

REQUEST FOR PROPOSALS

Grand Challenges Canada
at the McLaughlin-Rotman Centre for Global Health



Grand Challenges Canada™
Grands Défis Canada™^{MC}

BOLD IDEAS FOR HUMANITY.™

Saving Brains

Identify early life interventions that
promote the fulfillment of human capital

May 2011

Executive Summary

Grand Challenges Canada is creating an initiative to promote the fulfillment of human capital by focusing on interventions administered in the first thousand days of development – between conception and two years of age. Over 200 million children fail to reach their full cognitive developmental potential. Poverty is both a cause and a result of this failure. This creates a vicious cycle whereby malnutrition, infection, poor management of pregnancy and birth complications, and a lack of cognitive stimulation and nurturing before two years of age—all risks to cognitive development—have long-lasting effects that decrease productivity in adulthood. In parallel with strengthening of health systems and tackling broader determinants of poor health, interventions targeted against these risk factors in the first thousand days have the potential to increase the productive wealth embodied in the intellectual, social and physical capability of the individual, which is key to the development of individuals, communities, and whole societies.

The ultimate aim of this initiative is to identify and develop effective and efficient means to promote cognitive development in the first thousand days with lasting impact on human capital in low- and middle-income countries. This request for proposals solicits proposals for projects that evaluate the long-term effect of interventions delivered in the first thousand days of development on human capital by re-enrollment and assessment of cohorts who have participated in intervention studies.

This request for proposals commits up to \$10 million CDN to be awarded over 2 years. The topic areas for evaluation of early interventions are: 1) nutrition; 2) infection; 3) pregnancy and birth management; and 4) cognitive stimulation and nurturing. In keeping with the Grand Challenges Canada mission to support global health innovation in developing countries, eligible projects must be based in low- or middle-income countries and include low- or middle-income country investigator leadership.



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1. Introduction

Grand Challenges Canada is creating an initiative to promote the fulfillment of human capital by focusing on interventions in the first thousand days of development. **Human capital** is defined as the productive wealth embodied in the intellectual, social and physical capability of the individual, and is key to the development of individuals, communities, and whole societies. More specifically, human capital reflects the cognitive abilities, social functioning (e.g., behaviour and psychological functioning), physical capacity and health status that allow an individual to be a productive member of society.

The key role of governments and international agencies in providing strong policy and health care environments that nurture early child development was recently emphasized in a report by the Knowledge Network for Early Childhood Development of the WHO Commission on the Social Determinants of Health.¹ In parallel to strengthening of health systems and tackling broader determinants of poor health, the implementation of interventions administered during the first thousand days of development—between conception and two years of age—has the potential to lead to dramatic improvements in health and productivity in adulthood. Therefore, this initiative has significant transformational potential in that it can unlock the potential of individuals and communities and, over a generation, help to break the cycle of poverty that has entrapped so many developing countries.

This is a request for proposals for follow-up studies based in low- and middle-income countries. Eligible investigators are invited to submit proposals for projects that evaluate the long-term effect on human capital of interventions in the first thousand days that address risk factors to cognitive development such as malnutrition, infections, management of pregnancy and birth complications, and lack of cognitive stimulation. Together with focused modeling of prevalent risk factors and cost-effectiveness of interventions, this will constitute the Focus Phase of the initiative. We anticipate that a second phase, the Solution Phase, of this initiative will focus on innovative, scaleable and sustainable solutions to promote human capital formation. In concert with approaches that enhance the social determinants of health in developing communities and countries, such interventions could offer significant health benefits and help to break the cycle of poverty.

The concept of **Integrated Innovation™** plays a key role in Grand Challenges Canada's work.² Integrated Innovation is the coordinated application of scientific/technological, social and business innovation to develop solutions to complex challenges. This approach does not discount the singular benefits of each of these types of innovation alone, but rather highlights the powerful synergies that can be realized by aligning all three to address a single challenge. Further, Integrated Innovation recognizes that

¹ Irwin LG, Siddiqi A, Hertzman C. Early child development: a powerful equalizer—final report of the early child development knowledge network of the Commission on Social Determinants of Health. Geneva: World Health Organization, 2007. <http://whqlibdoc.who.int/hq/2007/a91213.pdf>. (accessed Dec 19, 2010).

² Grand Challenges Canada/Grand Défis Canada, "Integrated Innovation", September 2010
<http://www.grandchallenges.ca/files/news/integratedInnovation.pdf>

scientific and/or technological innovations have a greater chance of going to scale and achieving global impact if they are developed from the outset with appropriate social and business innovations. Thus, projects supported by this program will undertake an assessment of the social, cultural and commercialization barriers to scale up delivery of the proposed intervention in a sustainable manner.

1.1 GRAND CHALLENGES CANADA

In the 2008 Federal Budget, the Government of Canada announced the creation of the Development Innovation Fund to:

...
"support the best minds in the world as they search for breakthroughs in global health and other areas that have the potential to bring about enduring changes in the lives of millions of people in poor countries."

"For example, new vaccines and cures could save millions of lives lost to tropical diseases. Higher-yield, drought-resistant crops could prevent future famines. And lower-emission energy sources could power industrial development and job creation with a minimal carbon footprint."

Grand Challenges Canada, a Canadian not-for-profit organization, is the vehicle to deliver the Development Innovation Fund, in a consortium with the International Development Research Centre (a Canadian Crown corporation); and the Canadian Institutes of Health Research (a Government of Canada agency). Grand Challenges Canada is hosted by the McLaughlin-Rotman Centre for Global Health (University Health Network and University of Toronto).

The **vision** of Grand Challenges Canada is to develop a consortium of world-leading Canadian and international scientists, research organizations, and leaders from the business sector, to develop breakthrough solutions to global challenges and ensure that these solutions are available to those who need them the most.

Grand Challenges Canada's **mission** is to identify global grand challenges, fund a global community of researchers and related institutions on a competitive basis to address them and support the implementation/commercialization of the solutions that emerge.

Grand Challenges Canada's core **values** include: scientific excellence, collaboration and partnership, and accountability for results.

Grand Challenges Canada is funded by Canada's international development assistance envelope. Canada is the first country to take a grand challenges approach to global health innovation through foreign aid.

1.2 BACKGROUND

Currently, over 200 million children are not able to fulfill their developmental potential. This impaired development is often measured in terms of small body size: fetal growth restriction, low height-for-age, and low weight-for-age. Fetal, newborn and child growth restriction accounts for 27% of the global disability-adjusted life years in children less than 5 years of age.

A less visible effect of impaired development—but with a significant economic impact—is the reduction of cognitive abilities and associated social capacities. Physically stunted children may also have stunted brain development and stunted potential. A child with reduced growth by two years of age is at increased risk for cognitive and educational deficits, translating into less time spent in school, and perhaps less learned per school year. It is estimated that these childhood deficits result in greater than a 20% loss in adult income, potentially locking these individuals into poverty.

Poor pregnancy and birth outcomes, exposure to malnutrition and infection, and lack of cognitive stimulation and nurturing during development are all associated with childhood cognitive impairment in developing countries. Trials of some interventions to prevent or reverse the effects of these risk factors in the first thousand days of development have shown effectiveness in improving cognitive development into childhood. However, few studies have assessed the long-term effects of these interventions. Since the relative contribution of each of the risk factors on cognitive development is unknown, the most effective way to increase human capital in adulthood is also unknown.

1.3 PROGRAM GOAL AND KEY OBJECTIVES

We seek to identify interventions administered in the first thousand days of development that have positive long-term effects on human capital.

To achieve this goal, the following **key objectives** are important:

1. To provide evidence for the relative effect size on human capital of interventions in the first thousand days of development that are relevant to low- and middle-income countries. These interventions will address risk factors for cognitive development such as malnutrition, infection, poor pregnancy or birth outcomes, and lack of cognitive stimulation.
2. To map the prevalence of risk factors to cognitive development and human capital formation, and the cost-effectiveness of reducing exposure to the prevalent risk factors in the first thousand days of development in low- and middle-income countries.
3. To provide proof-of-concept for innovative scaleable and sustainable solutions delivered in the first thousand days to promote human capital formation. It is expected that sustainable implementation of the interventions will require innovative social or business models that function within the context of

strengthening health systems and improving socio-economic determinants of poor health.

The first phase of the initiative, the **Focus Phase**, is designed to address Key Objectives 1 and 2. This request for proposals is focused exclusively on funding the Focus Phase re-enrollment and follow-up studies that will address Key Objective 1. We intend to solicit innovative methods to scale-up priority early life interventions that increase human capital (Key Objective 3) in a second phase, the **Solution Phase**. The Solution Phase will be open to all innovators, regardless of their participation in the Focus Phase.

2. Approach

2.1 PROGRAM SCOPE

The focus of this request for proposals is exclusively to fund projects that re-enroll intervention study participants and assess the long-term effect on human capital of interventions delivered in the first thousand days of development.

Therefore, we are currently soliciting proposals for:

Projects that evaluate the effect on human capital of interventions administered in the first thousand days of development (from peri-conception and two years of age) that address risk factors to cognitive development, namely malnutrition, infection, poor pregnancy and birth outcomes, and lack of cognitive stimulation. Proposed projects must be based in low- or middle-income countries and include leadership by investigators in low- or middle-income countries.

To leverage prior research investments that have resulted in well designed, controlled, and well executed intervention studies, we are looking to fund follow-up studies. These follow-up studies will assess the longer-term impact on cognitive development or human capital of interventions administered in the first thousand days by re-enrollment and assessment of a representative population from the original completed intervention studies. In order to execute re-enrollment and assessment, involvement of investigator(s) from the original study and/or access to data from the original study is required. Please note: We will not fund intervention studies under this program.

It is expected that these original intervention studies will be randomized controlled or cluster randomized trials with a documented impact on either cognitive development or on any of the postulated risk factors for cognitive development (e.g., nutritional status or infection). In cases where cognitive development was a measured outcome of the original intervention trial, proposed study participants should be, at a minimum, at the age of school entry (5-7 years) at the time of longer-term assessment. In cases where cognitive development was not a measured outcome of the original intervention study, proposed study participants may be younger. In all cases, applicants must clearly describe the scientific rationale for the long-term follow-up of the intervention, and the suitability of the original study to an assessment of its longer-term effect on human

capital. Interventions that are suited to implementation in low-resource settings will be favoured.

Applicants are required to provide evidence that the characteristics of the proposed study site is comparable with respect to demography, socioeconomic, ecology and infrastructure to a larger, relevant, target population to which the study findings would be applicable.

Studies with low attrition rates from the original cohort will be favoured. Applicants must clearly describe re-enrollment approaches and expected attrition rates, discuss the impact these will have on the interpretation of the findings, and fully explain mitigation strategies for risks to project success. Furthermore, a comprehensive analysis of any interim events experienced by the cohort or study site that may be confounding factors to an accurate assessment of the long-term effects of the intervention must be presented.

The proposed assessment of the impact on human capital should, at a minimum, encompass measurements of cognitive abilities; social functioning; health status; and educational readiness, academic achievement, or economic productivity, as appropriate for cohort age. An assessment of non-cognitive social capabilities that are critical for successful adult functioning (e.g., psychological functioning and behaviour) is encouraged. A willingness to make relevant use of advanced technologies (e.g., neurological imaging, physiologic function measurement tools, psychometric assessment tools, biochemical analyses) to enhance the understanding of the long-term impact of the intervention should be demonstrated. Research teams should include appropriate expertise to design, execute and analyze the proposed assessments.

To ensure comparability of results across the program, a common set of assessment measurements will be required (see Section 2.4). This common set of assessment measurements will be determined with the participation of research teams successful at the letter of intent stage and other experts.

With a view towards a more complete understanding of interventions that positively impact adult human capital, proposed studies should include means of increasing the feasibility of future cohort assessments. These might include use of geographic information system (GIS) mapping and identification of existing databases (e.g. school reports) to track progress and events between assessments.

Interventions that adopt, or are amenable to, an Integrated Innovation approach are desired. To improve the ability of the interventions to be implemented at scale in a sustainable manner, projects will be required to capture the social, cultural and commercialization barriers that currently prevent the proposed intervention from being widely implemented. Funded projects will be expected to develop an initial plan for taking their intervention to scale.

2.2 SIZE AND LENGTH OF GRANTS

Projects will be funded for up to 2 years. The total funds available to support a portfolio of responses from this request for proposal is \$10 million CDN. Through this request for proposal, approximately 10-12 proposals will be funded assuming a sufficient number of applications of merit are received. The value of the grants is expected to vary, and will be commensurate to the proposed project. The level of funding requested should be sufficient to assure completion of the goals in the stated time frame.

2.3 TOPIC AREAS

Each applicant must classify her or his proposal as one of the following Topic Areas depending upon the intervention being proposed for follow-up assessment. Each proposal can address only one Topic Area. Applicants addressing more than one Topic Area must submit a separate proposal for each Topic Area. Multiple proposals from the same organization are permitted.

In all cases, applicants must clearly describe the scientific rationale for the follow-up of the intervention, as well as the suitability of the original study to an assessment of its longer-term effect on human capital. Interventions that are suited to implementation within low-resource settings and in concert with approaches to improve social determinants of health will be favoured. We recognize that investigators in low- and middle-income countries are likely to have unique perspectives and skills to contribute to this initiative.

In order to assess the relative contribution to human capital of interventions addressing these factors, a portfolio of geographically diverse proposals from across the Topic Areas will be selected to maximize cohort age homogeneity, assuming a sufficient number of proposals of merit are received in each Topic Area.

Topic Area 1: Nutrition

These are interventions that increase the nutritional status of women around conception and during pregnancy, or of children up to two years of age. Such interventions may include supplementation or treatment with micronutrients (e.g., iron or vitamin A) or macronutrients (e.g., increased caloric intake), or social interventions that promote increased optimal breastfeeding or complementary food introduction practices.

Topic Area 2: Infection

These are interventions that decrease the prevalence or severity of infections in pregnant women or in children up to two years of age. Such interventions may include intermittent preventative therapy for parasitic infections, infection transmission blocking methods (e.g. insecticide-treated bednets), or behaviour changes that impact on infection.

Topic Area 3: Pregnancy and birth outcomes

These are interventions that decrease the prevalence or consequences of fetal growth restriction, premature birth or complications during delivery. Such interventions may include the detection and management of preeclampsia, improved methods for neonatal resuscitation, or targeted care for preterm or low birth weight neonates.

Topic Area 4: Cognitive stimulation and nurturing practices

These are interventions that promote the quantity and quality of social and cognitive stimulation in children up to two years of age. Such interventions may include methods to teach educational play techniques, increase infant responsiveness, or reduce maternal stress.

2.4 COMMON SET OF HUMAN CAPITAL ASSESSMENT MEASUREMENTS

In order to ensure the projects funded in this program provide intervention effect size outcomes that can be directly compared, a community of innovators (the successful applicants after a letter of intent stage and other experts) will be convened between the two stages of the application process to establish a common set of human capital assessment measurements. Among the assessments to be determined are the type of cognitive test(s) and neurological imaging techniques to use, in addition to the measurements of productivity, social functioning, anthropometry or health status appropriate for the age range and population spectrum represented in the letters of intent. It is expected that all applicants are willing to participate in the establishment of the common set of assessments, and that all successfully funded grantees will incorporate the common set of assessments into their project.

3. Activities & Deliverables

The investigators funded under this effort will be expected to engage in the activities and provide the specific deliverables listed below. The overall goal is to deliver evidence on the impact on human capital of interventions in the first thousand days. In addition to engaging in investigative activities related to their proposed project, applicants will be expected to:

- Actively participate in meeting(s) that set the common outcome measurements to ensure comparability of results between projects.
- Refine their project plans with the proposed set of critical milestones to achieve outcome measurement goals as set by the assembled community.
- Participate in a community of innovators on this topic, including attending two meetings per year.
- Commit to a Global Access Strategy (see Global Access Strategy document for more information).

The deliverables listed below will help demonstrate project progress and success:

- Progress reporting including quarterly conversations via teleconference, semi-annual written reports and annual site visit. Instruction for reporting will be provided to grant recipients.

- A final report that includes a clear assessment of the long-term effect of intervention of focus, including the common set of human capital assessment measurements (see Section 2.4).
- Dissemination of knowledge through publications in peer-reviewed literature, etc.
- Identification of social, cultural and commercialization barriers to implementation of intervention, and an initial plan for delivering the intervention at scale that addresses these barriers.

4. Rules and Guidelines

Grand Challenges Canada staff will be substantially involved in shaping this initiative over time. The Canadian Institutes of Health Research oversees the peer review process, and the Grand Challenges Canada Board of Directors makes the final funding decisions.

4.1 ELIGIBILITY CRITERIA

1. Applicant organizations must be individual non-profit organizations, for-profit companies, or other recognized institutions that can successfully execute the activities in their respective technical area.
2. Principal investigators must be primarily affiliated with an organization in a low- or middle-income country, as defined by the World Bank classification (i.e., investigators originating from low- or middle-income countries with primary affiliations with organizations based in high-income countries are not eligible as sole principal investigators). Where scientifically justified, investigators from high-income countries may be co-principal investigators. Proposals adopting a leadership structure with a co-principal investigator from a high-income country should include a verifiable plan to work toward building or supporting, as appropriate, low- or middle-income country scientific leadership.
3. Principal investigators in upper-middle income countries, or lower-middle income countries that are members of the G20 (i.e., India and China) according to World Bank classification, are encouraged to obtain co-funding. Given projects of equal merit, ones with more co-funding will be favoured. *Note:* Donations in kind (e.g., lab space at host institution) are not considered co-funding.
4. Collaborations with investigators affiliated with organizations in high-income countries may be included in the proposed project. *Note:* The majority of the budget must be spent in the low- or middle-income countries.

4.2 APPLICATION INSTRUCTIONS

Applicants must clearly state the overall goal(s) and the interim objectives to be achieved during the project, identify impediments or critical decision points that could

require a revision in the work plan or milestones, and provide a detailed schedule or timeline for the attainment of each milestone and/or goal.

This request for proposal will make use of a mandatory two-step application process:

Step 1: Submission of a letter of intent.

There is a five (5) page limit on the letter of intent. To submit the letter of intent, applicants must follow the application instructions found at www.grandchallenges.ca. Applicant organizations submitting a letter of intent must fully meet the eligibility criteria listed in section 4.1 and make certain that they are fully capable of complying with all the requirements and terms of award.

Successful applicants at the letter of intent stage will be invited to a workshop that will have two objectives. First, to develop a common set of human capital assessment measurements to ensure comparability across projects funded under this program (see Section 2.4). Second, for low- and middle-income country investigators, to develop and hone grant writing techniques with guidance from experienced grant writers, mentors, and peers. Costs to attend this workshop will be covered by Grand Challenges Canada. All applicants should make note and hold the dates of this workshop (see Application Schedule, Section 4.4).

Step 2: Submission of a full proposal, upon invitation only.

Instructions on the preparation of full proposals will be provided to applicants selected at the letter of intent stage.

Please note that Grand Challenges Canada will not provide individual critiques or feedback on why a letter of intent was not selected. Successful applicants at the letter of intent stage who are invited to go to the full proposal stage will receive constructive feedback on their proposals.

4.3 REVIEW PROCESS

The Canadian Institutes of Health Research is responsible for conducting the peer review of proposals at both the letter of intent and the full proposal stage. A review committee of external reviewers including experts from low- and middle-income countries will advise on the merit of proposals based on the evaluation criteria (see Section 4.5) and final selection decisions will be made by the Board of Directors of Grand Challenges Canada.

4.4 APPLICATION SCHEDULE

Key Deadlines	Event
August 1, 2011	Application deadline for letters of intent at 11:59 pm EST
September 9, 2011	Invitation for submission for full proposals
October 11-14, 2011	Core set of assessment and proposal development workshop for

	those invited to submit full proposals
December 12, 2011	Application deadline for full proposals at 11:59 EDT

4.5 EVALUATION CRITERIA

1. Significance

Demonstration that the intervention has the potential to promote human capital formation in low resource settings.

- The intervention is appropriate for implementation in low resource settings.
- The study population and study site is representative of other populations and regions likely to benefit from the intervention.

2. Original Study Design and Execution

Demonstration that the original intervention study was well designed, controlled, and well executed.

- The intervention successfully promoted cognitive development or addressed a risk factor of cognitive underdevelopment.
- The original intervention study is suitable for assessment of the long-term effects on human capital

3. Execution Plan

Extent to which the proposed study goals based on sound scientific analysis and technical rigour.

- The approach, evidence indicating the likelihood of success is clearly described and includes a rigorous assessment of risk factors and associated mitigation strategies.
- The proposed timeline and interim milestones are appropriate, feasible and technically sound.
- A willingness to apply advanced technologies to the assessment of human capital is demonstrated.

Extent to which the approach to re-enrolling a follow-up cohort that is representative of the original intervention study cohort, and that will be sufficient to assess the long-term impact is feasible.

- Changes (confounding factors) in the cohort or study site since the original study described and their potential effects on the study conclusions are reasonably assessed.
- Cohort attrition issues are thoroughly addressed, including expected attrition rate, effect on study outcome, and comparability to original study cohort.
- Methods to increase feasibility of future assessments of the cohort are incorporated into the plan.

4. Integrated Innovation

Extent to which the proposed intervention adopts or is amenable to an Integrated Innovation approach for implementation, and demonstration that social, cultural and commercialization aspects are being considered.

- The anticipated social or commercial value of the intervention is described.
- Significant social, cultural and commercialization barriers to implementation of proposed intervention are identified.
- Potential end users of the intervention (e.g., government ministries, community health workers, families, etc.) are identified, indicate demand for the intervention, and are engaged in the study design, implementation and evaluation.

5. Organizational and Investigator Capability

Extent to which the principal investigator, co-investigators and research team are appropriately trained, experienced, and suited to carry out the proposed work.

- In cases where leadership includes investigators with primary affiliations to high-income countries, measurable milestones towards building scientific leadership of the low- or middle-income country investigator is provided, if appropriate.

Demonstration of adequate evidence of institutional support.

- Institution is financially viable.

6. Best Value of Effort

Extent to which the scope of the proposed work and funds requested are reasonable and commensurate with the proposed study goals.

Demonstration of secured co-funding at the full proposal stage. *Note:* Donations in kind (e.g., lab space at host institution) are not considered co-funding.

- Co-funding is an asset for proposals from upper-middle income countries and lower-middle income countries, according to World Bank classifications, who are members of the G20 (India and China).

7. Willingness to Collaborate

Extent to which the applicant is willing to work within a collaborative framework to set and integrate a common set of human capital assessment measurements.

- At the letter of intent stage, willingness to collaborate is stated.
- At the full proposal stage, the common set of human capital assessment measurements is incorporated into the proposal.

4.6 ALLOWABLE COSTS

Grant funds may be used for the following cost categories: personnel, necessary travel, supplies, contracted services, sub-grants, and consultants. Partial or full support for equipment may be requested subject to the circumstances described below. Please provide budget estimates according to the categories above. In addition, please note:

- Personnel: Salary support is an allowable cost.
- Travel: Funds to participate in meetings twice a year for key members of the team are allowed.

- Equipment: Use of any equipment purchased with grant funds is limited to charitable purposes for the depreciable life of the equipment.
- Indirect costs: *Please note that Grand Challenges Canada will provide a limited amount of indirect costs based on the nature of the applicant organization, to a maximum of 13% of direct costs of the Grantee's administered grant value (1-7 outlined above).*

Also note that proposals with thoughtful and efficient use of resources will be preferred over proposals representing comparable efforts that do not have the same value for the investment. In some circumstances (e.g. rapidly changing technologies), subcontracting specific project activities to an outside institution with the infrastructure and expertise to deliver results may be considered advantageous over establishing in-house capacity.

4.7 PRIVACY NOTICE

To help us in the evaluation and analysis of projects, all proposals, documents, communications, and associated materials submitted to the Grand Challenges Canada (collectively, “Submission Materials”) will become the property of Grand Challenges Canada and will be shared with other members of the Grand Challenges Canada consortium (the International Development Research Centre and Canadian Institutes of Health Research). We will report publicly on the number of letters of intent received and the countries from which they originated. The proposals will be subject to confidential external review by independent subject matter experts and potential co-funders in addition to analysis by our 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, we recommend 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, we may publicly disclose all information contained in Submission Materials to the extent as may be required by law and as is necessary for potential 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.

4.8 WARRANTY

By providing any Submission Materials, the sender warrants Grand Challenges Canada that they have the right to provide the information submitted. Applicants with questions concerning the contents of their Submission Materials may contact Grand Challenges Canada at: www.grandchallenges.ca

4.9 INTELLECTUAL PROPERTY

The output of this program may lead to innovative technologies, services and/or products to promote human capital formation in developing countries, and the successful development of these products may require involvement and support of the private sector, 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 rights and the management of intellectual property rights are likely to play an important role in achieving the goals of this program. Grand Challenges Canada's Global Access Strategy will guide our approach to intellectual property, and we urge all applicants, even at the letter of intent stage, to consider their willingness to submit a full proposal in compliance with the Grand Challenges Canada Global Access Strategy, the guiding principles of which are as follows:

- 1.** Breakthrough solutions to global challenges are made accessible to those in need, particularly in the developing world. Accessibility relates to both price and availability.
- 2.** Knowledge gained through discovery is broadly, and as promptly as possible, distributed between related projects and to the global scientific community.
- 3.** Commercialization of resulting outputs is encouraged, as long as the first two principles are achieved.

Grantees will be required to develop and sign a Global Access Agreement with Grand Challenges Canada in line with the Guiding Principles. For further information, please refer to Grand Challenges Canada's intellectual property policy at www.grandchallenges.ca.

5. Research Assurances

It is the policy of Grand Challenges Canada that research involving human subjects, research with animals, and research subject to additional regulatory requirements must be conducted in accordance with the highest internationally recognized ethical standards. In order to receive funds from Grand Challenges Canada, initially and throughout the course of a research project, researchers must affirm and document compliance with the guiding ethical principles and standards outlined below.

- 1.** Research involving human participants must be conducted in a manner that demonstrates, protects and preserves respect for persons, concern for the welfare of individuals, families and communities, and justice.³

³ Modified from the core principles articulated in the draft second edition of TCPS (<http://pre.ethics.gc.ca/eng/policy-politique/initiatives/revised-revisee/chapter1-chapitre1/#toc01-1b>)

- 2.** Research involving animals must be conducted in a manner that ensures their humane care and treatment.
- 3.** Certain research endeavors, including but not limited to research with recombinant DNA, biohazards, and genetically modified organisms, may be subject to enhanced regulation and oversight.

While not necessary for the letter of intent, and as applicable to the individual project, Grand Challenges Canada 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. We 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. For further details, please see the Grand Challenges Canada Ethics policy at www.grandchallenges.ca.