

Improving Access to and Use of Safe and Appropriate Cesarean Section: A Grand Challenge

Rules and Guidelines

Applications due no later than Wednesday, April 22, 2020, 11:30 a.m. U.S. Pacific Time

I. Overview

Grand Challenges is a family of initiatives fostering innovation to solve key problems in global health and development for those most in need. Each initiative is an experiment in the use of challenges to focus innovation on making an impact. Individual challenges address some of the same problems, but from differing perspectives.

Grand Challenges principles:

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.*
2. *Projects are selected based on public and transparent calls for proposals seeking the best ideas. We aim to engage new innovators 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.*
4. *Projects are selected not only for excellence but also for the likelihood that they will achieve the desired scale and impact.*
5. *Researchers and innovators work to ensure that the fruits of their projects are accessible and available to those most in need.*

Tips for Applicants

- ❖ 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 will only fund projects responsive to the Request for Proposals.
- ❖ 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.**
- ❖ Your 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.

II. Application Instructions

Schedule

Key Dates	Event
February 26, 2020	Application period opens
Wednesday, April 22, 2020 11:30 AM US Pacific Time	Application deadline
July 2020	Reviews completed
By Oct 2020	Selections completed and notifications sent

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

Applicants can expect to hear if their proposal is selected for funding by October 2020.

How to Apply

Changes to the Rules and Guidelines and to the Frequently Asked Questions (FAQ) document will be posted periodically on the webpage for each open challenge at the [Grand Challenges website \(gchg.grandchallenges.org\)](http://gchg.grandchallenges.org), including any changes to the dates listed above. Please read the current FAQ before submitting any questions or concerns.

Application Format

We encourage you to consult the Application Instructions for detailed guidance. These instructions can be downloaded after clicking “Apply Now” and can also be found under “Supporting Materials” on [the challenge page](#). You are required to submit either a Microsoft Word® or PDF document. Please do not include a cover sheet with your proposal. A cover sheet will be automatically generated from your application data.

Funding Levels

This Grand Challenge will have 2 funding levels, each with its own specific requirements for additional materials. **Applicants must select to which level they are applying.**

Seed Grants – USD \$100,000 for up to 24 months. Seed Grants are intended to provide proof of concept of an intervention that is entirely novel at small scale (e.g., a single facility or district). **In addition to the standard application package, applicants for Seed Grants must also:**

- Verify that they have conducted a thorough literature search using a major database confirming their proposal has no documented evidence, which will be used as an indicator of novelty
- Briefly describe the databases searched and the exact search terms used

Answers to these essential questions will be provided within the application portal and will not require uploading additional documents.

Validation Grants – USD \$300,000 for up to 24 months. These grants are intended to demonstrate the feasibility of a single intervention or a combination of interventions at the scalable unit of a health system. **In addition to the standard application package, applicants for Validation Grants must also describe how the concept replicates, confirms, or more rigorously tests one intervention (or multiple interventions) that have previously demonstrated proof of concept at a smaller scale.**

This description of the proof of concept will be provided in a separate (1 page) document.

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 are not eligible to receive an award from the foundation as part of the Grand Challenges initiative.**

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 advisor or entity within your organization such as your grants or contracts department, finance, or office of sponsored research. 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 published under the Grand Challenges may include additional instructions with regard to specific limitations regarding eligibility for that challenge.

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 this [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 these [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.

This Grand Challenges application review process will be executed in four steps:

1. The first step consists of screening 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 also 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 Challenges programs are already investing, or avenues of inquiry we deem ill-suited to the Grand Challenges 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 researchers and comprise both experts in the topic area and experts in complementary areas. 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
 - **Topical 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 by an Executive Committee, which is chaired by a foundation representative.
 4. The fourth and final step is a due diligence review to ensure that applicants are appropriate recipients of foundation funds. Investigators will be contacted as part of the due diligence review.

Management of Conflict of Interest

To identify and avoid 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, subgrants, 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. 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 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 whether to disclose 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 (PRI) (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 all applicants seriously consider their willingness to submit a 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 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. Compliance with Laws and Other Requirements

1. **Compliance with Laws.** In carrying out the individual project, you will comply with all applicable laws, regulations, and rules and will not infringe, misappropriate, or violate the intellectual property, privacy, or publicity rights of any third party.
2. **Compliance with Requirements.** You will conduct, control, manage, and monitor the individual project in compliance with all applicable ethical, legal, regulatory, and safety requirements, including applicable international, national, local, and institutional standards (“Requirements”). You will obtain and maintain all necessary approvals, consents, and reviews before conducting the applicable activity. As a part of your annual progress report to the foundation, you must report whether the individual project activities were conducted in compliance with all Requirements.

If the project involves:

- (a) any protected information (including personally identifiable, protected health, or third-party confidential), You will not disclose this information to the foundation without obtaining the foundation’s prior written approval and all necessary consents to disclose such information;
- (b) children or vulnerable subjects, you will obtain any necessary consents and approvals unique to these subjects; and/or
- (c) any trial involving human subjects, you will adhere to current Good Clinical Practice as defined by the International Council on Harmonisation (ICH) E-6 Standards (or local regulations if more stringent) and will obtain applicable trial insurance.

Any activities by the foundation in reviewing documents and providing input or funding does not modify your responsibility for determining and complying with all Requirements for the project.

3. **Indemnification.** If the project involves clinical trials, trials involving human subjects, post-approval studies, field trials involving genetically modified organisms, experimental medicine, or the provision of medical/health services (“Indemnified Activities”), you will indemnify, defend, and hold harmless the foundation and its trustees, employees, and agents (“Indemnified Parties”) from and against any and all demands, claims, actions, suits, losses, damages (including property damage, bodily injury, and wrongful death), arbitration and legal proceedings, judgments, settlements, or costs or expenses (including reasonable attorneys’ fees and expenses) (collectively, “Claims”) arising out of or relating to the acts or omissions, actual or alleged, of you or your employees, subgrantees, subcontractors, contingent workers, agents, and affiliates with respect to the Indemnified Activities. You agree that any activities by the foundation in connection with the project,

such as its review or proposal of suggested modifications to the project, will not modify or waive the foundation's rights under this paragraph. An Indemnified Party may, at its own expense, employ separate counsel to monitor and participate in the defense of any Claim. Your indemnification obligations are limited to the extent permitted or precluded under applicable federal, state or local laws, including federal or state tort claims acts, the Federal Anti-Deficiency Act, state governmental immunity acts, or state constitutions. Nothing in this agreement will constitute an express or implied waiver of your governmental and sovereign immunities, if any.

4. **Insurance.** You will maintain insurance coverage sufficient to cover the activities, risks, and potential omissions of the project in accordance with generally-accepted industry standards and as required by law. You will ensure your subgrantees and subcontractors maintain insurance coverage consistent with this section.

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 document posted on the webpage for each open challenge at the Grand Challenges website (gcgh.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