

REQUEST FOR PROPOSALS

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Grand Challenges Canada™
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BOLD IDEAS FOR HUMANITY.™

Integrated Innovations in Global Mental Health

Improve Treatments and Expand Access to Care in Low- and
Middle-Income Countries

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Executive Summary

Mental health disorders are prevalent in all regions of the world, in every community and across every income level. An estimated 13% of the global burden of disease is attributable to mental health disorders, with almost three quarters of this burden affecting people in low- and middle-income countries. Mental health disorders are the largest contributor to the overall global burden of non-communicable disease, and are themselves risk factors for both communicable and non-communicable diseases, as well as disability.

In an effort to address the enormous burden of global mental health, the Grand Challenges in Global Mental Health initiative sought to systematically identify key research priorities in global mental health, in order to mobilize resources and communities of researchers. The McLaughlin-Rotman Centre for Global Health, which hosts Grand Challenges Canada, has played a leading role from the beginning of the Grand Challenges in Global Mental Health initiative. The initiative was implemented with leadership from the McLaughlin-Rotman Centre for Global Health, the U.S. National Institute of Mental Health, and the London School of Hygiene & Tropical Medicine; it was done in partnership with the Wellcome Trust, and under the aegis of the Global Alliance for Chronic Diseases. The outcomes of this study were recently published in *Nature*.¹

A Delphi process involving over 400 international experts and thought leaders from across mental health disciplines and professions identified key priorities and specific grand challenges in global mental health. The top 25 grand challenges in global mental health were categorized into six key overarching priorities, which serve as a platform for the coordination of resources among researchers/innovators and funders.

In this Request for Proposals, Grand Challenges Canada is seeking to address one of the six overarching priorities: **improve treatments and expand access to care** in low- and middle-income countries. This priority aims to address the large treatment gap that poses a major challenge for patients in low- and middle-income countries who wish to access evidence-based, high-quality mental health care. Specifically, proposals must provide innovative solutions to one (or more) of the following identified challenges within this priority area:

- Integrate screening and core packages of services into routine primary health care
- Reduce the cost and improve the supply of effective medications
- Provide effective and affordable community-based care and rehabilitation

¹Collins PY, Patel V, Joestl SS, March D, Insel TR, Daar AS; Scientific Advisory Board and the Executive Committee of the Grand Challenges on Global Mental Health, Anderson W, Dhansay MA, Phillips A, Shurin S, Walport M, Ewart W, Savill SJ, Bordin IA, Costello EJ, Durkin M, Fairburn C, Glass RI, Hall W, Huang Y, Hyman SE, Jamison K, Kaaya S, Kapur S, Kleinman A, Ogunniyi A, Otero-Ojeda A, Poo MM, Ravindranath V, Sahakian BJ, Saxena S, Singer PA, Stein DJ. Grand challenges in global mental health. *Nature*. 2011 Jul 6;475(7354):27-30. doi: 10.1038/475027a.

- Improve children's access to evidence-based care by trained health providers
- Develop effective treatments for use by non-specialists, including lay health workers with minimal training
- Incorporate functional impairment and disability into assessment
- Develop mobile and IT technologies (such as telemedicine) to increase access to evidence-based care

In addressing the need for improved treatments and expanding access to care, proposed solutions must take into account variations in health systems, local cultures, traditions and beliefs, and should address the stigma, discrimination and social exclusion faced by patients and families across cultural settings in seeking treatment and care.

Grand Challenges Canada is looking for solutions that integrate scientific/technological, social and business innovation, have the potential for real world impact, and demonstrate a path to scale and sustainability. Proposals must therefore take an Integrated Innovation approach, defined as 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. Integrated Innovation recognizes that scientific/technological innovations have a greater chance of going to scale and achieving global impact and sustainability if they are developed from the outset with appropriate social and business innovations.

Through this Request for Proposals, Grand Challenges Canada has committed up to \$20 million CAD for this initiative, to be awarded over three years. We expect to fund approximately 15-25 proposals from applicants in low- and lower-middle-income countries and Canada. Collaborations between low- or lower-middle-income country investigators and Canadian investigators are encouraged, but not required. In order to be considered eligible, Canadian principal investigators must apply with co-principal investigators in a low- or lower-middle-income country.

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1. Introduction

1.1 GRAND CHALLENGES CANADA

In the 2008 Federal Budget, the Government of Canada announced the Development Innovation Fund that will:

“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 new 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 at the University Health Network and the University of Toronto.

The **vision** of Grand Challenges Canada is to develop a consortium of world-leading Canadian and international scientists, research organizations and business leaders 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 grand challenges, and support the implementation and 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 adopts an **Integrated Innovation** approach to its work. 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. Integrated Innovation recognizes that scientific/technological innovations have a greater chance of going to scale and achieving global impact and sustainability if they are developed from the outset with appropriate social and business innovations. (Please see http://www.grandchallenges.ca/wp-content/uploads/integratedinnovation_EN.pdf)

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

The Problem

Mental health is critical to overall health—according to the WHO, there “can be no health without mental health.” We define ‘mental health disorders’ as including all mental, neurological and substance use disorders, such as depression, anxiety disorders, schizophrenia, bipolar disorders, alcohol and drug use disorders, emotional and behavioural disorders of childhood and adolescence, dementias, migraines and epilepsy.² Mental health disorders contribute to 13% of the global burden of disease; almost three quarters of this burden occurs in low- and middle-income countries.³ Mental health disorders make the largest contribution to the overall burden of non-communicable diseases, surpassing both cardiovascular disease and cancer.⁴ Moreover, mental health disorders are risk factors for both communicable (e.g., HIV/AIDS, malaria, tuberculosis) and non-communicable diseases (e.g., cardiovascular disease and cancer), and are a leading cause of disability globally.⁵

In an effort to address the enormous burden of global mental health, the Grand Challenges in Global Mental Health initiative recently sought to systematically identify key research priorities that will significantly impact the lives of people living with mental health disorders worldwide within the next 10 years. The McLaughlin-Rotman Centre for Global Health, which hosts Grand Challenges Canada, has played a leading role from the beginning of the Grand Challenges in Global Mental Health initiative. The initiative was implemented with leadership from the McLaughlin-Rotman Centre for Global Health, the U.S. National Institute of Mental Health, and the London School of Hygiene & Tropical Medicine; it was done in partnership with the Wellcome Trust, and under the aegis of the Global Alliance for Chronic Diseases. The outcomes of this study were recently published in *Nature*.⁶

² Defined by the Grand Challenges in Global Mental Health initiative and based on global burden of disease.

³ Mental Health Gap Action Programme: Scaling up care for mental, neurological, substance use disorders. World Health Organization, 2008.

⁴ The Global Burden of Disease: 2004 Update. World Health Organization, 2008.

⁵ Mental Health Gap Action Programme: Scaling up care for mental, neurological, substance use disorders. World Health Organization, 2008.

⁶ Collins PY, Patel V, Joestl SS, March D, Insel TR, Daar AS; Scientific Advisory Board and the Executive Committee of the Grand Challenges on Global Mental Health, Anderson W, Dhansay MA, Phillips A, Shurin S, Walport M, Ewart W, Savill SJ, Bordin IA, Costello EJ, Durkin M, Fairburn C, Glass RI, Hall W, Huang Y, Hyman SE, Jamison K, Kaaya S, Kapur S, Kleinman A, Ogunniyi A, Otero-Ojeda A, Poo MM, Ravindranath V, Sahakian BJ, Saxena S, Singer PA, Stein DJ. Grand challenges in global mental health. *Nature*. 2011 Jul 6;475(7354):27-30. doi: 10.1038/475027a.

A Delphi process involving over 400 international experts and thought leaders from across mental health disciplines and professions identified key priorities and specific grand challenges in global mental health. Grand challenges were defined as specific barriers that need to be overcome to make a large and sustained difference in the mental health disease burden. The initiative was global in scope and covered a range of mental health disorders.

The priority-setting exercise yielded 40 grand challenges that are diverse and span discovery science, preclinical science, etiology, treatment, implementation and policy research. The top 25 grand challenges in global mental health were categorized into six key overarching priorities that serve as a platform for the coordination of resources among researchers/innovators and funders.

One of the six key priorities identified from this initiative was to improve treatments and expand access to care, which is the focus of this Grand Challenges Canada Request for Proposals.⁷ Therefore, to address the global burden of mental health disorders, Grand Challenges Canada is seeking innovative solutions to improve treatments and expand access to care in low- and middle-income countries and address the large treatment gap for accessible, evidence-based, high-quality mental health care.

The Opportunity

Mental health resources are extremely scarce in low- and middle-income countries: investment in mental health for many of these countries represents less than 1% of the total health budget.⁸ Unfortunately, most of the people affected with mental health disorders—up to 75% of whom reside in low-income countries—do not have access to evidence-based treatment and care. Results from a large multi-country survey conducted by the WHO indicated that between 76-85% of serious mental health cases in less-developed countries had received no treatment in the previous year, as compared to 35-50% of cases in developed countries, indicating a significant treatment gap.⁹ Given the shortages in trained mental health professionals (e.g., psychiatrists, clinical psychologists, psychiatric nurses, and social workers), few hospitals and clinics, accessibility of effective medications and evidence-based interventions, and the associated stigma faced by individuals with mental disorders and their families seeking treatment and care in low- and middle-income countries; there is a tremendous opportunity for new and innovative solutions to address this current gap.

Therefore, through this Request for Proposals, we aim to address a subset of specific challenges identified by the Grand Challenges in Global Mental Health initiative to

⁷ Other priorities identified were: (i) identify root causes, risk, and protective factors, (ii) advance prevention and implementation of early interventions, (iii) raise awareness of the global burden, (iv) build human resource capacity, and (v) transform health-system and policy responses.

⁸ Patel, V. Mental health in low- and middle-income countries. *Br Med Bull.* 2007;81-82:81-96. Epub Apr 30, 2007.

⁹ mhGAP: Mental Health Gap Action Programme. Scaling up care for mental, neurological, and substance use disorders. World Health Organization, 2008.

improve treatments and expand access to care. Specific challenges within this priority area are listed under program scope. Solutions that can leapfrog conventional approaches for improving treatment and enhancing access to care for mental health disorders may be needed to overcome current health system barriers, including human resource capacity (e.g., professional mental health workers), infrastructure (e.g., clinics and hospitals) and accessibility to evidence-based interventions in low- and middle-income countries.

2. Approach

2.1 PROGRAM GOAL

The goal of this Request for Proposals is to solicit novel, innovative solutions for improving treatments and expanding access to care for mental health disorders in low- and middle-income countries. Bold, innovative, creative, transformational, outside-the-box solutions are encouraged.

2.2 PROGRAM SCOPE

This Request for Proposals is exclusively focused on funding innovative solutions to improve treatments and expand access to care for mental health disorders in low- and middle-income countries. The term 'mental health disorders' refers to depression, anxiety disorders, schizophrenia, bipolar disorders, alcohol and drug use disorders, emotional and behavioural disorders of childhood and adolescence, developmental disorders of childhood, migraines, dementias and epilepsy.

We encourage innovative ideas that are patient-oriented, cost-effective, sustainable and scalable in low-resource settings. To improve treatments and expand access to care, applicants must propose innovative solutions to one (or more) of the following specific challenges identified from the Grand Challenges in Global Mental Health initiative within this priority area:

- Integrate screening and core packages of services into routine primary health care
- Reduce the cost and improve the supply of effective medications
- Provide effective and affordable community-based care and rehabilitation
- Improve children's access to evidence-based care by trained health providers
- Develop effective treatments for use by non-specialists, including lay health workers with minimal training

- Incorporate functional impairment and disability into assessment
- Develop mobile and IT technologies (such as telemedicine) to increase access to evidence-based care

In addressing the need for improved treatments and expanding access to care, proposed solutions must take into account variations in local cultures, traditions, and beliefs, and should address the stigma, discrimination, and social exclusion faced by patients and their families in seeking treatment and care. Applicants may draw on the wealth of proven evidence-based interventions from developed countries and provide innovative approaches for implementation and scale up of these interventions in low- and lower-middle-income countries.

Grand Challenges Canada is looking for solutions that integrate scientific/technological, social and business innovation, have the potential for real world impact, and demonstrate a path to scale and sustainability. Proposals must therefore take an Integrated Innovation approach, defined as 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. Integrated Innovation recognizes that scientific/technological innovations have a greater chance of going to scale and achieving global impact and sustainability if they are developed from the outset with appropriate social and business innovations. (Please refer to http://www.grandchallenges.ca/wp-content/uploads/integratedinnovation_EN.pdf)

Proposed solutions should therefore include a combination of:

- **Scientific/Technological Innovation:** Proposed solutions should focus on the development and application of innovative ideas and/or technologies grounded in scientific evidence.
- **Social Innovation:** Proposed solutions should consider elements such as health systems, determinants of health, ethical/social/cultural/legal frameworks, public policies, and human resources, among others, that will be necessary to bring the solution to scale in local communities.
- **Business Innovation:** Proposed solutions should consider appropriate business models and systems (e.g., public-private-partnership, creative financing mechanisms) that will be necessary to enable the development and delivery of the solution affordably and sustainably to people in low- and lower-middle-income countries.

Interested applicants are therefore encouraged to form multidisciplinary/cross-sector teams with the requisite scientific, social, and business expertise. Proposals must describe the innovative solution and the path to take it to scale, such that it reaches target populations in low- and lower-middle-income countries. End users (e.g., patients and their families, teachers, healthcare workers, hospitals, clinics, policy-

makers, etc.) should be engaged in the project at the outset and throughout, to ensure that the resulting research is poised for adoption.

2.3 SIZE OF GRANTS

The total funding available to support this initiative is \$20 million CAD, to be awarded over three years. Approximately 15-25 proposals will be funded through this Request for Proposals. The value of the awards is expected to vary depending on project need.

3. Activities and Deliverables

Proposals must: (i) have a testable hypothesis, (ii) include an associated plan for how the idea would be tested or validated, (iii) yield interpretable and unambiguous data demonstrating proof-of-concept, and (iv) outline an approach for bringing the solution to scale to reach the intended end users.

The investigators funded under this effort will be expected to engage in the activities and provide the specific deliverables listed below. In addition to engaging in investigative activities related to their proposed project, applicants will be expected to:

- Participate in a community of innovators that will meet twice yearly.
- Leverage resources and learning amongst networks of multidisciplinary investigators.
- Commit to Grand Challenges Canada's Global Access and Ethics policies (see <http://www.grandchallenges.ca/grand-challenges/gc4-non-communicable-diseases/mentalhealth>).
- Engage the end users throughout the project.

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

- Regular progress reports, a final report and site visits to evaluate progress against project milestones. Instructions for the reports will be provided to grant recipients.
- Dissemination of knowledge through publications in peer-reviewed literature, conferences, social media, etc.

4. Rules and Guidelines

4.1 ELIGIBILITY CRITERIA

1. Eligible applicants include non-profit organizations, for-profit companies and other recognized institutions that can successfully execute the activities in their respective area. For-profit companies are encouraged to secure co-funding.
2. Principal investigators/innovators must be primarily affiliated either with an institution or organization in a low-, lower-middle-income country or Canada, according to World Bank classification (<http://data.worldbank.org/about/country-classifications/country-and-lending-groups>).
3. Proposals from low- or lower-middle-income country applicants in G20 countries (http://www.g20.org/about_what_is_g20.aspx) must secure 50% or greater co-funding. Applicants with primary affiliations to institutions or organizations in upper-middle-income countries and other high-income countries are not eligible to apply.
4. Collaborations between low- or lower-middle-income country investigators and Canadian investigators are encouraged, but not required. In order to be considered eligible, Canadian principal investigators/innovators must apply with co-principal investigators/innovators in low- or lower-middle-income countries and the budget would be expected to be primarily used in the low- or lower-middle-income country.
5. It is not the intention of this Request for Proposals to exclude existing productive collaborations between researchers in low- and middle-income countries and those in high-income countries other than Canada. If justified, these collaborations may be part of a proposal. However, the investigator/innovator in the low- or lower-middle-income country must be the principal investigator and the budget would be expected to be primarily used in the low- or lower-middle-income country.

4.2 APPLICATION INSTRUCTIONS

Application instructions and forms are posted on the Grand Challenges Canada website (<http://www.grandchallenges.ca/grand-challenges/gc4-non-communicable-diseases/mentalhealth>). Applicants can apply online through a Letter of Intent (LOI) that describes their idea/solution, goal, objectives and activities, approach and estimated budget.

Successful applicants at the Letter of Intent stage will be invited to a proposal development workshop to support the development of a Full Proposal. The workshop will provide low- and lower-middle-income country investigators an opportunity 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.

4.3 REVIEW PROCESS

The Canadian Institutes of Health Research is responsible for conducting the peer review of all submissions. 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.

Please note that Grand Challenges Canada will not provide individual critiques or feedback on why a proposal was not selected.

4.4 APPLICATION SCHEDULE

Key Deadlines	Event
October 4, 2011	Application deadline for Letters of Intent at 11:59 p.m. EDT
To Be Announced	Proposal development workshop for those invited to submit a Full Proposal
April 11, 2012	Application deadline for Full Proposals at 11:59 p.m. EDT

4.5 EVALUATION CRITERIA

1. Impact

Is the proposed innovation likely to be transformational? Is there indicated demand for the proposed innovation and have/will potential users of the knowledge/goods/services resulting from the research been engaged in the proposed research? Is the proposed solution appropriate for wider implementation in low-resource settings? What is the likelihood that this solution will yield impact and how will impact be evaluated and measured? Is it likely to save lives or improve health?

2. Integrated Innovation

Does the proposed solution integrate scientific/technological, social and business innovation? Is the approach truly novel and a departure from incremental or evolutionary improvements over current approaches? How achievable is the anticipated plan for taking this solution to scale and what is the likelihood of success?

3. Technical Merit/Execution Plan

Is the proposed innovation aligned with one (or more) specific challenges to improve treatments and expand access to care? Does the proposed solution address the stigma, discrimination and social exclusion of patients and families in seeking treatment and care? Are the proposed study goals based on sound scientific analysis, technical rigour and/or evidence-based? Do the applicants

provide a clear description of the approach, evidence indicating the likelihood of success, and a rigorous assessment of risks and associated mitigation strategies? Have the principal investigators/innovators and co-investigators/innovators dedicated sufficient time for proper execution of the plan? Are the proposed timelines and interim milestones appropriate, feasible and technically sound? Is the approach innovative?

4. Investigator Capability

Is the proposed research team appropriately trained, experienced and multidisciplinary to carry out the proposed work (i.e., scientific, social, and business expertise)? Collaborations between low- or lower-middle-income country and Canadian researchers are encouraged. Do Canadian principal investigators/innovators have a co-principal investigator/innovator in a low- or lower-middle-income country?

5. Best Value of Effort

Are the scope of the proposed work and the funds requested reasonable and commensurate with the proposed study goals? Proposals that represent particularly 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 the case of for-profit applicants, co-funding is encouraged. Has co-funding (50% or greater) been secured in the case of proposals from low- or lower-middle-income country applicants in G20 countries? *Note:* Donations in kind (e.g., lab space at host institution) are not considered co-funding.

4.6 ALLOWABLE COSTS

Grant funds may be used for the following cost categories:

1. Personnel: *Please note, salary support is an allowable cost.*
2. Travel
3. Consultants
4. Direct Supplies
5. Equipment: *Please note, partial or full support for equipment may be requested. Funding for infrastructure will be limited.*
6. Other Research Costs
7. Sub-grants/Sub-contracts
8. Indirect costs: *Please note, 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).

Please provide budget estimates (as outlined in the Letter of Intent Form) according to the categories outlined above.

In the case of collaborative proposals between Canadian investigators and those in low- and middle-income countries, the majority of the budget must be spent in low- and middle-income countries. 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.

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 by email at globalmentalhealth@grandchallenges.ca.

4.9 INTELLECTUAL PROPERTY

Since the output of this program may lead to innovative technologies and/or products for those that need them most in the developing world, 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:

- Breakthrough solutions to global challenges are made accessible to those in need, particularly in the developing world. Accessibility relates to both price and availability.
- Knowledge gained through discovery is broadly, and as promptly as possible, distributed between related projects and to the global scientific community.
- 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 <http://www.grandchallenges.ca/grand-challenges/gc4-non-communicable-diseases/mentalhealth>.

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.¹⁰

¹⁰ Modified from the core principles articulated in TCPS 2 (<http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/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 <http://www.grandchallenges.ca/grand-challenges/gc4-non-communicable-diseases/mentalhealth>.