

Next Phase of Grand Challenges, 2014

Rules & Guidelines

Applications due no later than Tuesday, January 13, 2015, 11:30 a.m. U.S. Pacific Standard Time

I. Overview

The Next Phase of Grand Challenges will support a portfolio of early-stage projects – including many ideas that have never before been tested – and scientists and innovators from a wide range of disciplines and regions. The Grand Challenges initiative funds innovative ideas that could lead to new vaccines, diagnostics, drugs, and other technologies targeting diseases that claim millions of lives every year, as well as improvements and innovations in agriculture development and social and business innovations spanning the priority strategy areas of the Bill & Melinda Gates Foundation.

The three new topics being launched as part of the Next Phase of Grand Challenges represent a renewed commitment to the Grand Challenges in Global Health, which was launched in 2003 to accelerate the discovery of new technologies to improve global health. To date, the foundation has committed over half a billion dollars to support hundreds of projects on topics such as making childhood vaccines easier to use in poor countries, and creating new ways to control insects that spread disease.

Key features of Grand Challenges initiatives include:

1. *Strategic and well-articulated Grand Challenges serve both to focus research and development efforts and to capture the imagination of and engage the world's best researchers and innovators.* The Grand Challenges model focuses on seeking solutions to well-defined problems. The initiative brings these problems to the attention of relevant communities of solvers, both individuals and organizations, and invites creative and forward-thinking approaches to address issues that, if solved, can dramatically improve the world we live in.
2. *Projects are selected based on public and transparent calls for proposals seeking the best ideas.* The Grand Challenges programs do not purport to know the solutions to the world's most pressing development issues—but they are willing to take risks and invest to create new solutions. The Grand Challenges model aims to engage new solvers with fresh ideas.
3. *Funders, innovators and other stakeholders actively collaborate to accelerate progress and promote advances to ensure they serve those most in need.* The public, private, academic and nonprofit sectors must work together to accelerate and scale up innovations that can improve the lives of those most in need.
4. *Projects are selected not only for scientific excellence, but also for the likelihood that they will achieve the desired scale and impact.* Successful applicants present projects that, when proven successful through the collection of rigorous evidence, have the potential to serve those most in need. Investing in scientific innovation—as well as in the business and social innovation needed to increase impact at scale—will help ensure that these efforts have the greatest possible impact in terms of lives saved or improved.
5. *Researchers and innovators work to ensure that the fruits of their projects are accessible and available to those most in need.* Fostering ties to industry, both by helping bridge the private and public sectors or by directly funding a company, can create sustainable enterprises, and reduce the time from discovery to development, production and impact. Key to this is developing global access strategies to ensure that those most in need benefit from new solutions.

Tips for Applicants

- ❖ Your proposal must demonstrate an innovative approach. Your proposal should convey what is exciting about your approach, why it is innovative, and how it differs from existing solutions. Applying expertise from outside the topic area is one of the sources of innovation often evident in funded projects.
- ❖ Your proposal must comply with all restrictions and guidelines for the challenge to which you are applying, and it must explain how it addresses a key need highlighted in the challenge description. In addition, the challenge description highlights ideas that will not be funded, so applicants should make sure that their idea does not fall into one of these categories. The foundation only funds projects responsive to the Request for Proposals as it has a number of other avenues of funding for the equally important research that is otherwise within currently accepted program paradigms.
- ❖ The work proposed in your application must include a clear set of key experiments or activities that test your idea in a way that could provide sufficient evidence to warrant funding. Proposals with vague descriptions or vague testing methodologies will not be funded.
- ❖ The proposed project should have a clearly articulated goal, usually in terms of proving a hypothesis that if proved could lead to significant impact if properly scaled. The project plan should be organized by objectives that are logically required to achieve the goal of the project and should include a plan to **prove or disprove the underlying hypothesis** in an efficient and logical manner.
- ❖ Not all the reviewers for each proposal will be deep experts in the field. To maximize the chance of being funded, proposals should be written in clear language without jargon specific to a particular field.
- ❖ Your organization must meet the eligibility requirements as specified in this document and further refined in each of the challenge calls.
- ❖ The impact of the proposed work must be focused on one of the foundation priority [strategic health and development strategies](#).

II. Application Instructions

Schedule

Key dates and deadlines for 2014 Grand Challenges

Key Dates*	Event
Tuesday, October 6 th , 2014	Topics Published
Tuesday, November 4 th , 2014	LOI Application period opens
Tuesday, January 13 th , 2015, 11:30 a.m. US Pacific Standard Time	LOI Application Deadline
Tuesday, April 14 th , 2015	Notification of invitation to submit full proposal
Tuesday, June 2 nd , 2015, 11:30 a.m. US Pacific Standard Time	Full Proposal Application deadline (invited proposals only)
July 2015	Proposals review completed
August 2015	Selections completed and notifications sent

**Note, any changes to these dates will be posted on the Grand Challenges website*

How to Apply

Changes to the Rules and Guidelines will be posted periodically on the [Frequently Asked Questions](#) page of the Grand Challenges website (www.grandchallenges.org), including any changes to the dates listed above. Please read the current FAQ before submitting any questions or concerns.

Subject to the foundation's [Privacy Policy](#), the foundation may share information you provide to us (either orally or in writing) with third parties, including external reviewers, consultants, key partners and co-funders. This document is subject to the foundation's [Terms of Use](#).

Letter of Inquiry (LOI) Application Format

We encourage you to use the provided RFP-specific LOI application form, which can be downloaded after clicking "Apply Now" on each application page: [Women & Girls at the Center of Development](#); [New Interventions for Global Health](#); [Creating and Measuring Integrated Solutions for Healthy Birth, Growth, and Development](#). You are required to submit either a Microsoft Word® or PDF document; no more than five pages in length. Please do not include a cover sheet with your proposal. A cover sheet will be automatically generated from your registration data.

The LOI application must include the following sections and must **not exceed the total page limit of 5 pages**. An outline for the LOI application including recommended page allocations is provided below:

- I. **Executive Summary (1/2 Page)**
 - **Must clearly define and describe key idea or hypothesis that motivates project**
- II. **Goals (1 Page)**
 - **Must clearly define the potential outcome of the project if the goal is achieved (assuming subsequent work might be needed to take the project to scale).**
 - **Must clearly describe the key idea or hypothesis and how this idea or hypothesis is to be tested**
 - **Includes preliminary data if applicable**
- III. **Approach (1 Page)**
 - **Must define critical experiments to prove or disprove idea or hypothesis**
 - **The project plan must be organized by the objectives needed to accomplish the goal of the project.**
- IV. **Organization and Investigator Capabilities (1/2 Page)**
 - **Includes the expertise and resources available**
- V. **Collaboration (1/2 page)**
 - **Includes collaborating individuals and organizations where relevant and their capabilities**
- VI. **Budget (1/2 Page)**
 - **Summary by objective**

Proposals for Grand Challenges 2014 must be submitted prior to the submission deadline of 11:30 a.m. Pacific Standard Time on Tuesday, January 13, 2015.

During the application process you will be required to confirm that you have read and understand the [Website Terms of Use and Privacy Policy](#), and these [Rules and Guidelines](#), and acknowledge that any information that you provide to us (either orally or in writing) will be subject to and handled in accordance with such provisions.

Eligibility Criteria

Grand Challenges is open to both foreign and domestic organizations, including non-profit organizations, for-profit companies, international organizations, government agencies and academic institutions. **Individuals and organizations classified as individuals for U.S. tax purposes (including sole proprietorships and some single member limited liability companies) are not eligible to receive an award as part of the Grand Challenges initiative from the foundation.**

Upon registration, applicants must provide information about the tax status of their organization as different terms and conditions may apply. You should confirm your organization's tax status with the appropriate advisory or entity within your organization such as your grants or contracts department, finance, or office of sponsored research. Please select the tax status that most closely reflects your current organization's status. The foundation may request additional information regarding your tax status. For information about tax statuses, you may check with your own advisors and review information provided on the Internal Revenue Service web site at: www.irs.gov.

Each challenge topic published under the Grand Challenges may include additional instructions with regard to specific limitations regarding eligibility for that challenge topic.

III. Review Process

The review of proposals is a critical element of the Grand Challenges initiative - its goal is to filter and harness creative ideas. For each challenge call, we advertise a set of challenges carefully defined to elicit innovative responses to critical barriers in global health and development.

Handling of Proposals

The foundation has put in place policies and procedures, exclusive to the Grand Challenges initiative, intended to restrict public dissemination of application materials. These policies and procedures include, when possible, having external reviewers sign confidentiality agreements and requiring that reviewers destroy or return to the foundation all copies of information acquired or created during the course of performing a review. In some instances, however, we are unable to put in place confidentiality agreements or to police the use of application materials.

Additionally, the foundation is required by the IRS to publish a list of its grants. The foundation also provides general descriptions of its grants on its web sites, in press releases, and in other marketing materials. Subject to the foundation's [Privacy Policy](#), the foundation may also share information you provide to us (either orally or in writing) with third parties, including external reviewers, consultants, contingent workers, key partners and co-funders. These Rules and Guidelines are subject to the foundation's [Terms of Use](#).

Review of Proposals

Due to the large number of proposals anticipated, applicants with proposals that are not selected for award will receive a notification of decline without specific feedback. Nonetheless, applicants are encouraged to submit ideas in future years.

The Grand Challenges application review process for Phase I is executed in four steps:

1. The first step consists of screening LOI applications to evaluate whether proposals address the key needs described in the topic. We screen for responses that are completely unrelated or specifically excluded in the topic description. Excluded responses encompass ideas related to the topic but that, for strategic reasons, we are not funding under the Grand Challenges initiative. In addition, we exclude proposals considered incremental advances, appropriate responses that are similar to work in which the foundation or other Grand Challenge programs are already investing, or avenues of inquiry we deem ill-suited to the Grand Challenge initiative. Applicants with proposals removed from consideration during the screening process will be notified that their proposals were declined but will not receive specific feedback.
2. In the second step, reviews are chaired or co-chaired by technical leads from the foundation and other funding partners and are conducted by reviewers both outside and within the foundation. Reviewers are selected from the world's leading innovative minds and comprise both experts in the topic area and experts in complementary areas with a track record of innovation. Not all reviewers have deep expertise in the topic; please consider this information when drafting your proposal. Unlike most scientific funding programs, reviewers are encouraged to champion specific projects to be funded as part of the portfolio, without the need for a broad consensus on selections.

In order of importance, the criteria considered in these reviews are:

- Potential to lead to solutions with substantial **impact** related to the specific topic
 - Scientific and technical excellence & innovation**, including:
 - creativity of the project’s approach and clear differentiation from existing approaches
 - a clear and rigorous conceptual framework for the activities
 - Project Plan, including:
 - investigator and organization capabilities and potential for collaboration
 - value** in terms of appropriateness of the budget and timeline relative to project complexity, risk, and potential impact
3. The third step is the validation and final selection of the LOI applications to be invited to submit full proposals by an Executive Committee. Invited proposals will be provided additional technical instructions at that time.
 4. The fourth step involves repeating step two, but with regard to evaluation of the full proposal and with the inclusion of a more detailed review of the project plan and capability to execute the work.
 5. The fifth step is the validation and final selection of the proposals to be funded by the Executive Committee. The Executive Committee may recommend the proposal be funded, subject to specific modifications which will be negotiated as part of the award process.
 6. The sixth and final step is a due diligence review to ensure that applicants are appropriate recipients of foundation funds and to directly discuss and negotiate any adjustments to the proposed project recommended by the Executive Committee. Investigators will be contacted as part of the due diligence review.

Management of Conflict of Interest

To identify and avert conflicts of interest among application reviewers, such reviewers will not be permitted to review proposals from organizations with which the reviewer has self-identified conflicts of interest.

IV. Eligibility and Notifications

A. Allowable Costs

Grant funds may be used for the following costs: 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 these categories.

1. **Indirect costs.** The foundation provides a limited amount of indirect costs based on the nature of the applicant organization.

B. Privacy Notice

To help foundation staff in their evaluation and analysis of projects, all documents, communications and associated materials submitted to the foundation (collectively, “Submission Materials”) will become the property of the foundation and may be subject to confidential external review by independent subject matter experts in addition to analysis by foundation employees, contingent workers and/or consultants. Please consider carefully the information included in the Submission Materials. If you have any doubts

about the wisdom of disclosure of confidential or proprietary information, the foundation recommends you consult with your legal counsel. 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 foundation may disclose all information contained in Submission Materials to the extent it determines is necessary to evaluate them and the manner and scope of potential funding and as may be required by law.

C. Disclaimer

Neither these Rules & Guidelines nor the associated challenge calls constitute an offer to contract or award grant funds. The foundation assumes no responsibility for the applicants' cost to respond to these calls.

D. Release and Verification

In exchange for the opportunity to be considered for a grant, contract or program-related investment (per the relevant challenge call), the applicant agrees that the foundation may, in its sole discretion: (1) amend or cancel any challenge calls, in whole or in part, at any time; (2) extend the deadline for submitting responses; (3) determine whether a response does or does not substantially comply with the requirements of the challenge call and/or these Rules & Guidelines; (4) waive any minor irregularity, informality or nonconformance with the provisions or procedures of the challenge call and/or these Rules & Guidelines; (5) issue multiple awards; (6) share responses generated by the challenge call and/or these Rules & Guidelines with foundation staff, consultants, contingent workers, subject matter experts, and potential co-funders; and (7) copy the responses.

Applicant agrees not to bring a legal challenge of any kind against the foundation relating to the foundation's selection and award of any grant, contract or award arising from these Rules & Guidelines and the associated challenge calls.

E. Warranty.

By providing any Submission Materials, the sender(s) and applicant warrant to the foundation that they have the right to provide the information submitted and that such information is accurate. Any material misrepresentation, including omissions, may disqualify Submission Materials from consideration for a grant, contract or PRI award. Applicants with questions concerning the contents of their Submission Materials may contact the foundation at: grandchallenges@gatesfoundation.org

F. Intellectual Property (IP)

Since the output of this program may lead to innovative technologies, techniques and/or products that will result in improved health and development-related products for those in greatest need 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 urgent global health and global development needs. IP rights and the management of IP rights are likely to play an important role in achieving the goals of this program. To this end, the foundation requires that, even at the LOI application stage, all applicants seriously consider their willingness to submit a full proposal in compliance with the foundation's proposal guidelines, a portion of which asks for certain information and intentions regarding intellectual property and global access concerns. Specifically, the

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 and information gained during the Project to be promptly and broadly disseminated, and (b) the intended product(s) to be made available and accessible at an affordable price to people most in need in the developing countries of the world. The foundation refers to this as “Global Access.”

As part of the 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 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; and (2) Commitment to promote the utilization, commercialization and availability of inventions for public benefit in, or the benefit of, 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 are also expected to make new information and materials known to the research and/or medical communities in a timely manner through publications, web announcements, progress reports to the 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, developed in connection with each grant awarded to each applicant who submits a successful proposal, will also include provisions defining these concepts.

G. Research Assurances

While not necessary for the LOI application, as applicable to the individual project, the 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 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.

- 1. 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.
- 2. Clinical Trials.** We do not expect projects to require clinical trials on human subjects; however, if human trials are included, a condition of a grant would be your agreement that the appropriate Institutional Review Boards (“IRBs”) and ethical committees will review and approve the clinical protocols prior to trial initiation. You further agree to conduct clinical trials associated with the project under the generally accepted principles of “Good Clinical Practices” as defined by the International Conference on Harmonization (ICH) E-6 Standard, the United States Food and Drug Administration (FDA) or the European Agency for the Evaluation of Medicinal Products (EMA), as applicable. You acknowledge and agree that, as between you and the foundation, you take and will have full responsibility for all compliance, data safety, monitoring, and audit requirements of the relevant regulatory agencies, both for yourself and all other sites included in the project, including those activities conducted through subgrants, subcontracts or other collaborative efforts. You acknowledge and agree that any activities by the foundation as the grantor funding the Project, including its review of the Proposal or suggested modifications to the Project, does not modify the provisions of this paragraph or constitute the basis for any claim by you against the foundation.

- 3. 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 paragraph 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.

- 4. 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 approval for biohazards and recombinant DNA. You agree to provide prompt notice to the foundation if the facts and circumstances change regarding the approval status of the IRBs or ethical committees for any final protocol(s).
- 5. 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.
- 6. Use of Animals in Research.** You agree to be responsible for the humane care and treatment of animals in projects supported in part or whole by foundation funds; and to adhere to the official guidelines for animal research applicable in the country and locality where the trial is being conducted. No grant funds may be expended on studies involving animals until all requisite approvals are in place, and notification to that effect has been provided to the foundation. For purposes of this provision, an "animal" is defined as any live, vertebrate animal used or intended for use in research, research training, experimentation, biological testing or for related purposes. In the case of multi-national collaborations, the standards of each country may be followed, as long as (i) differences do not interfere with the design and analysis of the Project, and (ii) regulations in your institution and host country do not conflict with the management of the Project.

You agree to take responsibility for compliance of all subgrantees or subcontractors (if any) with the appropriate animal welfare laws, rules and regulations. You must report annually as a part of your progress report that the activities are being conducted in accordance with applicable laws in each respective venue (e.g., U.S. grantees must use the U.S. Public Health Service standards). Non-U.S. grantees may cite national laws or the CIOMS International Guiding Principles for Biomedical

Research Involving Animals if there is not a relevant national standard, (see: http://cioms.ch/publications/guidelines/1985_texts_of_guidelines.htm).

V. Privacy Notice and Terms of Use

Our full privacy policy and terms of use are located at [Privacy and Terms of Use](#).

Representation: By providing any submission materials, the sender represents to the Bill & Melinda Gates Foundation that he/she (i) has the authority to bind the named Applicant to the terms set forth above, without amendment, (ii) agrees to be bound by such terms; and (iii) has the right to provide the information submitted.

Please direct all questions about this initiative to: grandchallenges@gatesfoundation.org

VIII. Frequently Asked Questions

Answers to many application questions can be found on the [Frequently Asked Questions](#) section of our website at: www.grandchallenges.org.

IX. Inquiries

Please direct all questions about this initiative, selection criteria or application instructions by e-mail to the following address: grandchallenges@gatesfoundation.org