

Launching Global Immunology and Immune Sequencing for Epidemic Response (GIISER) Sites in Africa

Rules & Guidelines

Applications due no later than Thursday May 13th, 2021 12:00pm, U.S. Pacific Time

GIISER Project Overview

The emerging SARS-CoV-2 variants of concern (VOC) demonstrate the urgent need for local scientific communities to have the capacity to rapidly detect and evaluate the immunological implications of new variants. The current VOC situation also provides the proving ground for such scientific collaborative infrastructure to inform and impact local and global equitable decision making around vaccines, herd immunity and therapeutics.

Global Immunology and Immune Sequencing for Epidemic Response (GIISER) is envisioned as a collection of geographically distinct sites that can pair their local pathogen sequencing surveillance and clinical epidemiology with local immunological understanding and tools. GIISER sites can connect via standard protocols, bioinformatics pipelines, data sharing guidelines and training opportunities to participate in coordinated international efforts to respond to emerging epidemic threats.

Importantly, the local immunological evaluation provided by GIISER extends to the rapid discovery of novel monoclonal antibodies that are critical tools for probing protein structure, detecting variant proteins, and identifying neutralizing epitopes for vaccine immunogen design. In addition, they may be developed as therapeutics for prevention or treatment of disease. Underlying all aspects of the work is the need for a global collaboration framework which includes rapid sharing of data and information with key international bodies (such as WHO, GISRS, and Africa CDC) and networks to inform an effective, equitable global pandemic response.

GIISER Project Goals

This specific effort aims to increase the in-country capacity for the rapid immunological evaluation of SARS-CoV-2 variants of concern on the African continent. It builds off of the African Pathogen Genomics Institute (PGI) sequencing capabilities ([Tessema et al, Lancet Microbe Oct 2020](#)), local human subjects research (clinical epidemiology), and adds in local virology and immunology expertise to allow in-country scientists to rapidly evaluate new variants for immune escape and cross protection. This data is essential for understanding the impact of new variants on vaccines, diagnostic assays, therapeutics, and natural immunity.

The near-term goals of the GIISER program are 1. Systematic production of data quantifying immune escape and cross protection for variants of local concern/interest and 2. Identification of monoclonal antibodies that specifically recognize and potentially neutralize variants of local concern/interest isolated from convalescent individuals with sequence-confirmed SARS-CoV-2 infections.

A successful GIISER site will leverage existing pathogen sequencing surveillance infrastructure to rapidly identify emerging SARS-CoV-2 variants, obtain sera and blood cells from the appropriate infected individuals with appropriate informed consent, and perform detailed

immunological characterization of sera/plasma (binding and neutralization assays), as well as single cell analytics for monoclonal antibody discovery. This information will be produced and communicated rapidly enough to inform public health decisions and policy makers within the local and international community. Many of these pieces already exist but are currently siloed. Some pieces need technological innovation to be rapid and effective. Other pieces are nascent but training of local scientists by collaborators willing and able to share knowledge and tools will create the necessary capabilities.

A long-term goal is to establish a sustainable, local infrastructure that can be activated to respond to any new emerging pathogen locally and strengthen connections and collaborations between sites and with international decision-making bodies.

Supporting Materials

- 1) [Full RFP – Launching GIIISER Sites in Africa](#)
- 2) [Application Instructions](#)
- 3) [Budget Template and Narrative](#)
- 4) [GIIISER Capacity Table](#)
- 5) [Frequently Asked Questions \(FAQs\)](#)

Application Information

Key dates and deadlines

Key Dates	Event
Tuesday April 20, 2021	Application period opens
Tuesday April 27, 2021 7:00am, US Pacific Time/ 3:00pm West Africa Time	Informational call with topic lead to answer applicant questions about RFP (You will receive a separate invitation to attend—optional)
Thursday May 13, 2021	Application period closes, deadline to submit
Spring/Summer 2021	Target grant start date, announcements made
November 2021	Finalists participate in Grand Challenges Annual Meeting

*Note, any changes to the Key Dates or Events, to include the request for additional information, will be directly communicated to invited applicants.

How to Apply

Please note, applications for this RFP will be accepted by **invitation only** and we will only accept **one proposal per institution**. Changes to the Rules and Guidelines and to the [Frequently Asked Questions \(FAQ\)](#) document will be posted periodically, including any changes to the dates listed above. Please read the current FAQ before submitting any questions or concerns. Your proposal package will consist of:

- (1) Applicant profile and information – completed via our application portal.
- (2) Your Proposal (3 pages maximum) – uploaded as a Microsoft Word® or Adobe® PDF file.

- (3) Budget table and narrative (1 page, see supporting materials for template) - uploaded as a Microsoft Word® or Adobe® PDF file.
- (4) GIISER Site Capacity Table (see supporting materials for template) - This will help address your scope of work outlined in the RFP. It does not count toward the 3-page proposal.

We will consider proposals for awards of up to USD \$300,000 for implementation of up to 24 months. If you are selected to receive a grant, your organization will be required to agree to the terms and conditions governing the grant award.

For detailed information application instructions, please see the Application Instructions document.

Proposals must be submitted prior to the deadline of Thursday May 13, 2021 12:00pm, U.S. Pacific Time

Awards

The funding level for the GIISER Project is **a grant of up to \$300,000 USD, provided to the organization**, with a term of up to twenty-four (24) months. Application budgets should be commensurate with the scope of work proposed and should include direct and indirect costs (subject to the [Bill & Melinda Gates Foundation's indirect cost policy](#)).

Please note:

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

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

Eligibility Criteria

This initiative is open to organizations that have been invited to apply, including non-profit organizations, for-profit companies, government agencies, and academic institutions. Individuals and organizations classified as individuals for U.S. tax purposes are not eligible to receive an award from the foundation as part of this initiative.

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

Please review the include additional instructions regarding specific limitations regarding eligibility for this initiative.

Review Process

Handling of Applications

When submitting materials to the Foundation please keep in mind that because we have a focus on achieving charitable outcomes, we view information that we obtain through our grantmaking as a public good. Subject to the [Foundation's Privacy Policy](#), the Foundation may also share information you provide to us (either orally or in writing) with third parties, including external reviewers, consultants, contingent workers, key partners and co-funders. You should assume that nothing will be kept confidential and should not include any information in the proposal, budget, supplemental materials, or reports that you consider proprietary.

Additionally, the foundation is required by the IRS to publish a list of its grants. The foundation also provides general descriptions of its grants on its web sites, in press releases, and in other marketing materials. These Rules and Guidelines are subject to these [Terms of Use](#).

Review of Applications

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

1. The first step consists of screening applications to evaluate whether proposals address the key needs described in the topic. We screen for responses that are completely unrelated or specifically excluded in the topic description. Excluded responses encompass ideas related to the topic but that, for strategic reasons, we are not funding under the Grand Challenges initiative. In addition, we exclude proposals considered incremental advances, appropriate responses that are similar to work in which the foundation or other Grand Challenges programs are already investing, or avenues of inquiry we deem ill-suited to the Grand Challenges initiative. Applicants with proposals removed from consideration during the screening process will be notified that their proposals were declined but will not receive specific feedback.
2. In the second step, reviews are chaired or co-chaired by technical leads from the foundation and, in some cases, other funding partners and are conducted by reviewers both outside and within the foundation. Reviewers are selected from the world's leading researchers and comprise both experts in the topic area and experts in complementary areas. Not all reviewers have deep expertise in the topic; please consider this information when drafting your proposal.

The criteria considered in these reviews are:

- Potential to lead to solutions with substantial impact related to the specific topic.
- Scientific and technical excellence & innovation, including:
 - creativity of the project's approach and clear differentiation from existing approaches
 - a clear and rigorous conceptual framework for the activities
- Project Plan, including:
 - investigator and organization capabilities and potential for collaboration
 - value in terms of appropriateness of the budget and timeline relative to project complexity, risk, and potential impact
- Applicant's capability to execute the work, and the appropriateness of the budget request.

3. The third step is the validation and final selection of the proposals to be funded by the Executive Committee. The Executive Committee may recommend the proposal be funded, subject to specific modifications which will be negotiated as part of the award process.
4. The fourth and final step is a due diligence review and to directly discuss and negotiate any adjustments to the proposed project recommended by the Executive Committee. Investigators will be contacted as part of the due diligence review.

Management of Conflict of Interest

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

Eligibility and Notifications

A. Allowable Costs

Grant funds may be used for the following costs: personnel, necessary travel, supplies, contracted services, sub-grants, and consultants. Partial or full support for equipment may be requested subject to the circumstances described below. Please provide budget estimates according to these categories. The foundation provides a limited amount of indirect costs based on the nature of the applicant organization.

B. Privacy Notice

To help foundation staff in their evaluation and analysis of projects, all documents, communications and associated materials submitted to the foundation (collectively, "Submission Materials") will become the property of the foundation and may be subject to external review by independent subject matter experts in addition to analysis by foundation employees, contingent workers and/or consultants. Please consider carefully the information included in the Submission Materials. If you have any doubt about whether to disclose confidential or proprietary information, the foundation recommends you consult with your legal counsel. You may wish to consider whether such information is critical for evaluating the submission, and whether more general, non-confidential information may be adequate as an alternative for these purposes. We respect confidential information we receive. Nonetheless, notwithstanding your characterization of any information as being confidential, the foundation may disclose all information contained in Submission Materials to the extent it determines is necessary to evaluate them and the manner and scope of potential funding and as may be required by law.

C. Disclaimer

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

D. Release and Verification

In exchange for the opportunity to be considered for a grant, contract or program-related investment (PRI) (per the relevant challenge call), the applicant agrees that the foundation may, in its sole discretion: (1) amend or cancel any challenge calls, in whole or in part, at any time; (2) extend the deadline for submitting responses; (3) determine whether a

response does or does not substantially comply with the requirements of the challenge call and/or these Rules & Guidelines; (4) waive any minor irregularity, informality or nonconformance with the provisions or procedures of the challenge call and/or these Rules & Guidelines; (5) issue multiple awards; (6) share responses generated by the challenge call and/or these Rules & Guidelines with foundation staff, consultants, contingent workers, subject matter experts, and potential co-funders; and (7) copy the responses.

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

E. Warranty

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

F. Intellectual Property (IP)

Since the output of this program may lead to innovative technologies, techniques and/or products that will result in improved health and development-related products for those in greatest need in the developing world, the successful development of these high priority products may require substantial involvement and support of private sector industries as sub-contractors, and may also involve collaborations with multiple organizations, including academic and/or non-profit research institutions.

It is the intent of this program to support the formation of appropriate public-private partnerships that are essential to meet urgent global health and global development needs. IP rights and the management of IP rights are likely to play an important role in achieving the goals of this program. To this end, the foundation requires that, even at the LOI application stage, all applicants seriously consider their willingness to submit a full proposal in compliance with the foundation's proposal guidelines, a portion of which asks for certain information and intentions regarding intellectual property and global access concerns. Specifically, the foundation requires that you agree to use good faith efforts to conduct and manage the research, technologies, information and innovations involved in the Project in a manner that enables (a) the knowledge and information gained during the Project to be promptly and broadly disseminated, and (b) the intended product(s) to be made available and accessible at an affordable price to people most in need in the developing countries of the world. The foundation refers to this as "Global Access."

As part of the foundation's review and evaluation of each full proposal, due diligence will be conducted with respect to each participant's ability and commitment to manage intellectual property in a manner consistent with the stated scientific and charitable goals of the foundation. Due diligence activities may include inquiry into an applicant's: (1) Freedom to operate (FTO) and ability to freely use and acquire needed background technology; and (2) Commitment to promote the utilization, commercialization, and availability of inventions for public benefit in, or the benefit of, developing countries. In order to facilitate this due diligence process applicants are encouraged to provide information with respect to the items above in their Submission Materials.

Applicants are also expected to make new information and materials known to the research and/or medical communities in a timely manner through publications, web announcements, progress reports to the foundation, and other appropriate mechanisms. These concepts may be discussed at some length with the applicants invited to submit full proposals and will be addressed (to the extent appropriate) within each final grant agreement. The Global Access Strategy, developed in connection with each grant awarded to each applicant who submits a successful proposal, will also include provisions defining these concepts.

G. Compliance with Laws and Other Requirements

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

If the project involves:

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

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

- 3. Indemnification.** If the project involves clinical trials, trials involving human subjects, post-approval studies, field trials involving genetically modified organisms, experimental medicine, or the provision of medical/health services ("Indemnified Activities"), you will indemnify, defend, and hold harmless the foundation and its trustees, employees, and agents ("Indemnified Parties") from and against any and all demands, claims, actions, suits, losses, damages (including property damage, bodily injury, and wrongful death), arbitration and legal proceedings, judgments, settlements, or costs or expenses (including reasonable attorneys' fees and expenses) (collectively, "Claims") arising out of or relating to the acts or omissions, actual or alleged, of you or your employees, subgrantees, subcontractors, contingent workers, agents, and affiliates with respect to the Indemnified Activities. You agree that any activities by the foundation in connection with the project, such as its review or proposal of suggested modifications to the project, will not modify or waive the foundation's rights under this paragraph. An Indemnified

Party may, at its own expense, employ separate counsel to monitor and participate in the defense of any Claim. Your indemnification obligations are limited to the extent permitted or precluded under applicable federal, state or local laws, including federal or state tort claims acts, the Federal Anti-Deficiency Act, state governmental immunity acts, or state constitutions. Nothing in this agreement will constitute an express or implied waiver of your governmental and sovereign immunities, if any.

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

Privacy Notice and Terms of Use

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

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

Frequently Asked Questions

Answers to many application questions can be found on the [Frequently Asked Questions](#) document.

Inquiries

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