pradesh, Bihar, Odisha, and Uttar Pradesh. We will accept studies drawing on work from other LMICs with direct application to the countries in this list.

What is the length of a grant that will be considered? We will consider research studies that propose a rational timeline from inception to research completion that do not exceed 4 years.

What is the budget that will be considered? We will consider research studies that propose appropriate costs for the study length, outcomes, and methods, and that propose strong value for money.

Where can I ask more questions? Please visit the Agriculture for Nutrition and Health Academy's website (www.anh-academy.org) for an open forum where you can post questions and receive a response.

PRIVACY NOTICE

To help the Gates Foundation staff in their evaluation and analysis of projects, all proposals, documents, communications, and associated materials submitted to the Gates Foundation (collectively, "Submission Materials") will become the property of the Gates Foundation and may be subject to external review by independent subject matter experts and co-funders in addition to analysis by the Gates Foundation staff. Please carefully consider the information included in the Submission Materials. If you have any doubts about the wisdom of disclosure of confidential or proprietary information, the Gates Foundation recommends you consult with your legal counsel and take any steps you deem necessary to protect your intellectual property. You may wish to consider whether such information is critical for evaluating the submission, and whether more general, non-confidential information may be adequate as an alternative for these purposes.

We respect confidential information we receive. Nonetheless, notwithstanding your characterization of any information as being confidential, the Gates Foundation may publicly disclose all information contained in Submission Materials to the extent as may be required by law and as is necessary for co-funders and external reviewers, such as government entities, to evaluate them and the manner and scope of potential funding consistent with appropriate regulations and their internal guidelines and policies.

WARRANTY

By providing any Submission Materials, the sender warrants the Gates Foundation that they have the right to provide the information submitted. Applicants with questions concerning the contents of their Submission Materials may contact the Gates Foundation at: Info@gatesfoundation.org

INTELLECTUAL PROPERTY

Since the output of this program may lead to innovative technologies and/or products that could result in improved diagnostics or interventions ('products', intellectual or otherwise, which may include, but are not exclusively defined as: devices, drug or formulations, biologics, or patentable processes or approaches) for those that need of them most in the developing world, the successful development of these high priority products may require substantial involvement and support of private sector industries as sub-contractors, and may also involve collaborations with multiple organizations, including academic and/or non-profit research institutions. It is the intent of this program to support the formation of appropriate public-private partnerships that are essential to meet these urgent global health needs. Intellectual property (IP) rights and the management of IP rights are likely to play an important role in achieving the ultimate goals of this initiative. To this end, the Gates Foundation requires that, even at the Concept Memo stage, all applicants seriously consider their willingness to submit a full proposal in compliance with the Gates Foundation's proposal guidelines, a portion of which asks for certain information and intentions regarding intellectual property and global access concerns. Specifically, the Gates Foundation requires that you agree to use good faith efforts to conduct and manage the research, technologies, information and innovations involved in the Project in a manner that enables (a) the knowledge gained during the Project to be promptly and broadly disseminated, and (b) the intended product(s) to be made available and accessible at reasonable cost to the developing countries of the world. The Gates Foundation refers to this as "Global Access."

As part of the Gates Foundation's review and evaluation of each full proposal, due diligence will be conducted with respect to each participant's ability and commitment to manage intellectual property in a manner consistent with the stated scientific and charitable goals of the Gates Foundation. Due diligence activities may include inquiry into an applicant's:

- 1) Freedom to operate (FTO) and ability to freely use and acquire needed background technology;
- 2) Commitment to promote the utilization, commercialization and availability of inventions for public benefit in developing countries

In order to facilitate this due diligence process applicants are encouraged to provide information with respect to the items above in their submission materials. Applicants should consider whether the protection through IP (in particular through patents) new pathways or mechanisms that will directly inform the development of interventions would best further the goals of this project to improve the health and development of children in the developing world. To be clear, the goal is not to develop a position for or against such IP, but to articulate the role that IP would play in furthering the specific goals of this project.

Applicants will be required to prepare a Global Access Strategy reflecting how they will achieve the Global Access requirements described above.

Applicants are also expected to make new information and materials known to the research and medical communities in a timely manner through publications, web announcements, progress reports to the Gates Foundation, and other appropriate mechanisms. These concepts may be discussed at some length with the applicants invited to submit full proposals, and will be addressed (to the extent appropriate) within each final grant agreement. The Global Access Strategy will also include provisions defining these concepts.

DATA ACCESS PRINCIPLES

In accordance with its charitable mission, the Gates Foundation is committed to optimizing the use of data to translate knowledge into life-saving interventions. To this end, it is essential that data are made widely and rapidly available to the broader global health community through good data access practices. We are committed to ensuring that data collected is made open access in alignment with the Global Open Data for Agriculture and Nutrition (GODAN). For more information on GODAN, please click [here](#).

Data access is intended to promote:

- *Innovation*, by encouraging diversity of analysis and opinion, facilitating evaluation of alternative hypotheses, permitting meta-analysis, and facilitating synthesis of results from individual projects into a larger whole, thereby promoting potentially lifesaving new insights.
- *Collaboration*, between teams and institutions, and among diverse disciplines, resulting in greater productivity and creativity.
- *Efficiency*, by preventing unnecessary duplication of effort, enabling secondary analyses of existing data, and enabling the redirection of resources to the most promising research endeavors, thereby maximizing the potential impact of investments.
- *Accountability*, by encouraging independent verification and analysis, thereby improving data quality
- *Capacity Strengthening*, by facilitating the education of new researchers and evaluators and enabling broader access to data for secondary analysis, which is of particular importance to investigators in developing countries.

Please also see the Gates Foundation's Open Access Policy [here](#).

RESEARCH ASSURANCES

While not necessary for the Concept Memo, as applicable to the individual project, the Gates Foundation will require that for each venue in which any part of the project is conducted (either by your organization or a subgrantee or subcontractor) all legal and regulatory approvals for the activities being conducted will be obtained in advance of commencing the regulated activity. The Gates Foundation will further require you to agree that no funds will be expended to enroll human subjects until the necessary regulatory and ethical bodies' approvals are obtained.

RESEARCH INVOLVING HUMAN SUBJECTS

You agree that no funds will be expended to enroll human subjects in any research project subject to Institution Review Board (IRB) or independent ethics committee (IEC) approval until such approval has been obtained for each site (see below sections for more information).

PROVISION OF CARE FOR HUMAN SUBJECTS RESEARCH

In keeping with "Good Clinical Practice" standards, you will disclose to subjects and the IRBs what care and/or referrals will be available through participation in the study. Institutional policies regarding what care will be provided to personnel who are injured as a result of their work on the Project should similarly be developed, approved and implemented with notice to the employees.

INSTITUTIONAL REVIEW BOARD (IRB) APPROVAL

You agree to obtain the review and approval of all final protocols by the appropriate IRBs and ethical committees prior to enrollment of the first human subject and when using human material. A similar provision applies to Institutional Animal Care and Use Committee approval of studies involving animals, and Institutional Biosafety Committee for biohazards and recombinant DNA. You agree to provide prompt notice to the Gates Foundation if the facts and circumstances change regarding the approval status of the IRBs or ethical committees for any final protocol(s).

INDEMNIFICATION

For all clinical trials, the Gates Foundation requires that you agree to indemnify, defend and hold the Gates Foundation harmless from and against any and all liability, loss, and expense (including reasonable attorneys' fees and expenses) or claims for injury or damages arising out of or resulting from, or that are alleged to arise out of or result from, the actions or omissions by you or of any of your officers, agents, employees, subgrantees, contractors or subcontractors with respect to the grant. You agree that any activities by the Gates Foundation in connection with the Project, such as its review or proposal of suggested modifications to the Project, will not modify or waive the Gates Foundation's rights under this paragraph.

COVERAGE FOR ALL SITES

You agree that for each venue in which any part of the Project is conducted (either by your organization or a subgrantee or subcontractor) all legal and regulatory approvals for the activities being conducted will be obtained in advance of commencing the regulated activity. You further specifically agree that no funds will be expended to enroll human subjects until the necessary regulatory and ethical bodies' approvals are obtained.

REGULATED ACTIVITIES

The coverage requirements set forth in the preceding paragraphs include but are not limited to regulations relating to: research involving human subjects; clinical trials, including management of data confidentiality; research involving animals; research using substances or organisms classified as Select Agents by the U.S. Government; use or release of genetically modified organisms; research use of recombinant DNA; and/or use of any organism, substance or material considered to be a biohazard, including adherence to all applicable standards for transport of specimens, both locally and internationally, as appropriate. As applicable, regulated activities and their documentation are to be conducted under the applicable international, national, and local standards. Documentation of research results should be consistent with regulations and the need to establish corroborated dates of invention and reduction to practice with respect to inventions where this is relevant.

ALLOWABLE COSTS

Grant funds may be used for the following costs. Please provide budget estimates according to these categories: personnel; travel; sub-grants; consultants; capital equipment; and other direct costs, including non-capital equipment, supplies, and other costs directly attributable to the project. Indirect costs: The Gates Foundation provides limited indirect cost in accordance with its policy. Please review the Gates Foundation's [indirect cost policy](#).

About the Bill & Melinda Gates Foundation

Guided by the belief that every life has equal value, the Bill & Melinda Gates Foundation works to help all people lead healthy, productive lives. We work with partner organizations worldwide to tackle critical problems in four program areas. Our Global Development Division works to help the world's poorest people lift themselves out of hunger and poverty. Our Global Health Division aims to harness advances in science and technology to save lives in developing countries. Our United States Division works to improve U.S. high school and postsecondary education and support vulnerable children and families in Washington State. And our Global Policy & Advocacy Division seeks to build strategic relationships and promote policies that will help advance our work. Our approach to grantmaking emphasizes collaboration, innovation, risk-taking, and, most importantly, results.

To learn more about the Gates Foundation's work, visit www.gatesfoundation.org.

About the UK Department for International Development

The Department for International Development (DFID) leads the UK's work to end extreme poverty, deliver the Global Goals, and tackle global challenges in line with the government's [UK Aid Strategy](#). We are tackling the global challenges of our time including poverty and disease, mass migration, insecurity and conflict. Our work is building a safer, healthier, more prosperous world for people in developing countries and in the UK too.

DFID's Research and Evidence Division (RED) helps DFID to deliver results at scale by supporting the development of new technologies and innovations, helping to find better and more cost-effective ways of delivering development, and improving understanding of key development questions and data to support policy choices and to shape design of investments.

DFID is a ministerial department, supported by [two agencies and public bodies](#). Read more about what DFID does: <https://www.gov.uk/government/organisations/department-for-international-development/about>