

II. Application Instructions

Schedule: Key dates and deadlines for Round 2

Key Dates*	Event
2 September 2008	Account Creation and Application Opens
2 November 2008	Proposal Application deadline
March 2009	Proposal review completed
April 2009	Selection completed
May 2009	Decision published on www.grandchallenges.org

How To Apply

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

Any information submitted by you or on your behalf with respect to the Grand Challenges Explorations Initiative (including your proposal, reports, and any related documentation and communications) will be subject to and handled in accordance with the provisions in the [Privacy Policy](#).

The Grand Challenges Explorations Initiative will publish topics and invite proposals twice a year, in two separate rounds. Each round, grant seekers must select only one of the topics under which to submit and may submit only one proposal - submit your best idea. You may submit multiple ideas in partnership with collaborators, but an individual PI 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 log in your account. All new users please create an account, select your topic, and upload your proposal.

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 2 pages in length. References to academic publications are not required and, if included, must fall within the 2 page limit. Please do not include a cover sheet with your proposal. A cover sheet will be automatically generated from your registration data. **No personal or organizational information should be included in the uploaded application.** The review and evaluation of your application is not based on your past history or institutional capabilities. Proposals that do not adhere to these restrictions may be blocked from submission and will not be reviewed

Proposals for Round 2 must be submitted prior to the submission deadline on November 2, 2008.

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.

Upon registration, applicants must provide information about the tax status of their organization as different grant terms and conditions may apply.

In addition, during the application process we will require you to answer the following questions:

1. *To help us better understand the potential scope of activity in this area of research, and to possibly assist you in building necessary relationships with other organizations, please identify any third party that owns intellectual property encompassing or related to the intended health product, technology, or approach that is the focus of this proposed project. We anticipate that you will identify any known third parties based*

only on your current knowledge. We do not require that you conduct any type of inquiry into the intellectual property rights of third parties.

2. *Do you authorize the foundation to communicate with you on topics that we think might be of interest to you (for example, sharing with you future opportunities for funding)"?*
3. *Confirm that you have read and understand the [Website Terms and Conditions](#), [Privacy Policy](#), and Rules and Guidelines Document, and acknowledge that any information submitted on their behalf with respect to the Grand Challenges Explorations Initiative (including your proposal, reports, and any related documentation and communications) will be subject to and handled in accordance with such provisions.*

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 of the initiative, we will advertise a set of challenges carefully defined to elicit innovative responses to critical barriers to health solutions that fall within the context of the Grand Challenges in Global Health.

All data and proposal information uploaded through the submission site will be considered sensitive and protected from public view. The goal of the review is to filter and harness creative ideas. Proposals will not be compared to each other directly. Proposals will be sent to reviewers without personal or organizational information.

Due to the large number of proposals anticipated, applicants for 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 will be executed in four steps:

1. The first step will consist of screening submissions by staff to address whether the proposal addresses the key needs described in the topic. We will screen for completely unrelated responses as well as specifically excluded related responses outlined in the topic description. These excluded responses encompass ideas related to the topic but for strategic reasons, we would not plan to fund under this initiative. In addition we will exclude proposals consider as incremental advances, appropriate responses that are similar to work the Global Health Program is already investing in, or avenues of inquiry we deem ill suited to the Grand Challenges Explorations grant structure. Our approach to this screening process will be strongly biased to include any proposals for which there exists any doubt for further evaluation. Applications excluded during the screening process will be notified that their proposals were declined.
2. For the second step of the evaluation, reviews will be chaired by the President of the Global Health Program, with reviewers drawn from the world's leading innovative minds, who do not necessarily have deep domain expertise for the full range of topics. Unlike most scientific funding programs, individual reviewers are empowered to make funding decisions without panel consensus on selections. Proposals will be sent to reviewers without any personal or organizational information.

In order of importance, the criteria for these reviews are:

- **Topic Responsiveness** – 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 GCE award and if successful, would it be sufficient to show a clear path to further support?

As part of this step in the review we may choose to create one or more small pools of proposals based on a discipline, sector or geography where we have insufficient response to ensure a balanced portfolio of investments.

3. The third step will be a validation and final selection by an Executive Committee of the proposals initially selected by reviewers in the second step of the evaluation. The Executive Committee will be chaired by the Director of Global Health Discovery, Global Health.
4. The fourth and final step will be a due diligence review to ensure that the potential grantee is an appropriate recipient of foundation funding. While the first three steps of the review will largely be blind to the institution and investigator, the due diligence review will ensure that the investigator and institution have the basic capacity to receive the grant and perform the work described. Individuals with successful projects will be contacted at this point. Investigators with unsuccessful projects will receive notice that their project was not selected. **Due to the large volume of proposals we will not be able to give specific feedback as to why an individual proposal was not selected.**

Phase II Review Process

A final report will be prepared by the grantee to be submitted at the completion of their Phase I project. Phase I awardees will be invited to submit a proposal for continued activities in Phase II. Ideally, we will have the reviewers who had originally championed the Phase I selection of the proposal, review the Phase II application. A more detailed description of the Phase I reporting and Phase II proposal process will be provided at the time of award.

Management of Conflict of Interest

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

IV. Key Elements of GCE Phase I Grant Terms and Conditions

The detailed Sample Grant Terms and Conditions can be found in the Appendix at the end of this document. These Terms and Conditions have been developed specifically for the Grand Challenges Explorations initiative and are not negotiable. You are advised to ensure that your institution can accept these Terms and Conditions at the time of proposal submission. If your proposal is selected, you will be provided 30 days post notification of award to accept the grant and return the award letter with an appropriate institutional signature.

1. The term of the Phase I grants expires 12 months from the date of the offer of award. The grant award will be \$100,000 USD. A single 6 month no-cost extension can be requested.
2. The grant award offer is only valid for 30 days – the applicant must return a fully executed Grant Agreement to the foundation within this time to receive a GCE Phase I grant award.
3. For non-profit grantees, funds will be disbursed upon return of a fully executed Grant Agreement to the foundation. For-profit grantees must submit quarterly invoices of expenditures in order to receive disbursement of funds. Specific instructions for invoicing for for-profit grantees will be provided at the time of the award.
4. An annual meeting of GCE grantees will be hosted by the foundation. Additional funds will be provided to support up to two investigators from the project to participate in the annual meeting.
5. No grantee will be permitted to make subgrants, but all grantees will be permitted to contract out for services, up to a maximum of one-third (1/3) of the grant funds (\$33,000 USD). Phase II grants will not have this limitation.

6. All grantees will be entitled to purchase equipment, provided that each item must be \leq \$5,000 USD and that the aggregate purchases cannot exceed 1/4 of the grant funds (\$25,000 USD). Phase II grants will not have this limitation.
7. The funds may be used to cover the full direct costs of the project, but no grantee will be entitled to use grant funds to cover indirect costs. Please see sample Terms and Conditions for the definition of indirect costs. Phase II grants will follow the foundation's normal guidelines for indirect costs.
8. Non-US grantees will not be allowed to use grant funds for US expenditures. Note that items such as equipment, reagents, or other consumable purchased from US-based distributors are not subject to this restriction. However, using grant funds to travel to or from the United States is subject to this restriction. Phase II grants will not have this limitation.
9. Grant funds may be used for human subjects research (including, but not limited to, the use of any human tissue samples or the conduct of human clinical trials), but grantees must have all appropriate approvals, assurances and certifications (including, but not limited to, IRB approvals) on the date the Grant Agreement is fully executed. Grantees do not need to have all required Approvals in place at the time of application, however they must receive them as of the date the Grant Agreement is fully executed
10. The grantee must agree, to the extent it is within their reasonable control, to conduct and manage support of the research, product development and innovations funded by this grant in a manner that facilitates the achievement of the Global Access Objectives with respect to knowledge, intellectual property, and products arising from the research. Please see paragraph V of the Terms and Conditions in the Appendix describing the Global Access Objectives.

Additional details with regard to the Grant Terms can be found in the Sample Terms and Conditions provided as an appendix to this document. Please note that the specific set of Sample Terms and Conditions that would apply to the grant is dependent on the tax status of the grantee organization.

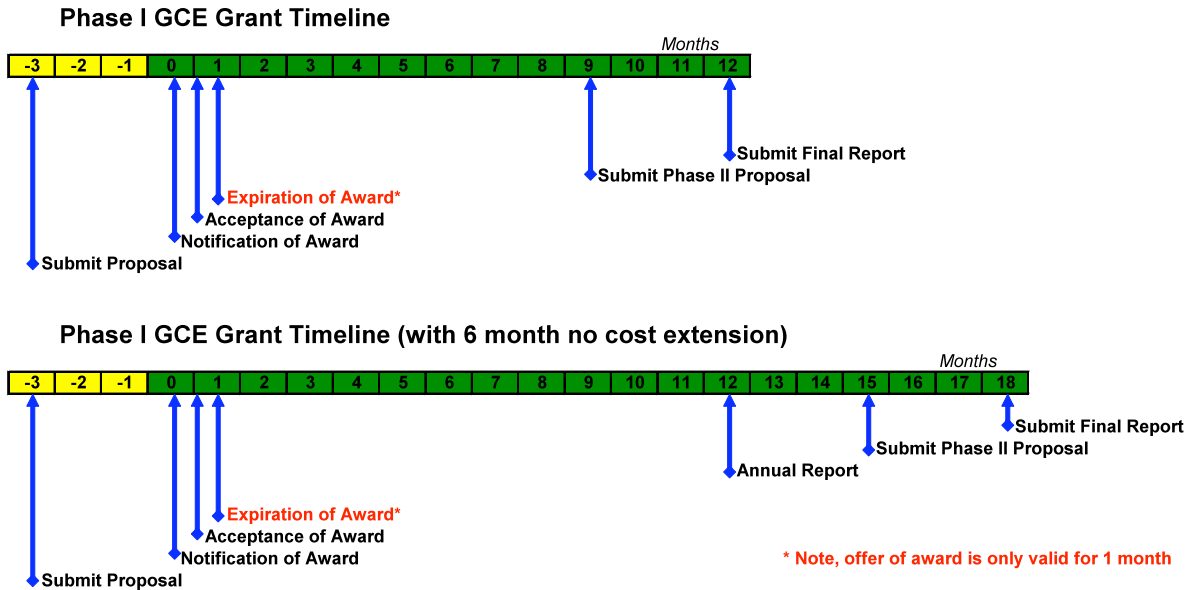
V. Phase I Reporting

A final Financial and Scientific Progress Report will be prepared by the grantee. This report is due at the completion of the term of the award. The report is to be submitted electronically and should be a cumulative, stand-alone document that describes the work proposed in the grant award. The scientific section of the report must include any technical data gathered, models developed, and summary conclusions. This financial section of the report should include an account of the funds expended. Detailed instructions for the reporting format, including the format for the optional Phase II proposal will be provided at the time of award. If a 6 month no-cost extension is granted, the grantee must submit an additional Interim Financial and Scientific Progress Report no later than 12 months from the date of grant award offer in addition to the Final Financial and Scientific Progress Report.

VI. Phase II Grand Challenges Explorations Initiative Awards

During the Phase I grant period, the grantee may compete for Phase II awards of \$1,000,000 USD. Phase II grants will have a term of two years. Only Phase I grantees will be eligible to compete for Phase II awards. To be considered for a Phase II award, the grantee must submit a Phase II application no later than nine (9) months from the date of grant award offer. If a 6 month no-cost extension is granted, then the grantee may submit the Phase II application no later than fifteen (15) months from the date of grant award offer. Additional details regarding the Phase II grants will be provided to Phase I grantees at the time of award.

The timing for submission of reports and Phase II proposals is displayed below:



VII. Privacy Notice and Terms of Use

Our full privacy policy and terms of use is located at <http://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: GCExplorations@gatesfoundation.org

VIII. Frequently Asked Questions

Changes to this document will be made displayed as [Frequently Asked Questions](#) at www.grandchallenges.org. Please refer to these [Frequently Asked Questions](#) regularly, as they may impact the structure of program.

IX. Inquiries

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

Under exceptional circumstances, we will consider accepting submissions from those unable to use the online tool. To discuss this option please call 1-800 5555 4423 and for callers within the United States 866 940 4423 for further instructions. Note: this is not a direct line but a voice mail message service – we will return calls to this line if you indicate that you are unable to submit via the online tool. Alternatively, you may submit an application via mail to:

Bill and Melinda Gates Foundation
GCE Applications
PO Box 23350
Seattle, Washington 98102

Note: This option is ONLY for those unable to use the online tool.

Appendix

Sample Grand Challenges Explorations Terms and Conditions

I. Organizational Eligibility and Use of Funds

Tax-Exempt Status. The Foundation will make grants in reliance on the correct representation in your grant application as to the tax status of your organization. You must indicate which of the following descriptions applies to your organization.

The organization is:

- Exempt from United States Federal income tax under section 501(c)(3) of the United States Internal Revenue Code of 1986 (the “Code”) and not a private foundation;
- A United States government unit described in section 170(c)(1) of the Code;
- A foreign government or an agency or instrumentality of a foreign government that has provided to the Foundation a Foreign Government Affidavit;
- A foreign (non-U.S.) non-profit charitable organization that has provided to the Foundation, prior to the execution of the Grant Agreement, a completed Foreign Public Charity Equivalency Affidavit sufficient to allow the Foundation to make a good faith determination that your organization is described in section 501(c)(3) of the Code and not a private foundation;
- Not a tax-exempt organization under the U.S. Internal Revenue Code of 1986 or a private foundation under such U.S. tax law. As a result, the Foundation is required to exercise expenditure responsibility with respect to this grant. As a condition to receipt of the grant funds, you agree to take all actions necessary to facilitate the Foundation’s compliance with its expenditure responsibility obligations.

Use of Grant Funds. The use of the grant funds must be restricted solely to the purposes of the Project described in the Proposal. Grant funds may not be used: (a) for any purpose other than the Project; (b) to carry on propaganda or otherwise attempt to influence legislation; (c) to influence the outcome of any public election or to carry on, directly or indirectly, any voter registration drive; (d) to make a subgrant to any individual or to any other organization; or (e) for any purpose other than charitable, scientific, literary or educational purposes. Any portion of the grant funds unexpended or uncommitted at the end of the grant period must be promptly returned to the Foundation.

FOR NON-U.S. GRANTEES: All payments will be made in US dollars and will not be adjusted to reflect currency fluctuations. Grant funds may not be used to support activities in the United States, including travel to or from the United States.

Limitations on Capital Assets. You may use the grant funds to purchase capital assets such as equipment so long as (1) the assets are used exclusively for the Project during the term of the grant; (2) the cost of any single capital item does not exceed US\$5,000; and (3) the aggregate amount of Foundation grant funds used to purchase capital assets does not exceed one-quarter (1/4) of the total grant funds (US\$25,000).

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.

Anti-Terrorism. You acknowledge that you are familiar with the U.S. Executive Orders and laws that prohibit the provision of resources and support to individuals and organizations associated with terrorism and the terrorist related

lists promulgated by the U.S. Government. You will use reasonable efforts to ensure that you do not support or promote violence, terrorist activity or related training, or money laundering.

II. Compliance and Indemnification

Compliance By All Parties. As the grantee for the Project, you agree that (1) all agreements with subcontractors to which you pay Foundation grant funds will be consistent with the terms and conditions of the Grant Agreement; and (2) all subcontractors to which you pay Foundation grant funds shall be in compliance with the terms of the Grant Agreement (including but not limited to all limitations on the use of grant funds). You also agree that any activities by the Foundation in association with the Project or the Proposal will not modify the provisions of the Grant Agreement or constitute the basis for any claim by you against the Foundation. You warrant that you have or will obtain all necessary regulatory and governmental licenses required to pursue the Project.

Conflict of Interest. You represent that you and any subcontractors selected by you to participate in the Project shall have in place and agree to comply with a conflict of interest policy, and that such policy complies with all relevant regulatory and legal requirements.

Indemnification. You agree to indemnify, defend and hold harmless the Foundation from and against any and all liability, loss, and expense (including reasonable attorneys' fees) on claims for injury or damages arising out of or resulting from, or that are alleged to arise out of or result from, the actions or omissions by you or of any of your officers, agents, employees, or subcontractors with respect to the Project; except to the extent that any such liability, loss and/or expense is the result of the Foundation's negligence or willful misconduct. You acknowledge and agree that any activities by the Foundation in association with the Project or the Proposal will not modify or constitute the basis for any claim of waiver by you of the Foundation's rights under this paragraph. Your obligation to indemnify the Foundation shall be limited to the extent that you are afforded sovereign immunity under applicable federal, state or local laws.

III. Research Practice Assurances

Limitations on Human Subjects Research. Grant funds may be used for human subjects research (including, but not limited to, the use of any human tissue samples or the conduct of human clinical trials), but you must have all appropriate approvals, assurances and certifications (including, but not limited to, IRB approvals) as of the date the Grant Agreement is fully executed.

Compliance For All Sites. You agree for each venue in which any part of the Project is conducted, you and your subcontractors shall comply with all laws and regulations applicable to the conduct of the Project (including, but not limited to, any research or other activities that are governed by human subjects, animal welfare, and/or biosafety guidelines, laws or regulations), as well as to comply with and assure and gain timely, appropriate prior approval for all activities subject to regulation and/or other types of required assurances, certifications or legal requirements. All appropriate approvals, assurances and certifications must be obtained no later than the date the Grant Agreement is fully executed. You acknowledge and agree that, as between you and the Foundation, you take and will have full responsibility for all such compliance, both for yourself and all other sites included in the Project, including without limitation those activities conducted through subcontracts.

IV. Payment and Reporting Schedules

Payment. The Foundation will disburse grant funds to tax-exempt organizations under the U.S. Internal Revenue Code of 1986 or a private foundations under such U.S. tax law via check or wire transfer within 10 business days of receipt of the countersigned Grant Agreement.

FOR FOR-PROFIT GRANTEES: Subject to the Foundation's receipt of the countersigned Grant Agreement, the Foundation will disburse grant funds to you via check or wire transfer based on your performance of all obligations under this Grant Agreement, and upon your submission of invoices to the Foundation for any amounts receivable under this Grant Agreement. Invoices shall be submitted quarterly and each shall contain enough detail to enable the Foundation to determine the accuracy of the amount(s) requested. Except for amounts the Foundation withholds

in good faith, the Foundation's payment to you of each properly submitted and correct invoice will be due thirty (30) days after the Foundation receives that invoice. All invoices shall be sent to the Grand Challenges Explorations Program Coordinator at GCECoordinator@gatesfoundation.org.

Reporting. You agree to provide the Foundation with a Final Financial and Scientific Report no later than twelve (12) months from the date of grant award offer. If you wish to be considered for a Grand Challenges Explorations Phase II grant, you agree to provide the Foundation with your Phase II Grant Proposal no later than nine (9) months from the date of grant award offer. You may apply for one 6 month no-cost extension for each of these deadlines, provided that you agree to submit an Interim Financial and Scientific Progress Report no later than 12 months from the date of grant award offer in addition to the Final Financial and Scientific Progress Report. We will email you the Foundation's Reporting Guidelines and template. Your reports should be submitted electronically to the Grand Challenges Explorations Program Coordinator at GCECoordinator@gatesfoundation.org.

Subcontracts. Although you may not subgrant any funds received under the Grant Agreement, you may subcontract with third parties to conduct Project activities, so long as the aggregate amount of Foundation grant funds paid to subcontractors does not exceed one-third (1/3) of the total grant funds (US\$33,000). As the grantee for the Project, your organization has sole responsibility for selection and oversight of any and all subcontractors. The Foundation does not approve the selection of any of your subcontractors, and will not oversee their respective activities. Therefore, no implication should be made to investors, media or the general public that the Foundation supports the activities of any subcontractor. The Foundation requires that you include this stipulation in any agreements with subcontractors you engage to assist with the Project.

FOR FOR-PROFIT GRANTEES: Record Maintenance and Inspection. You agree to maintain (and cause your subcontractors to maintain) adequate technical and financial records to enable the Foundation to easily determine how the grant funds were expended. Such records shall be maintained for at least three years following termination of the Grant Agreement, and will be available for review by the Foundation personnel or our designee upon reasonable notice.

V. Global Access Objectives

You understand and acknowledge that the Foundation is making the grant in furtherance of its charitable purposes, which includes the objectives of ensuring that (a) the knowledge gained during funded projects will be promptly and broadly disseminated to the scientific community, subject to a limited delay to seek intellectual property ("IP") protection if such protection could best facilitate the achievement of the following objective, and (b) the intended product(s) could be made accessible (with respect to cost, quantity and applicability) to the people most in need within the developing countries of the world. The Foundation refers to these as Global Access Objectives. You agree, to the extent it is within your reasonable control, to conduct and manage support of the research, product development and innovations funded by this grant in a manner that facilitates the achievement of the Global Access Objectives. The purpose and intent of this paragraph is to evidence your commitment to manage IP rights created in whole or in part with funding from this grant in a manner that furthers the Global Access Objectives.

VI. Mandatory Participation in Designated Grand Challenge Explorations (GCE) Activities

GCE Initiative Meetings. You agree to participate in the Foundation's annual GCE initiative meeting, and the Foundation will pay certain travel expenses associated with your participation (either as a supplement to the grant funds or otherwise as determined by the Foundation).

Collaboration. 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 will identify to you the other entities with which you should consider collaboration.

VII. Publication

Publication. You agree to prepare data sets and findings resulting from the Project for public presentation on the Grand Challenges for Global Health website (www.grandchallenges.org) as soon as practical following conclusion of the Project, after first evaluating whether there is a need to secure IP rights in order to facilitate the achievement

of the Global Access Objectives. All investigators supported in whole or in part by funds from this grant must be made aware of this obligation, and should be encouraged to publish or otherwise disseminate the Project findings as broadly and promptly as reasonably possible. All publications must include the acknowledgement, "Funded by a grant from the Bill & Melinda Gates Foundation through the Grand Challenges Exploration Initiative".

Grant Announcements; Public Reports and Use of Foundation Name and Logo. The Foundation will include information on this grant in its periodic public reports and may make information about this grant public at any time on its web page and as part of press releases, public reports, speeches, newsletters, and other public documents. If you wish to issue a press release or report announcing this grant, or otherwise use the Foundation's name or logo, please contact the Foundation as outlined in the Grant Agreement at least two weeks before the desired announcement or publication date. You agree to obtain advance approval from the Foundation of the press release and the date of release, or of any other use of the Foundation's name or logo. The Foundation requests an opportunity to review and comment on subsequent press releases or reports that are directly related to the grant.

VIII. Term of Offer

Grant award offers are only valid for 30 days. You must return a fully executed Grant Agreement to the foundation within 30 days of grant offer to receive a GCE Phase I grant award.