Grand Challenges Explorations Round 13 Rules & Guidelines

Proposals due Tuesday, May 6, 2014, 11:30 a.m. U.S. Pacific Daylight Time

I. Overview

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

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. More recently, GCE has expanded to include global development and communications challenges. 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 Grand Challenges Explorations initiative are:

- A short application. Instructions are available online at: http://www.grandchallenges.org/Explorations/Pages/ApplicationInstructions.aspx
- Rapid turnaround time. We will select projects in approximately five months from the proposal submission deadline. All applicants will be notified of the status of their application via e-mail when final decisions are made.
- We review for novel ideas that show great promise. Our review process is blinded and championbased, where reviewers with a track record in identifying innovative ideas select the proposals they find most pioneering - no consensus or peer review is needed.
- 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 <u>innovative</u> 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 are at risk of being automatically removed from consideration.
- ➤ 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 13

Key Dates	Event
March 2014	Application period opens
Tuesday, May 6, 2014, 11:30 a.m.	Application deadline
Pacific Daylight Time	
August 2014	Proposal review completed
November 2014	Selections completed and notifications
	sent

How to Apply

Changes to the Rules and Guidelines will be posted on the <u>Frequently Asked Questions</u> page of the Grand Challenges in Global Health website (<u>www.grandchallenges.org</u>), including any changes to the dates listed above. Please read the current FAQ before submitting any questions or concerns.

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

The Grand Challenges Explorations initiative publishes topics and invites proposals in 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. You must select a topic prior to submitting a proposal. View the detailed topic descriptions and determine which topic best suits your idea. You may change your topic and edit your proposal any time before the application deadline.

If you are an existing user, you can <u>log in to your existing account</u>. New users must create a new account and submit proposals through our <u>online portal</u>.

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. Please describe your project without identifying personal or organizational information and describe potential project partners without using proper names. Proposals that do not adhere to these restrictions may be removed from consideration.

Proposals for Round 13 must be submitted prior to the submission deadline of 11:30 a.m. Pacific Daylight Time on Tuesday, May 6, 2014.

During the application process you will be required to confirm that you have read and understand the Website Terms of Use, Privacy Policy, and Rules and Guidelines Document, 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 Explorations is open to both foreign and domestic non-profit organizations, for-profit companies, international organizations, government agencies and academic institutions. Individuals are not eligible to receive an award as part of the Grand Challenges Explorations initiative from the foundation. Additionally, organizations that are classified as individuals for U.S. tax purposes (including sole proprietorships and some single member limited liability companies) are similarly not eligible to receive an award from the foundation.

Upon registration, applicants must provide information about the tax status of their organization as different terms and conditions may apply. We recommend that you 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. If selected for further due diligence, we 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.

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 (FCRA), 2010. 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 the organization is exempt from such registration requirements. 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 project.

III. Review Process

Review and Handling of Proposals

The review of proposals is a critical element of the Grand Challenges Explorations 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 to Global Health and Development solutions that fall within the context of the Grand Challenges Explorations initiative.

The foundation has put in place policies and procedures exclusive to the Grand Challenges Explorations initiative that are 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 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 writing) with third parties, including external reviewers, key partners and co-funders. The Rules and Guidelines are subject to the foundation's Terms of Use.

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. Excluded responses encompass ideas related to the topic but, for strategic reasons, we are

not funding them in the Grand Challenges Explorations initiative. In addition, we exclude proposals considered incremental advances, appropriate responses that are similar to work in which the foundation is already investing, or avenues of inquiry we deem ill-suited to the Grand Challenges Explorations initiative. Applications excluded during the screening process will be notified that their proposals were declined but will not receive specific feedback.

2. For the second step of the evaluation, reviews are chaired by a foundation program lead. Reviews are conducted by reviewers drawn from the world's leading innovative minds. These reviewers do not necessarily have deep domain expertise for the full range of topics and your proposal should be drafted accordingly. Unlike most scientific funding programs, individual reviewers are empowered to make funding decisions about a portion of the portfolio, without consensus on selections. Proposals are sent to reviewers without any 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. While the first three steps of the review are largely blind to the institution and investigator, this due diligence review ensures that the investigator and institution have the basic capacity to receive the award and perform the work described. 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 conflicts of interest.

IV. Key Elements of GCE Phase I Agreements

Two sets of detailed sample Agreements provisions, one for non-profit organizations and one for for-profit organizations can be found in the Appendix at the end of this document. The provisions of the Agreements have been developed specifically for the Grand Challenges Explorations initiative <u>and are not negotiable</u>. 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 a very limited amount of time 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. 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 grantees, funds will be disbursed upon the foundation's receipt of a fully executed agreement. The foundation will not pay funds to a for-profit entity until the foundation has received and approved the entity's invoiced expenditures. Specific invoicing instructions for for-profit entities will be provided at the time of the award.

- 3. No awardee is permitted to make sub-grants, but all awardees will be permitted to contract out for services, up to a maximum of \$49,999 USD. Phase II projects are not subject to these limitations.
- 4. All awardees are entitled to purchase equipment, provided that each item is less than \$5,000 USD. Phase II projects are not subject to this equipment limitation.
- 5. 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. Please see the Sample Agreements (located in the Appendix of this document) for the definition of indirect costs. Phase II projects follow the foundation's normal guidelines for indirect costs.
- 6. Certain non-US awardees are subject to restrictions on the amount of funds they may use for expenditures in the US. Phase II projects are not subject to this limitation.
- 7. Phase I 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.
- 8. 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" as that term is defined in the Agreements) in a manner that ensures "Global Access." Please see the Global Access Section of the Sample Agreements included in the Appendix for more information about these obligations.

Additional details can be found in the two detailed sample Agreements provisions, one for non-profit organizations and one for for-profit organizations included in the Appendix. Please note that the Agreement and specific provisions of the Agreements that apply to a project depends on the tax status of each organization. We strongly encourage you to share the Sample Agreements with the appropriate entity within your organization such as your grants and contracts department, legal department or office of sponsored research to ensure that your organization can accept its terms.

V. Phase I Reporting

All Grand Challenges Explorations 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 Sample 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.

VI. Phase II Grand Challenges Explorations Awards

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

VII. Privacy Notice and Terms of Use

Our full privacy policy and terms of use are located at www.grandchallenges.org/about/Pages/TermsofUse.aspx

Representation: By providing any submission materials, the sender represents to the Bill & Melinda Gates Foundation that they have the right to provide the information submitted.

Applicants with questions concerning the contents of their submission materials may contact the Bill & Melinda

Gates Foundation at: GCEhelp@gatesfoundation.org.

VIII. Frequently Asked Questions

Answers to many application questions can be found on the <u>Frequently Asked Questions</u> section of our website at <u>www.grandchallenges.org</u>.

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

Grand Challenges Explorations initiatives awards are conditional upon a successfully executed agreement and offers are only valid until the date indicated by the Grants and Contracts Management team. Agreements received after the given 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 13 GCE Phase I projects is November 1, 2014.

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

THIS AGREEMENT is between <<>> ("<<>>" or "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." As a condition of this grant, the Parties enter into this Agreement by having their authorized representatives sign the Agreement.

GRANT AGREEMENT

GRANT AMOUNT AND REPORTING & PAYMENT SCHEDULE

GRANT AMOUNT

The Foundation will pay You a one-time amount of \$100,000.

PAYMENTS

The Foundation will disburse the grant funds to you via check or wire transfer within ten business days of receipt of the countersigned Agreement.

REPORTING

You will submit a final Financial and Scientific Report using the Foundation's template or form, which the Foundation will make available to You and which may be modified from time to time. You will submit Your final Financial and Scientific Report via email to the Program Coordinator no later than December 15, 2015

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

The Foundation is awarding You this grant to carry out the project described in the Proposal Narrative (the, "*Project*") in order to further the Charitable Purpose.

EVALUATION

You agree to notify the Foundation and provide copies of any reports or findings if You conduct or commission any research or evaluation regarding the Project. If You are selected to participate in Foundation-funded research or evaluation related to the Project, You agree to: (a) designate a primary point of contact; (b) cooperate with the Foundation's evaluation partner as reasonably required to implement an evaluation plan; (c) provide or facilitate the collection of data as reasonably required; and (d) permit dissemination of resulting reports or findings.

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. 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 Grant Funds (collectively, "Income"). Any Income must be used for the Project.

Include for ER Grantees: SEGREGATION OF FUNDS

You must maintain Grant Funds in a physically separate bank account or a separate bookkeeping account maintained as part of Your financial records and dedicated to the Project.

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.

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

For the purpose of achieving Global Access, You will seek prompt publication of any Funded Developments consisting of data and results in a peer-reviewed journal, treatise, or trade publication, as applicable. Such 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 the charitable purpose of this Agreement. You will also use good faith efforts to ensure that Your subgrantees, subcontractors, agents, and affiliates, as applicable, likewise seek prompt publication of any Funded Developments consisting of data and results.

SUBGRANTS AND SUBCONTRACTS

SUBGRANTS AND SUBCONTRACTS

You have the exclusive right to select subcontractors to assist with the Project. The aggregate amount of Grant Funds paid to subcontractors may not exceed \$49,999. You acknowledge that the Foundation has not and will not earmark the use of any Grant 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 or related to parties on the List of Specially Designated Nationals (www.treasury.gov/sdn); or (c) with or related to countries against which the U.S. maintains a comprehensive embargo (currently, Cuba, Iran, (North) Sudan, Syria, and North Korea), 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.

Include for Indian Grantees: FCRA COMPLIANCE

For an organization has <u>not</u> 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.

For an 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.

POLITICAL ACTIVITY AND ADVOCACY

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 may not use Grant 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 Grant 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.

REGULATED ACTIVITIES

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.

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 RESEARCH

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.

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. The Foundation expects that grantees pursuing similar grand challenges and overarching goals will communicate and collaborate on a periodic basis in achieving progress towards these solutions. The Foundation may identify to You the other entities with which you should consider collaboration.

PUBLICITY BY YOU

You must obtain the Foundation's prior written approval before: (a) issuing a press release or other public announcement regarding the award of this grant; and (b) any other public use of the Foundation's name or mark. For any subsequent press releases or other public announcements directly related to the award of this grant, please email Your request to Grantee Communications two weeks in advance to provide the Foundation an opportunity to review and comment.

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.

OTHER

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 rights of any third party.

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.

TERM AND TERMINATION

TERM

This Agreement commences on the Start Date and continues until the End Date.

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; or (d) You fail to comply with this Agreement.

RETURN OF FUNDS

Any Grant 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.

Include for Indian Grantees: if FCRA Registration Required: Any Grant 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 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 related to the Project, to the extent consistent with applicable law.

RECORD KEEPING

You will maintain adequate accounting records and copies of any reports submitted to the Foundation related to the Project. You will retain such records and reports for 4 years after Grant Funds are fully spent and will make

such records and reports available to enable the Foundation to monitor and evaluate how Grant Funds have been used.

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 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

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.

III. Sample Agreement for For-Profit Organization

PROJECT AGREEMENT

THIS AGREEMENT is between <<>> ("<<>>" or "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 the Agreement.

PAYMENT AND REPORTING

MAXIMUM AMOUNT

The Foundation will pay You up to \$100,000 pursuant to the terms described in the Invoicing Section, below.

REPORTING

You will submit a final Financial and Scientific Report using the Foundation's template or form, which the Foundation will make available to You and which may be modified from time to time. You will submit Your final Financial and Scientific Report via email to the Program Coordinator no later than December 15, 2015.

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

INVOICING

You will be paid in arrears for work performed under the terms of this Agreement. You will invoice the Foundation every three to six months. All invoices shall be sent to the Grand Challenges Explorations Program Coordinator.

INVOICE DETAIL

Submitted invoices must be accurate, comply with the terms of this Agreement, and include the following information:

- Investment ID
- Investment period
- Enough detail to enable the Foundation to determine the accuracy of the amount(s) requested
- Amount due

PAYMENTS

Except for amounts the Foundation withholds in good faith, the Foundation will pay invoiced amounts within 45 days of receiving an invoice.

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 Narrative ("Project") in order to further the Charitable Purpose.

EVALUATION

You agree to notify the Foundation and provide copies of any reports or findings if You conduct or commission any research or evaluation regarding the Project. If You are selected to participate in Foundation-funded research or evaluation related to the Project, You agree to: (a) designate a primary point of contact; (b) cooperate with the Foundation's evaluation partner as reasonably required to implement an evaluation plan; (c) provide or facilitate the collection of data as reasonably required; and (d) permit dissemination of resulting reports or findings.

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.

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.

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.

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

For the purpose of achieving Global Access, You will seek prompt publication of any Funded Developments consisting of data and results in a peer-reviewed journal, treatise, or trade publication, as applicable. Such 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 the charitable purpose of this Agreement. You will also use good faith efforts to ensure that Your subgrantees, subcontractors, agents, and affiliates, as applicable, likewise seek prompt publication of any Funded Developments consisting of data and results.

SUBGRANTS AND SUBCONTRACTS

SUBGRANTS AND SUBCONTRACTS

You have the exclusive right to select subcontractors to assist with the Project. The aggregate amount of Grant Funds paid to subcontractors may not exceed \$49,999. You acknowledge that the Foundation has not and will not earmark the use of any Grant 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 or related to parties on the List of Specially Designated Nationals (www.treasury.gov/sdn); or (c) with or related to countries against which the U.S. maintains a comprehensive embargo (currently, Cuba, Iran, (North) Sudan, Syria, and North Korea), 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.

FOR INDIAN FOR-PROFITS FCRA COMPLIANCE

By signing this Agreement, You certify that You: (a) are not subject to the Foreign Contribution Regulation Act of 2010 (FCRA) as a result of this Agreement or otherwise; (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 agree to 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.

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.

REGULATED ACTIVITIES

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.

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 RESEARCH

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.

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. The Foundation expects that awardees pursuing similar grand challenges and overarching goals will communicate and collaborate on a periodic basis in achieving progress towards these solutions. The Foundation may identify to you the other entities with which you should consider collaboration.

PUBLICITY BY YOU

You must obtain the Foundation's prior written approval before: (a) issuing a press release or other public announcement regarding the Project or this Agreement; and (b) any other public use of the Foundation's name or mark. For any subsequent press releases or other public announcements directly related to the Project or this Agreement, please email Your request to: Grantee.Comms@gatesfoundation.org two weeks in advance to provide the Foundation an opportunity to review and comment.

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.

OTHER

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 rights of any third party.

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.

TERM AND TERMINATION

TERM

This Agreement commences on the Start Date and continues until the End Date.

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; or (d) You fail to comply with this Agreement.

RETURN OF FUNDS

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

RECORD KEEPING

You will maintain adequate accounting records and copies of any reports submitted to the Foundation related to the Project. You will retain such records and reports for 4 years after Project Funds are fully spent and will make such records and reports available to enable the Foundation to monitor and evaluate how Project Funds have been used.

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 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

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.