

Grand Challenges Explorations Round 22

Rules & Guidelines

Proposals due by Wednesday, November 14, 2018 11:30 a.m. U.S. Pacific Standard Time

I. Overview

Grand Challenges Explorations (GCE) supports hundreds of early-stage projects – including many ideas that have never before been tested – and innovators from a wide range of disciplines and regions. The GCE 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 other priority areas of the Bill & Melinda Gates Foundation.

GCE is an extension of the foundation’s commitment to the [Grand Challenges in Global Health](#), which was launched in 2003 to accelerate the discovery of new technologies to improve global health. Since then, GCE has expanded to include global development and communications challenges, and the Grand Challenges family of programs launched [additional funding opportunities](#) in 2014. A history of the program and current funding opportunities offered by the Grand Challenges family of programs can be found on the [Grand Challenges website](#). 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 the GCE initiative are:

- A two-page application.
- Rapid turnaround time. We select projects within approximately five months of the proposal submission.
- Blinded and champion-based review process. Reviewers with a track record in identifying innovative ideas select the proposals they find most pioneering without need for consensus.
- **Awards of \$100,000 USD** are made in **Phase I**. Phase I awardees have **one** opportunity to apply for a follow-on **Phase II award of up to \$1,000,000 USD**.

Tips for Applicants

- Your proposal must demonstrate an innovative approach that complies with all restrictions and guidelines for the topic to which you are applying. The foundation only funds projects responsive to the topics included in each round as it has a number of other avenues of funding for the equally important research that is otherwise within currently accepted program paradigms.
- Proposals are sent to reviewers without personal or organizational information. **Do not include this information in the body of your proposal.** Proposals that include personal or organizational information in the body of the proposal may be automatically removed from consideration.
- In addition to subject matter experts, your proposal will be reviewed by a panel with broad expertise and a track record in identifying innovations – these reviewers may not be deep domain experts in your field. You must describe your idea in clear language without the use of jargon unique to your field.
- 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.

II. Application Instructions

Schedule

Key dates and deadlines for Round 22

Key Dates	Event
September 2018	Application period opens
Wednesday, November 14, 2018, 11:30 a.m. US Pacific Standard Time	Application deadline
February 2019	Proposal review completed
April 2019	Selections completed, and notifications sent
May 2019	Awarded projects start date

How to Apply

Changes to the Rules and Guidelines will be posted on the [Frequently Asked Questions](#) page of the Grand Challenges website (gch.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 [Website Terms of Use and Privacy and Information Policy](#), the foundation may share information you provide to us (either orally or in writing) with third parties, including external reviewers, key partners and co-funders.

The GCE initiative publishes topics and invites proposals two rounds a year. An applicant must submit under only one topic each round and may submit only one proposal. Submit your best idea. You may submit multiple ideas in partnership with collaborators, but an individual Principal Investigator may lead the submission of only one proposal each round. View the detailed topic descriptions and determine which topic best suits your idea. You must select a topic prior to submitting a proposal. You may change your topic and edit your proposal any time before the application deadline.

If you are an existing user, you can [log in to your existing account](#). New users must create an account and submit proposals through our [online portal](#).

Application Format

We encourage you to use the provided application form, which can be downloaded at: [Explorations Application Form](#). You are required to submit either a Microsoft Word® or PDF document; no more than two 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 review and evaluation of your application are not based on your past history or institutional capabilities. **Describe your project without identifying personal or organizational information and do not refer to potential project partners by names or other identifying information. Proposals that do not adhere to these restrictions may be removed from consideration.**

Proposals for Round 22 must be submitted prior to the submission deadline of 11:30 a.m. Pacific Standard Time on Wednesday, November 14, 2018.

During the application process you will be required to confirm that you have read and understand the [Website Terms of Use and Privacy and Information 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

GCE is open to both foreign and domestic organizations, including non-profit organizations, for-profit companies, international organizations, government agencies, and academic institutions.

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 person or group 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 and other organizational information. For information about tax statuses, you may check with your own advisors and refer to information provided on the Internal Revenue Service web site at: www.irs.gov.

Applicants planning to conduct project activities in India may be required to register with the Ministry of Home Affairs under the Foreign Contribution Regulation Act of 2010 (FCRA). As part of the foundation's diligence we may ask for a copy of your organization's registration under FCRA or a written certification that FCRA registration is not required. Failure to comply with the requirements of FCRA may subject your organization to financial and/or criminal penalties. You should consult with your own advisors to determine whether FCRA applies to your organization or project.

III. Review Process

The review of proposals is a critical element of the GCE initiative - its goal is to filter and harness creative ideas. For each round, 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 GCE 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.

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

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 rounds.

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

1. The first step consists of screening submissions 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. In addition, we exclude proposals considered incremental advances, responses similar to work in which the foundation is already investing, or avenues of inquiry we deem ill-suited to the GCE initiative. Applicants with proposals removed from consideration during the screening process will be notified that their proposals were declined but will not typically receive specific feedback.

2. In the second step, responsive proposals are reviewed. The reviews are chaired by a foundation program lead 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 grants initiatives, individual reviewers are empowered to make funding decisions about a portion of the portfolio, without consensus on selections. Proposals are sent to reviewers without an applicant's personal or organizational information.

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

- **Topic Responsiveness** – How well does the proposal address a key need illustrated in the topic description?
 - **Innovative Approach** – Does the idea offer an unconventional, creative approach to the problem outlined in the topic?
 - **Execution Plan** – Is the work described feasible within the budget and time allocated for a Phase I project and, if successful would it have a clear need for further support?
3. The third step is the validation and final selection by an Executive Committee at the foundation of the proposals selected by reviewers in the second step of the evaluation. The Executive Committee is chaired by a foundation program director.
 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 avert conflicts of interest among reviewers, reviewers will not be permitted to review proposals from organizations with which the reviewer has self-identified a conflict of interest.

IV. Key Elements of GCE Phase I Agreements

Detailed sample provisions for each of the two GCE Agreements, one for non-profit organizations and one for for-profit organizations, are included in the Appendix to these Rules and Guidelines. Please note that these provisions are merely sample terms. The terms in the agreements between the foundation and GCE awardees are subject to change at the foundation's discretion.

The provisions have been developed specifically for the GCE initiative **and are not negotiable**. You are advised to ensure that your institution can accept the provisions of the relevant Agreement at the time of proposal submission. If your proposal is selected, you will have only a few weeks after notification of the award in which to have the appropriate institutional officer sign the Agreement and return it to the foundation.

1. Phase I projects have a term of 18 months beginning on the project start date. The amount awarded is up to \$100,000 USD.
2. Project funds may not be used to reimburse expenses incurred prior to the project start date.
3. The applicant must return a fully executed agreement to the foundation no later than the date and time indicated by the Grants and Contracts Management team to receive a GCE Phase I award. For non-profit awardees, funds will be disbursed upon the foundation's receipt of a fully executed agreement. Funds to for-profit entities will be disbursed in two payments of \$50,000. Upon receipt of a fully executed agreement, the foundation will disburse the first \$50,000. The foundation will disburse the second \$50,000 upon receipt of a report describing progress on the project and use of at least \$45,000 of the initial \$50,000 disbursement.
4. No awardee is permitted to make sub-grants, but all awardees will be permitted to contract for services, up to a maximum of \$49,999 USD. Please be aware that this limit applies to funds paid by an awardee to any

other organization (or an individual employed at another organization) as a subcontractor, **including payments to co-PIs working at another organization.**

5. All awardees are entitled to purchase equipment, provided that the cost of each item is less than \$5,000 USD.
6. Phase I project funds may be used to cover the full direct costs of the project, but no awardee will be entitled to use funds to cover indirect costs. See the Sample Agreements for the definition of indirect costs.
7. For-profit non-US awardees are subject to restrictions on the amount of funds they may use for expenditures in the US (see sample agreement for for-profit organizations).
8. Project funds may not be used 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.
9. Awardees must agree to conduct and manage the project and the products, services, processes, technologies, materials, software, data other innovations, and intellectual property resulting from the project (including modifications, improvements, and further developments to “Background Technology”) in a manner that ensures “Global Access.” See the Global Access Section of the Sample Agreements for more information about these obligations.
10. Awardees must agree to abide by the foundation’s Open Access Policy which requires all peer-reviewed published research, and underlying data sets resulting from foundation funded research to be immediately available upon publication. As noted in the Open Access Policy, the foundation is responsible for individual article processing charges and fees to the extent required to comply with the foundation’s Open Access Policy. These fees should not be included in project budgets. Open access management and fees will be managed via Chronos, a new service for foundation-funded research. Chronos simplifies and manages the process of publishing under the foundation's Open Access Policy terms. Primary contacts will receive a Chronos account activation email 6 weeks after the agreement start date.

The Agreement and specific provisions that apply to a project depend on the tax status of the applicant. We strongly encourage you to share the Sample Agreements with the appropriate person or group within your organization such as your grants and contracts department, legal department, finance or office of sponsored research at the time you submit your proposal to ensure that your organization can agree to the relevant provisions.

V. Phase I Reporting

All GCE awardees must prepare and submit a Final Financial and Scientific Report. Awardees must submit the report electronically by the date described in the Reporting section of the Agreements. The report should be a cumulative, stand-alone document that describes the work performed with the project funds during the project term. The scientific section of the report must include any technical data gathered, models developed, and summary conclusions. The financial section of the report should include an account of the manner in which you spent the project funds.

Additionally, GCE awardees will be required to participate in the online outputs and outcomes reporting system operated by Researchfish, the vendor selected by the foundation for this purpose, during the term of the award and for four years after the award term. The foundation will provide GCE awardees with guidance after the award regarding the timing and scope of required reporting through the Researchfish platform.

VI. Phase II GCE Awards

Phase II is an opportunity to apply for additional support for projects that demonstrate innovative solutions towards the GCE goals and are critical to on-going foundation strategies. Phase I awardees have **one** opportunity to apply for Phase II funding of **up to \$1,000,000 USD with a grant term of up to two (2) years.**

Phase II projects are not subject to the same limitations as Phase I grants. Phase II grant terms follow standard grant-making practices at the foundation.

VII. Terms of Use, Privacy Notice and Information Security

This document and your application are subject to the Terms of Use and Privacy & Information Security Policy which are located at <https://gcgh.grandchallenges.org/privacy-policy-and-terms-use>

VIII. Frequently Asked Questions

Answers to many application questions can be found on the [Frequently Asked Questions](https://gcgh.grandchallenges.org) section of our website at: <https://gcgh.grandchallenges.org>

IX. Inquiries

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

Appendix

I. Term of Offers

GCE awards are conditioned upon the foundation's receipt of an executed agreement by the date indicated by the Grants and Contracts Services team in the email to which the Agreement is attached. Agreements received after the deadline may not be considered for funding. More information will be sent to those being considered for an award. The scheduled start date for all Round 22 GCE Phase I projects is May 1, 2019.

Set forth below are samples of the Agreements used in making GCE awards. Please note that these provisions are merely sample terms. The terms in the agreements between the foundation and GCE awardees are subject to change at the foundation's discretion.

II. Sample Agreement for Non-Profit Organizations (See below for Sample Agreement for For-Profit Organizations)

THIS AGREEMENT is between <<>> ("<<>>," "You" or "Grantee") and the Bill & Melinda Gates Foundation ("*Foundation*") and is effective as of the date of last signature. Each party to this Agreement may be referred to individually as a "*Party*" and together as the "*Parties*." As a condition of this grant, the Parties enter into this Agreement by having their authorized representatives sign below.

GRANT AMOUNT AND REPORTING & PAYMENT SCHEDULE

GRANT AMOUNT

The Foundation will pay You the total grant amount specified in the Reporting & Payment Schedule below. The Foundation's Primary Contact must approve in writing any Budget cost category change of more than 10%.

REPORTING & PAYMENT SCHEDULE

Payments are subject to Your compliance with this Agreement, including Your achievement, and the Foundation's approval, of any applicable targets, milestones, and reporting deliverables required under this Agreement. The Foundation may, in its reasonable discretion, modify payment dates or amounts and will notify You of any such changes in writing.

REPORTING

You will submit reports according to the Reporting & Payment Schedule using the Foundation's templates or forms, which the Foundation will make available to You and which may be modified from time to time. For a progress or final report to be considered satisfactory, it must demonstrate meaningful progress against the targets or milestones for that investment period. If meaningful progress has not been made, the report should explain why not and what adjustments You are making to get back on track. Please notify the Foundation's Primary Contact if You need to add or modify any targets or milestones. The Foundation must approve any such changes in writing. You agree to submit other reports the Foundation may reasonably request.

TERMS & CONDITIONS

This Agreement is subject to the following terms and conditions.

PROJECT SUPPORT

PROJECT DESCRIPTION AND CHARITABLE PURPOSE

The Foundation is awarding You this grant to carry out the project described in the Proposal Narrative (collectively, "Project") in order to further the Charitable Purpose. The Foundation, in its discretion, may approve in writing any request by You to make non-material changes to the Proposal Narrative.

MANAGEMENT OF FUNDS

USE OF FUNDS

You may not use funds provided under this Agreement ("*Grant Funds*") for any purpose other than the Project. You may not use Grant Funds to reimburse any expenses You incurred prior to the Start Date. At the Foundation's request, You will repay any portion of Grant Funds and/or Income used or committed in material breach of this Agreement, as determined by the Foundation in its discretion.

LIMITATIONS ON CAPITAL ASSETS

You may use the Grant Funds to purchase capital assets such as equipment so long as the assets are used exclusively for the Project during the term of the grant and the cost of any single capital item does not exceed \$5,000.

INDIRECT COSTS

Grant funds may not be used to pay any indirect costs. Indirect costs are defined as (1) overhead expenses incurred as a result of the Project, but that are not easily identifiable with the Project and (2) administrative expenses that are related to overall general operations and are shared among projects and/or functions. Examples of indirect costs include, but are not limited to, executive oversight, accounting, grants management, legal expenses, utilities, facility maintenance

INVESTMENT OF FUNDS

You must invest Grant Funds in highly liquid investments with the primary objective of preservation of principal (e.g., interest-bearing bank accounts or a registered money market mutual fund) so that the Grant Funds are available for the Project. Together with any progress or final reports required under this Agreement, You must report the amount of any currency conversion gains (or losses) and the amount of any interest, or other income generated by the Grant Funds (collectively, "*Income*"). Any Income must be used for the Project.

GLOBAL ACCESS

GLOBAL ACCESS COMMITMENT

You will conduct and manage the Project and the Funded Developments in a manner that ensures Global Access. Your Global Access commitments will survive the term of this Agreement. "*Funded Developments*" means the products, services, processes, technologies, materials, software, data, other innovations, and intellectual property resulting from the Project (including modifications, improvements, and further developments to Background Technology). "*Background Technology*" means any and all products, services, processes, technologies, materials, software, data, or other innovations, and intellectual property created by You or a third party prior to or outside of the Project used as part of the Project. "*Global Access*" means: (a) the knowledge and information gained from the Project will be promptly and broadly disseminated; and (b) the Funded Developments will be made available and accessible at an affordable price (i) to people most in need within developing countries, or (ii) in support of the U.S. educational system and public libraries, as applicable to the Project.

PUBLICATION

Consistent with Your Global Access commitments, if the Project description specifies Publication or Publication is otherwise requested by the Foundation, You will seek prompt Publication of any Funded Developments consisting of data and results. "*Publication*" means publication in a peer-reviewed journal or other method of public dissemination specified in the Project description or otherwise approved by the Foundation in writing. Publication may be delayed for a reasonable period for the sole purpose of seeking patent protection, provided the patent application is drafted, filed, and managed in a manner that best furthers Global Access. If You seek Publication in a peer-reviewed journal, such Publication shall be under "open access" terms and conditions consistent with the Foundation's Open Access Policy available at: www.gatesfoundation.org/How-We-Work/General-Information/Open-Access-Policy, which may be modified from time to time. Nothing in this section shall be construed as requiring Publication in contravention of any applicable ethical, legal, or regulatory requirements. You will mark any Funded Development subject to this clause with the appropriate notice or attribution, including author, date and copyright (e.g., © 20<> <Name>).

INTELLECTUAL PROPERTY REPORTING

During the term of this Agreement and for 5 years after, You will submit upon request annual intellectual property reports related to the Funded Developments, Background Technology, and any related agreements using the Foundation's templates or forms, which the Foundation may modify from time to time.

SUBGRANTS AND SUBCONTRACTS

SUBGRANTS AND SUBCONTRACTS

You have the exclusive right to select subcontractors to assist with the Project. The aggregate amount of Project Funds paid to subcontractors may not exceed \$49,999. You acknowledge that the Foundation has not and will not earmark the use of any Project Funds for a specific subcontractor. You may not make subgrants under this Agreement.

SCHOLARSHIPS AND FELLOWSHIPS

You will have sole discretion over Your selection of any scholarship and fellowship recipients under this Agreement and must conduct the selection process independently of the Foundation.

TRAVEL STIPENDS AND CONFERENCE FEES

You will have sole discretion over Your selection of any recipients of travel stipends or conference expense reimbursements under this Agreement and must conduct the selection process independently of the Foundation. Foundation trustees and employees are not eligible to receive travel stipends or conference expense reimbursements.

RESPONSIBILITY FOR OTHERS

You are responsible for (a) all acts and omissions of any of Your trustees, directors, officers, employees, subgrantees, subcontractors, contingent workers, agents, and affiliates assisting with the Project, and (b) ensuring their compliance with the terms of this Agreement.

PROHIBITED ACTIVITIES

ANTI-TERRORISM

You will not use funds provided under this Agreement, directly or indirectly, in support of activities (a) prohibited by U.S. laws relating to combating terrorism; (b) with persons on the List of Specially Designated Nationals (www.treasury.gov/sdn) or entities owned or controlled by such persons; or (c) in or with countries or territories against which the U.S. maintains comprehensive sanctions (currently, Cuba, Iran, Syria, North Korea, and the Crimea Region of Ukraine), including paying or reimbursing the expenses of persons from such countries or territories, unless such activities are fully authorized by the U.S. government under applicable law and specifically approved by the Foundation in its sole discretion.

ANTI-CORRUPTION; ANTI-BRIBERY

You will not offer or provide money, gifts, or any other things of value directly or indirectly to anyone in order to improperly influence any act or decision relating to the Foundation or the Project, including by assisting any party to secure an improper advantage. Training and information on compliance with these requirements are available at www.learnfoundationlaw.org.

***{Indian grantees where FCRA Registration is Required}* FCRA COMPLIANCE**

If organization has not yet registered under FCRA: If You are conducting Project activities in India, the Foundation will not make payments, and You may not incur expenses under, this Agreement until the Foundation has received a copy of Your registration with the Ministry of Home Affairs under the Foreign Contribution (Regulation) Act (FCRA), 2010, or written evidence that You are exempt from such registration requirements. You must advise the Foundation immediately if there is any change in Your FCRA registration during the term of this Agreement.

If organization has registered under FCRA: The Foundation has verified with the Ministry of Home Affairs Your registration under the Foreign Contribution (Regulation) Act (FCRA), 2010, and/or received a copy of such registration from You. You must advise the Foundation immediately if there is any change in Your FCRA registration during the term of this Agreement.

If organization is an Indian government entity that is exempt under FCRA: By signing this Agreement, You certify that You: (a) are not, as a result of this Agreement or otherwise, subject to the Foreign Contribution (Regulation) Act (FCRA), 2010; (b) understand that the Foundation is entering into this Agreement in reliance on this representation; and (c) understand that You would be subject to any financial and/or criminal penalties imposed for non-compliance with FCRA. You must advise the Foundation immediately if there is any change in FCRA's applicability to You in connection with Your activities under this Agreement or otherwise.

LOBBYING AND ELECTIONEERING PROHIBITION

You may not use Grant Funds to influence the outcome of any election for public office or to carry on any voter registration drive. You acknowledge that the Foundation has not earmarked Grant Funds to support lobbying activities or to otherwise support attempts to influence legislation. Activities will be conducted consistent with the private foundation lobbying rules and exceptions under Internal Revenue Code Section 4945 and related regulations. You confirm that the Budget (or the combined project budget if there are multiple funders) accurately reflects that You will expend at least the amount of the Grant Funds on (a) non-lobbying activities in the project year, or (b) for multiple year projects, the total non-lobbying portion of the project.

OTHER LOBBYING, GIFT, AND ETHICS RULES

You agree to comply with any national, state, local, or other lobbying, gift, and ethics rules applicable to the Project. The Foundation is not retaining or employing You to engage in lobbying activities.

PUBLICITY

PUBLICITY BY THE FOUNDATION

The Foundation may include information about the award of this grant, including Your name, in its periodic public reports and may make such information available on its website and as part of press releases, public reports, speeches, newsletters, tax returns, and other public disclosures.

PUBLICITY BY YOU

You must obtain the Foundation's prior written approval before: (a) issuing a press release or other public announcement regarding this grant; and (b) any other public use of the Foundation's name or logo. Please email Your request to: grantee.comms@gatesfoundation.org two weeks in advance to provide the Foundation an opportunity to review and comment. Detailed guidelines are available at: http://www.gatesfoundation.org/grantseeker/documents/guidelines_communications_for_grantees.doc.

PUBLICITY BY OTHERS

You and Your subgrantees, subcontractors, contingent workers, agents, or affiliates may not state or otherwise imply to third parties that the Foundation directly funds or otherwise endorses their activities.

OTHER

LEGAL ENTITY AND AUTHORITY

You confirm that: (a) You are an entity duly organized or formed, qualified to do business, and in good standing under the laws of the jurisdiction in which You are organized or formed; (b) You are not an individual (i.e., a natural person) or a disregarded entity (e.g., a sole proprietor or sole-owner entity) under U.S. law; (c) You have the right to enter into and fully perform this Agreement; and (d) Your performance will not violate any agreement or obligation between You and any third party. You will notify the Foundation immediately if any of this changes during the term of this Agreement.

COMPLIANCE WITH LAWS

In carrying out the 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.

COMPLIANCE WITH REQUIREMENTS

You will conduct, control, manage, and monitor the 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 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.

RELIANCE

You acknowledge that the Foundation is relying on the information You provide in reports and during the course of any due diligence conducted prior to the Start Date and during the term of this Agreement. You represent that the Foundation may continue to rely on this information and on any additional information You provide regarding activities, progress, and Funded Developments.

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.

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.

TERM AND TERMINATION

TERM

This Agreement commences on the Start Date and continues until the End Date, unless terminated earlier as provided in this Agreement. The Foundation, in its discretion, may approve in writing any request by You for a no-cost extension, amend the End, and adjust any affected reporting requirements.

TERMINATION

The Foundation may modify, suspend, or discontinue any payment of Grant Funds or terminate this Agreement if: (a) the Foundation is not reasonably satisfied with Your progress on the Project; (b) there are significant changes to Your leadership or other factors that the Foundation reasonably believes may threaten

the Project's success; (c) there is a change in Your control; (d) there is a change in Your tax status; or (e) You fail to comply with this Agreement.

RETURN OF FUNDS

Any Grant Funds that have not been used for, or committed to, the Project upon expiration or termination of this Agreement must be (a) returned promptly to the Foundation, (b) applied to another Foundation-funded project (current or under consideration), or (c) applied to another mutually-agreed upon charitable purpose, as directed in writing by the Foundation. Any Income that has not been used for, or committed to, the Project must be either applied to another Foundation-funded project (current or under consideration) or applied to another mutually-agreed upon charitable purpose, as directed in writing by the Foundation.

For Indian grantees if FCRA Registration is required: Any Grant Funds, plus any Income, that have not been used for, or committed to, the Project upon expiration or termination of this Agreement, must be returned promptly to the Foundation to the extent consistent with applicable law. If applicable law does not permit such return, then You must transfer such Grant Funds to another charitable organization designated or approved by the Foundation for purposes relating to the Project, to the extent consistent with applicable law

MONITORING, REVIEW, AND AUDIT

N/A if grantee is a government unit or international executive order organization:

The Foundation may monitor and review Your use of the Grant Funds, performance of the Project, and compliance with this Agreement, which may include onsite visits to assess Your organization's governance, management and operations, discuss Your program and finances, and review relevant financial and other records and materials. In addition, the Foundation may conduct audits, including onsite audits, at any time during the term of this Agreement, and within four years after Grant Funds have been fully spent. Any onsite visit or audit shall be conducted at the Foundation's expense, following prior written notice, during normal business hours, and no more than once during any 12-month period.

INTERNAL OR THIRD PARTY AUDIT

N/A if grantee is a government unit or international executive order organization:

If during the term of this Agreement You are audited by your internal audit department or by a third party, You will provide the audit report to the Foundation upon request, including the management letter and a detailed plan for remedying any deficiencies observed ("*Remediation Plan*"). The Remediation Plan must include (a) details of actions You will take to correct any deficiencies observed, and (b) target dates for successful completion of the actions to correct the deficiencies.

RECORD KEEPING

You will maintain complete and accurate accounting records and copies of any reports submitted to the Foundation relating to the Project. You will retain such records and reports for 4 years after Grant Funds have been fully spent. At the Foundation's request, You will make such records and reports available to enable the Foundation to monitor and evaluate how Grant Funds have been used or committed.

SURVIVAL

A Party's obligations under this Agreement will be continuous and survive expiration or termination of this Agreement as expressly provided in this Agreement or otherwise required by law or intended by their nature.

GENERAL

ENTIRE AGREEMENT AND AMENDMENTS

This Agreement contains the entire agreement of the Parties and supersedes all prior and contemporaneous agreements concerning its subject matter. Except as specifically permitted in this Agreement, no modification, amendment, or waiver of any provision of this Agreement will be effective unless in writing and signed by authorized representatives of both Parties.

NOTICES AND APPROVALS

Written notices, requests, and approvals under this Agreement must be delivered by mail or email to the other Party's primary contact specified on the Agreement Summary & Signature Page, or as otherwise directed by the other Party.

SEVERABILITY

Each provision of this Agreement must be interpreted in a way that is enforceable under applicable law. If any provision is held unenforceable, the rest of the Agreement will remain in effect.

ASSIGNMENT

You may not assign, or transfer by operation of law or court order, any of Your rights or obligations under this Agreement without the Foundation’s prior written approval. This Agreement will bind and benefit any permitted successors and assigns.

COUNTERPARTS AND ELECTRONIC SIGNATURES

Except as may be prohibited by applicable law or regulation, this Agreement and any amendment may be signed in counterparts, by facsimile, PDF, or other electronic means, each of which will be deemed an original and all of which when taken together will constitute one agreement. Facsimile and electronic signatures will be binding for all purposes.

III. Sample Agreement for For-Profit Organizations

PROJECT AGREEMENT

AGREEMENT SUMMARY & SIGNATURE PAGE

THIS AGREEMENT is between <>> (“<>>”, “You”) and the Bill & Melinda Gates Foundation (“*Foundation*”), and is effective as of the date of last signature. Each party to the Agreement may be referred to individually as a “*Party*” and together as the “*Parties*.” In consideration of the mutual promises contained in this Agreement, the Parties enter into this Agreement by having their authorized representatives sign below.

PROJECT AMOUNT AND REPORTING & PAYMENT SCHEDULE

MAXIMUM AMOUNT

The Foundation will pay You up to \$100,000.

REPORTING & PAYMENT SCHEDULE

Payments are subject to Your compliance with this Agreement, including Your achievement, and the Foundation’s approval, of any applicable targets, milestones, and reporting deliverables required under this Agreement. The Foundation may, in its reasonable discretion, modify payment dates or amounts and will notify You of any such changes in writing.

REPORTING

You will submit reports according to the Reporting & Payment Schedule using the Foundation's templates or forms, which the Foundation will make available to You and which may be modified from time to time. You will submit Your Reports via email to the Program Coordinator according to the payment table below, at GCE@gatesfoundation.org. For a progress or final report to be considered satisfactory, it must demonstrate meaningful progress against the targets or milestones for that investment period. If meaningful progress has not been made, the report should explain why not and what adjustments You are making to get back on track. The Foundation must approve any such changes in writing. You agree to submit other reports the Foundation may reasonably request.

ACCOUNTING FOR PERSONNEL TIME

You will track the time of all employees, contingent workers, and any other individuals whose compensation will be paid in whole or in part by Project Funds. Such individuals will keep records (e.g., timesheets) of actual time worked on the Project in increments of sixty minutes or less and a brief description of tasks performed. You will report actual time worked consistent with those records in Your

progress and final budget reports. You will submit such copies of records to the Foundation upon request.

REPORTING & PAYMENT SCHEDULE				
<i>Investment Period</i>	<i>Reporting Deliverable</i>	<i>Due By</i>	<i>Payment Date</i>	<i>Payment Amount (U.S.\$)</i>
	Counter Signed Project Agreement	October TBD OR April TBD	Within 15 days after receipt of countersigned Agreement	\$50,000
Start Date to Date on or after first \$45,000 of Project Funds Expended	Second Payment Release Progress Report*	Reasonable period of time after first \$45,000 of Project Funds expended	45 days after report is received	Up to \$50,000
Start Date to October 31, 20XX or April 30, 20XX	12-Month Progress Report**	November 30, 20XX OR May 31, 20XX	–	–
Start Date to End Date	Final Financial and Scientific Report	December 15, 20XX OR June 15, 20XX		
Total Project Amount				Up to \$100,000

*If this report is submitted after the 12-month Progress Report it needs to describe only the progress and spending of Project Funds not covered in the 12-month Progress Report.

**The 12-Month Report must be submitted by its due date, which may be before or after submission of the Second Payment Release Progress Report. If the 12-Month Report is submitted after the Second Payment Progress Report, the 12-Month Report needs to describe only the progress and spending of Project Funds not covered in the Second Payment Progress Report.

All questions regarding Your reporting obligations should be submitted electronically to the Grand Challenges Explorations Program Coordinator at the email address listed above.

TERMS & CONDITIONS

This Agreement, is subject to the following terms and conditions.

PROJECT SUPPORT

PROJECT DESCRIPTION AND CHARITABLE PURPOSE

You agree to carry out the project described in the Proposal (“*Project*”) in order to further the Charitable Purpose.

MANAGEMENT OF FUNDS

USE OF FUNDS

You may not use funds provided under this Agreement (“Project Funds”) for any purpose other than the Project. You may not use Project Funds to reimburse any expenses You incurred prior to the Start Date. Together with the final report required under this Agreement, You must report investment activities and the amount of any currency conversion gains (or losses) and the amount of any interest or other income generated by the Project Funds (collectively, “Income”). Any Income must be used for the Project.

For Foreign Organizations Only

ACTIVITIES IN THE U.S.

You may not use more than 20% of Project Funds for activities in the U.S., including travel to or from the U.S.

SEGREGATION OF FUNDS

You must maintain Project Funds in a physically separate bank account dedicated to the Project.

LIMITATIONS ON CAPITAL ASSETS

You may use the Project Funds to purchase capital assets such as equipment so long as the assets are used exclusively for the Project during the term of the Agreement and the cost of any single capital item does not exceed \$5,000.

INDIRECT COSTS

Project funds may not be used to pay any indirect costs. Indirect costs are defined as (1) overhead expenses incurred as a result of the Project, but that are not easily identifiable with the Project and (2) administrative expenses that are related to overall general operations and are shared among projects and/or functions. Examples of indirect costs include, but are not limited to, executive oversight, accounting, agreement management, legal expenses, utilities, facility maintenance.

GLOBAL ACCESS

GLOBAL ACCESS COMMITMENT

You will conduct and manage the Project and the Funded Developments in a manner that ensures Global Access. Your Global Access commitments will survive the term of this Agreement. “*Funded Developments*” means the products, services, processes, technologies, materials, software, data, other innovations, and intellectual property resulting from the Project (including modifications, improvements, and further developments to Background Technology). “*Background Technology*” means any and all products, services, processes, technologies, materials, software, data, other innovations, and intellectual property created by You or a third party prior to or outside of the Project used as part of the Project. “*Global Access*” means: (a) the knowledge and information gained from the Project will be promptly and broadly disseminated; and (b) the Funded Developments will be made available and accessible at an affordable price (i) to people most in need within developing countries, or (ii) in support of the U.S. educational system and public libraries, as applicable to the Project.

PUBLICATION

Consistent with Your Global Access commitments, if the Project description specifies Publication or Publication is otherwise requested by the Foundation, You will seek prompt Publication of any Funded Developments consisting of data and results. “Publication” means publication in a peer-reviewed journal or other method of public dissemination specified in the Project description or otherwise approved by the Foundation in writing. Publication may be delayed for a reasonable period for the sole purpose of seeking patent protection, provided the patent application is drafted, filed, and managed in a manner that best furthers Global Access. If You seek Publication

in a peer-reviewed journal, such Publication shall be under “open access” terms and conditions consistent with the Foundation’s Open Access Policy available at: www.gatesfoundation.org/How-We-Work/General-Information/Open-Access-Policy, which may be modified from time to time. Nothing in this section shall be construed as requiring Publication in contravention of any applicable ethical, legal, or regulatory requirements. You will mark any Funded Development subject to this clause with the appropriate notice or attribution, including author, date and copyright (e.g., © 20<> <Name>).

SUBGRANTS AND SUBCONTRACTS

SUBGRANTS AND SUBCONTRACTS

You have the exclusive right to select subcontractors to assist with the Project. The aggregate amount of Project Funds paid to subcontractors may not exceed \$49,999. You acknowledge that the Foundation has not and will not earmark the use of any Project Funds for a specific subcontractor. You may not make subgrants under this Agreement.

RESPONSIBILITY FOR OTHERS

You are responsible for all acts and omissions of any of Your trustees, directors, officers, employees, subcontractors, contingent workers, agents, and affiliates assisting with the Project and ensuring their compliance with the terms of this Agreement.

PROHIBITED ACTIVITIES

ANTI-TERRORISM

You will not use funds provided under this Agreement, directly or indirectly, in support of activities (a) prohibited by U.S. laws related to combatting terrorism; (b) with persons on the List of Specially Designated Nationals (www.treasury.gov/sdn) or entities owned or controlled by such persons; or (c) in or with countries or territories against which the U.S. maintains comprehensive sanctions (currently, Cuba, Iran, Syria, North Korea, and the Crimea Region of Ukraine), including paying or reimbursing the expenses of persons from such countries or territories, unless such activities are fully authorized by the U.S. government under applicable law and specifically approved by the Foundation in its sole discretion.

ANTI-CORRUPTION AND ANTI-BRIBERY

You will not offer or provide money, gifts, or any other things of value directly or indirectly to anyone in order to improperly influence any act or decision relating to the Foundation or the Project, including by assisting any party to secure an improper advantage. Training and information on compliance with these requirements are available at www.learnfoundationlaw.org.

POLITICAL ACTIVITY AND ADVOCACY

You may not use Project Funds to influence the outcome of any election for public office or to carry on any voter registration drive. You may not use Project Funds to support lobbying activity or to otherwise support attempts to influence local, state, federal, or foreign legislation. Your strategies and activities, and any materials produced with Project Funds, must comply with applicable local, state, federal, or foreign lobbying law. You agree to comply with lobbying, gift, and ethics rules applicable to the Project.

OTHER LOBBYING, GIFT, AND ETHICS RULES

You agree to comply with any national, state, local, or other lobbying, gift, and ethics rules applicable to the Project. The Foundation is not retaining or employing You to engage in lobbying activities

OTHER

LEGAL ENTITY AND AUTHORITY

You confirm that: (a) You are an entity duly organized or formed, qualified to do business, and in good standing under the laws of the jurisdiction in which You are organized or formed; (b) You are not an individual (i.e., a natural person) or a disregarded entity (e.g., a sole proprietor or sole-owner entity) under U.S. law; (c) You have the right to enter into and fully perform this Agreement; and (d) Your performance will not violate any agreement or obligation between You and any third party. You will notify the Foundation immediately if any of this changes during the term of this Agreement.

COMPLIANCE WITH LAWS

In carrying out the 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.

COMPLIANCE WITH REQUIREMENTS

You will conduct, control, manage, and monitor the 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 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.

{For Indian for-profit organizations } FCRA COMPLIANCE

{For Indian grantee where FCRA Compliance is NOT Required} By signing this Agreement, You certify that You: (a) are not, as a result of this Agreement or otherwise, subject to the Foreign Contribution (Regulation) Act (FCRA), 2010 and that You have received written advice from a third-party professional advisor with relevant experience that is consistent with this certification; (b) understand that the Foundation is entering into this Agreement in reliance on this representation; and (c) understand that You would be subject to any financial and/or criminal penalties imposed for non-compliance with FCRA. You must advise the Foundation immediately if there is any change in FCRA's applicability to You in connection with Your activities under this Agreement or otherwise.

{For Indian organization that has registered under FCRA} The Foundation has verified with the Ministry of Home Affairs Your registration under the Foreign Contribution (Regulation) Act (FCRA), 2010, and/or received a copy of such registration from You. You must advise the Foundation immediately if there is any change in Your FCRA registration during the term of this Agreement.

{For Indian for-profit organizations } TAX WITHHOLDING

The Foundation may withhold and remit taxes due as required by the India Tax Deducted at Source. The Foundation will not withhold any amounts for employment-related taxes. The Foundation will not be liable to You for any withheld amounts. At Your request, the Foundation will provide You with documentation verifying remittance.

{For Indian for-profit organizations } TAX RESPONSIBILITY

You are responsible for remitting all other taxes related to Your performance of the Project (e.g., sales tax, services tax, Goods and Services Tax (“GST”) and value-added tax (“VAT”)) and Your receipt of payments under this Agreement (e.g., business and occupation tax, employment-related taxes, and income tax), and agree that You will comply with all obligations to remit any such taxes.

RELIANCE

You acknowledge that the Foundation is relying on the information You provide in reports and during the course of any due diligence conducted prior to the Start Date and during the term of this Agreement. You represent that the Foundation may continue to rely on this information and on any additional information You provide regarding activities, progress, and Funded Developments.

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.

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.

PUBLICITY

PUBLICITY BY THE FOUNDATION

The Foundation may include information about the Project and this Agreement, including Your

name, in its periodic public reports and may make such information available on its website and as part of press releases, public reports, speeches, newsletters, tax returns, and other public disclosures.

PUBLICITY BY YOU

You must obtain the Foundation's prior written approval before: (a) issuing a press release or other public announcement regarding this Agreement; and (b) any other public use of the Foundation's name or logo. Please email Your request to: Grantee.Comms@gatesfoundation.org two weeks in advance to provide the Foundation an opportunity to review and comment. Detailed guidelines are available at:

http://www.gatesfoundation.org/grantseeker/documents/guidelines_communications_for_grantees.doc.

PUBLICITY BY OTHERS

You and Your subcontractors, contingent workers, agents, or affiliates may not state or imply to third parties that the Foundation directly funds or otherwise endorses their activities.

TERM AND TERMINATION

TERM

This Agreement commences on the Start Date and continues until the End Date, unless terminated earlier as provided in this Agreement. The Foundation, in its discretion, may approve in writing any request by You for a no-cost extension, including amending the End Date and adjusting any affected reporting requirements.

TERMINATION

The Foundation may modify, suspend, or discontinue any payment of Project Funds or terminate this Agreement if: (a) the Foundation is not reasonably satisfied with Your progress on the Project; (b) there are significant changes to Your leadership or other factors that the Foundation reasonably believes may threaten the Project's success; (c) there is a change in Your control; (d) there is a change in Your tax status; or (e) You fail to comply with this Agreement.

RETURN OF FUNDS

Any Project Funds, plus any Income, that have not been used for, or committed to, the Project by the End Date, must be returned promptly to the Foundation.

{For Indian for-profit organizations } RETURN OF FUNDS

Any Project Funds, plus any Income, that have not been used for, or committed to, the Project upon expiration or termination of this Agreement, must be returned promptly to the Foundation to the extent consistent with applicable law. If applicable law does not permit such return, then You must transfer such Project Funds to another charitable organization designated or approved by the Foundation for purposes relating to the Project, to the extent consistent with applicable law.

MONITORING, REVIEW, AND AUDIT

N/A if grantee is a government unit or international executive order organization:

The Foundation may monitor and review Your use of the Project Funds, performance of the Project, and compliance with this Agreement, which may include onsite visits to assess Your organization's governance, management and operations, discuss Your program and finances, and review relevant financial and other records and materials. In addition, the Foundation may conduct audits, including onsite audits, at any time during the term of this Agreement, and within four years after Project Funds have been fully spent. Any onsite visit or audit shall be conducted at the Foundation's expense, following prior written notice, during normal business hours, and no more than once

during any 12-month period.

INTERNAL OR THIRD PARTY AUDIT

N/A if grantee is a government unit or international executive order organization:

If during the term of this Agreement You are audited by your internal audit department or by a third party, You will provide the audit report to the Foundation upon request, including the management letter and a detailed plan for remedying any deficiencies observed (“*Remediation Plan*”). The Remediation Plan must include (a) details of actions You will take to correct any deficiencies observed, and (b) target dates for successful completion of the actions to correct the deficiencies.

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You will maintain complete and accurate accounting records and copies of any reports submitted to the Foundation relating to the Project. You will retain such records and reports for 4 years after Project Funds have been fully spent. At the Foundation’s request, You will make such records and reports available to enable the Foundation to monitor and evaluate how Project Funds have been used or committed.

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