Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Institute of Allergy and Infectious Diseases (NIAID)
Funding Opportunity Title	Genomics Centers for Infectious Diseases (U19 Clinical Trial Not Allowed)
Activity Code	U19 Research Program – Cooperative Agreements
Announcement Type	Reissue of RFA-AI-18-004
Related Notices	NOT-OD-22-189 -Implementation Details for the NIH Data Management and Sharing Policy NOT-OD-22-195 -New NIH "FORMS-H" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2023 NOT-OD-22-198 Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023 NOT-OD-23-012 Reminder: FORMS-H Grant Application Forms & Instructions Must be Used for Due Dates On or After January 25, 2023 - New Grant Application Instructions Now Available
Funding Opportunity Announcement (FOA) Number	RFA-AI-23-015
Companion Funding Opportunity	None
Number of Applications	See Section III. 3. Additional Information on Eligibility.
Assistance Listing Number(s)	93.855
Funding Opportunity Purpose	The purpose of this Funding Opportunity Announcement (FOA) is to solicit applications for a Genomic Centers for Infectious Disease (GCID) Program. This renewal initiative will support GCIDs to advance the development and use of innovative genomic and bioinformatics tools with an emphasis on human pathogens and their interactions with the host and microbiome, and to rapidly respond to emerging needs, especially during disease outbreaks. The Program will address basic, translational, and clinically relevant questions in host-pathogen interactions and support the development of genomics-based tools to diagnose, prevent, and treat infectious diseases. In the event of an infectious disease outbreak, the GCIDs will be poised to leverage the expertise and resources within the network to assist in a coordinated research response.

Key Dates

Posted Date	February 24, 2023
Open Date (Earliest Submission Date)	May 02, 2023
Letter of Intent Due Date(s)	30 days prior to the application due date

Application Due Dates			Review and Award Cycles		
New	**Renewal / Resubmission / Revision (as allowed)**	**AIDS**	**Scientific Merit Review**	**Advisory Council Review**	**Earliest Start Date**
June 02, 2023	June 02, 2023	Not Applicable	November 2023	January 2024	April 2024

All applications are due by 5:00 PM local time of applicant organization.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Expiration Date	June 03, 2023
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

It is critical that applicants follow the Multi-Project (M) Instructions in the SF424 (R&R) Application Guide, except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts*). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

   Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons to track your application. Check with your institutional officials regarding availability.

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Section I. Funding Opportunity Description

Purpose

The purpose of this Funding Opportunity Announcement (FOA) is to solicit applications for a Genomic Centers for Infectious Disease (GCID) Program. This renewal initiative will support GCIDs to advance the development and use of innovative genomic and bioinformatics tools with an emphasis on human pathogens and their interactions with the host and microbiome, and to rapidly respond to emerging needs, especially during disease outbreaks. The GCID Program will address basic, translational, and clinically relevant questions in host-pathogen interactions and support the development of genomics-based tools to diagnose, prevent, and treat infectious diseases. In the event of an infectious disease outbreak, the GCIDs will be poised to leverage the expertise and resources within the network to assist in a coordinated research response.

Background

High-throughput genomic and transcriptomic sequencing is frequently used to answer infectious disease questions. For example, genomic sequencing enabled SARS-CoV-2 diagnosis and viral variant detection, and millions of viral genome sequences have been generated and shared publicly during the pandemic. Sequencing was instrumental to advancing our knowledge about SARS-CoV-2 evolution, the development of drug resistance, antibody evasion, and viral transmission during localized outbreaks. Sequencing is also critical for the diagnosis and management of infections, including those caused by antimicrobial-resistant bacteria, fungi, and parasites. It further advances our understanding of pathogen biology, pathogenesis, and interactions with the host, including the microbiome.

The NIAID GCID Program was established in 2004 to apply and promote genomics to address important scientific questions and knowledge gaps in infectious diseases, to increase the number of pathogen genome sequences and gold standards in public databases, and to develop and advance the necessary tools for genomic data analysis. Since then, the GCID Program has made key contributions to technological advances, including the development of improved laboratory protocols, tools, and platforms to effectively process challenging samples. The GCIDs have also been developers and early adopters of novel and emerging approaches, including synthetic biology, microbiome analyses, metagenomics, CRISPR-based approaches, and cloud computing. In addition to technology development, the GCID Program has a long history of supporting NIAID's priority pathogen research and emergency responses, including those to anthrax, influenza, Zika and Ebola virus, and SARS-CoV-2, among others. The GCID are arranged into scientific projects that focus on different pathogens groups (i.e., viruses, bacteria, fungi, and parasites, with the inclusion of their vectors, as applicable) that are supported by a technology and data core to drive innovation in genomics across domains and to ensure rapid sharing of high-quality data. Current projects supported by the GCID Program are listed at https://www.niaid.nih.gov/research/genomic-centers-infectious-diseases.

Although substantial progress in sequencing technologies has resulted in routine use of sequencing in many research, clinical, and public health settings, significant obstacles in both clinical and research settings continue to hinder the broad use of large scale genomics for all infectious diseases, including in the areas of diagnostics, therapeutics, microbial-host interactions, and functional genomics. These obstacles include but are not limited to (1) the still relatively high cost of end-to-end workflows from sample isolation to receiving actionable results, (2) the requirement of expert personnel to perform multi-step laboratory and data analysis workflows, and (3) technological and bioinformatic challenges that limit fast and high-throughput sample processing, data analysis and integration, and the sharing of the large amounts of generated and complex data.

This renewal builds on the GCID Program's rich history and will continue to apply innovative and large-scale genomics technologies and bioinformatics analysis tools to address these challenges. Such efforts will provide state-of-the art technologies and advance our understanding of key areas in infectious diseases, including for epidemic and pandemic threats and emerging pathogens. The renewed Program will also continue to support NIAID's efforts to understand and respond to high-priority, emerging and continuing infectious disease threats.

Research Objectives and Scope

The purpose of the GCID Program is to devise genome-scale methods to develop cutting-edge technologies and critical computational tools; develop methods and protocols to successfully use high-throughput sequencing and genomic technologies to study infectious diseases including host-pathogen-microbiome interactions; and advance genomics in clinical and basic research for different pathogens, including those with more complex genomes, and emerging pathogens during epidemic and pandemic disease outbreaks.

It is expected that embedded in an overall theme, GCID research approaches will develop, use, and improve high-throughput sequencing and related genomic technologies such as transcriptomics and metagenomics of microorganisms, vectors and hosts, and host microbiomes to address knowledge gaps. The approaches should be innovative and provide rapid and cost-efficient production of high-quality sequences. It is further expected that projects will incorporate emerging genomic technologies into all areas of the program. The scope of the research is both basic and translational, and the use of clinical samples already at hand or retrieved through collaborations is encouraged.

Overall themes and research areas could include, but are not limited to:

- Systematic, genomic-scale approaches, including bioinformatic tools and methods that help understand pathogens and gene functions.
- Research to evaluate genomic variations in human pathogens and across the human and animal reservoir genomes to identify genetic associations with observable phenotypes in the pathogen and in the human host.
- Computational tools and metagenomic approaches to better understand microbial populations, communities, their interactions, and common traits across taxa as it relates to infectious diseases.
- New and innovative genomic, transcriptomic, and computational methods to explore and advance genomic epidemiology to understand pathogen and vector evolution, the development of drug resistance, and disease transmission.
- Emerging technologies to explore unknown areas and aspects of pathogen or vector genomes, e.g., non-coding regions, post-transcriptional modifications, areas of hyper-evolution, genome copies, and their role in pathogenesis, transmission, and disease.

Applications including the following types of studies will be considered non-responsive and will not be reviewed:

- Studies that focus exclusively on genomic technology development without using the technology to sequence and characterize human pathogens and/or their interaction with the host.
- Studies that do not have genomic technology development and propose only hypothesis-driven research projects.
- Studies that exclusively focus on the host immune response
- Studies proposing genome editing of human embryonic stem cells.
- Studies/Applications that propose clinical trials
- Studies on HIV or AIDS
- Applications that to not include a Plan for Enhancing Diverse Perspectives (PEDP)
- Applications that do not have all the required components
- Applications with a Technology and Data Cores that does not support all Research Projects
- Applications with an Optional Scientific Core that does not support at minimum 2 Research Projects

Pathogens: Scientific projects can address a wide variety of pathogens and are encouraged to include microorganisms from NIAID's List of Emerging Infectious Diseases and NIAID's recently identified Prototype Pathogens. Projects should propose sequencing of multiple strains and/or isolates of specific species, populations, and/or communities rather than sequencing of individual microorganisms or vectors.

Pandemics, Epidemics, and Outbreak Responses: It is expected that the GCIDs will continue to support epidemic and pandemic infectious disease outbreak responses and emerging infectious diseases by leveraging available expertise and resources. This can be accomplished through Emergency Response or Collaborative Pilot Projects, as outlined under the Administrative Core and Research Projects.

Data and Resource Sharing: A primary objective of the GCID Program is to stimulate rapid progress in infectious disease genomics, with data and resource sharing being an essential part of this process. NIAID expects that all products and data of the GCID Program will become available to the community throughout the duration of the award to enhance reproducibility of research results and secondary use, as appropriate and consistent with achieving the goals of the GCID Program.

Scientific and Fiscal Flexibility (for Emergency Responses only): For Emergency Responses, a GCID has the authority to re-prioritize and re-allocate some resources/funds according to GCID operating policies and procedures proposed in the application and in consultation with NIAID, as long as these changes are within the scope of the award's scientific priorities and the structure and minimum number of components of the GCID are maintained.

GCID Program Components:

The Program shall consist of an Administrative Core; 4 Research Projects each addressing a different pathogen group (viruses, bacteria, fungi, and parasites, including their vectors, as applicable); one Technology and Data Core, and up to 1 Optional Scientific Core. The Technology and Data Core shall support all Research Projects. Applications that do not have the required components are considered incomplete and will be withdrawn.

Administrative Core: Each GCID must include an Administrative Core, headed by the Contact PD/PI, that will be responsible for Center activities, including but not limited to: supervising, managing, coordinating, and monitoring Center progress, activities, milestones and timelines; overseeing the Project Management and Staffing Plan, including scientific and fiscal flexibility considerations; overseeing the Data Management and Sharing Plan; administering and overseeing Collaborative Pilot and Emergency Response Projects and the implementation of the Plan for Enhancing Diverse Perspectives; and communicating with NIAID staff.

Collaborative Pilot Projects (CPPs): This FOA supports Collaborative Pilot Projects for small-scale studies in areas of shared scientific or technological interest between the funded GCIDs, and of benefit to the broader scientific community. The projects will be identified by the Administrative Core with input from the Administrative Core Leader and with NIAID consultation.

Emergency Response Projects (ERPs): This FOA supports Emergency Response Projects to develop critical genomics-based technological tools, methods, and studies that advance our understanding of pathogens during pandemic and epidemic outbreaks. Similar to the CPPs, the projects will be identified by the Administrative Core and its leaders, with NIAID consultation.

Plan for Enhancing Diverse Perspectives (PEDP): This initiative requires a Plan for Enhancing Diverse Perspectives submitted as attachment (see Section IV). The Administrative Core will oversee and ensure implementation of the Center's PEDP.

Technology and Data Core: Each GCID must include a single Technology and Data Core. The Core will support research and development to offer innovative genomic and data technologies as a shared resource to all research projects. The Core synergizes with the Research Projects to 1) develop innovative genome and related sequencing technologies and approaches, including large-scale high-throughput sequencing, transcriptomics and metagenomics; 2) provide data analysis and management capabilities and support, including innovative bioinformatics, computational and data visualization and integration approaches; and 3) efficiently and rapidly disseminate generated data, analysis tools, reagents, and other resources generated to the broader scientific community via open-domain repositories and knowledgebases in adherence to the requirements and timelines described in the NIH Guidelines (https://sharing.nih.gov/).

Optional Scientific Core: Each GCID may include a maximum of 1 Optional Scientific Core to support resources and/or facilities that are essential for the activities of two or more Research Projects, but inclusion of Scientific Cores is not required. Optional Cores must be well justified and provide support to at least 2 Research Projects.

Research Projects: Each application must propose 4 Research Projects, each addressing a different human pathogen group centered around the theme of viruses, bacteria, fungi, and parasites and vectors. Applicants are encouraged to incorporate pathogens in the NIAID priority pathogens list and Prototype Pathogens, as well as microbiome analysis where appropriate and relevant. Research Projects are expected to incorporate state-of-the-art technologies and approaches and use a combination of genomic sequencing, functional genomics, and bioinformatics analyses to understand infectious diseases. It is further expected that during pathogen outbreaks, the relevant research project is prepared to undertake Emergency Response Projects to support NIAID's infectious disease response and to advance knowledge about emerging pathogens.

Programmatic Meetings and Annual Site Visits

An initial Program kick-off and annual programmatic meetings will be held to establish the major roles and function of the Program and to facilitate communication and collaboration among funded GCIDs. The annual meetings will report progress, seek new research directions and ideas, provide opportunity for collaboration, and update NIAID on issues of need. The meetings will be virtual (in years 2, 4, and 5) and in-person (in year 3 in Rockville, MD), and the meeting organization is expected to rotate between each of the GCIDs. NIAID will organize the kick-off and year 3 meetings.

Annual site visits will be used by NIAID program staff to review and discuss progress; problems and obstacles and approaches to overcoming identified problems and obstacles; recommendations for modifications in project timelines, objectives, and research approaches/methodologies based on outcomes to date; and future plans.

Plan for Enhancing Diverse Perspectives (PEDP)

This FOA requires a Plan for Enhancing Diverse Perspectives (PEDP) as part of the application (see further below). Applicants are strongly encouraged to read the FOA instructions carefully and view the available PEDP guidance material. Applications must include a Plan for Enhancing Diverse Perspectives (PEDP) submitted as Other Project Information as an attachment (see Section IV). The PEDP will be assessed as part of the scientific and technical peer review evaluation, as well as considered among programmatic matters with respect to funding decisions.

The GCID Program aims to continue to contribute to the training and development of the next generation of scientists and future leaders in the areas of pathogen genomics, technological development, and bioinformatics to enhance infectious disease and host-pathogen research. As such, the PEDP should also extend to any proposed training goals of the GCID.

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument	Cooperative Agreement: A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, NIH scientific or program staff will assist, guide, coordinate, or participate in project activities. See Section VI.2 for additional information about the substantial involvement for this FOA.
Application Types Allowed	New Renewal The OER Glossary and the SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this FOA.
Clinical Trial?	Not Allowed: Only accepting applications that do not propose clinical trials. Need help determining whether you are doing a clinical trial?
Funds Available and Anticipated Number of Awards	NIAID intends to commit $9.24 million in 2024 to fund 2-3 awards.
Award Budget	Application budgets are not expected to exceed $2.85 million in direct costs per year, which includes up to $50,000 in direct costs for one Collaborative Pilot Project per year. Application budgets need to reflect the actual needs of the proposed project.
Award Project Period	The scope of the proposed project should determine the project period. The maximum period is 5 years.

NIH grants policies as described in the NIH Grants Policy Statement will apply to the applications submitted and awards made from this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Local Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)

Federal Governments

- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.

Foreign components, as defined in the *NIH Grants Policy Statement*, **are** allowed.

Required Registrations

Applicant organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- System for Award Management (SAM) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
  - NATO Commercial and Government Entity (NCAGE) Code – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
  - Unique Entity Identifier (UEI) - A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- eRA Commons - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registration; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov – Applicants must have an active SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from diverse backgrounds, including underrepresented racial and ethnic groups, individuals with disabilities, and women are always encouraged to apply for NIH support. See, Reminder: Notice of NIH's Encouragement of Applications Supporting Individuals from Underrepresented Ethnic and Racial Groups as well as Individuals with Disabilities, NOT-OD-22-019.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

2. Cost Sharing

This FOA does not require cost sharing as defined in the NIH Grants Policy Statement.

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The NIH will not accept duplicate or highly overlapping applications under review at the same time, per 2.3.7.4 Submission of Resubmission Application. This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see 2.3.9.4 Similar, Essentially Identical, or Identical Applications).

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST or an institutional system-to-system solution. A button to apply using ASSIST is available in Part 1 of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the Multi-Project (M) Instructions in the SF424 (R&R) Application Guide, except where instructed in this funding opportunity announcement to do otherwise and where instructions in the Application Guide are directly related to the Grants.gov downloadable forms currently used with most NIH opportunities. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent to:

Mohammed Aiyegbo, Ph.D.
Telephone: 301-761-7106
Email: mohammed.aiyegbo@nih.gov

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits must be followed.

Component	Component Type for Submission	Page Limit	Required/Optional	Minimum	Maximum
Overall	Overall	12	Required	1	1
Admin Core	Admin Core	12	Required	1	1
Technology and Data Core	Core	12	Required	1	1
Scientific Core	FOA Specific	6	Optional	0	1
Project	Project	12	Required	4	4

Instructions for the Submission of Multi-Component Applications

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing a multi-component application.

The application should consist of the following components:

- Overall: required
- Administrative Core: required (maximum 1)
- Technology and Data Core: required (maximum 1)
- Scientific Core: optional (maximum 1)
- Research Projects: required (minimum 4, maximum 4)

Overall Component

When preparing your application, use Component Type 'Overall'.

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions, as noted.

SF424(R&R) Cover (Overall)

Complete entire form.

PHS 398 Cover Page Supplement (Overall)

Note: Human Embryonic Stem Cell lines from other components should be repeated in cell line table in Overall component.

Research & Related Other Project Information (Overall)

Follow standard instructions, with the following additional instructions:

Other Attachments:

Plan for Enhancing Diverse Perspectives (PEDP)

In an "Other Attachment" entitled "Plan for Enhancing Diverse Perspectives," all applicants must include a summary of strategies to advance the scientific and technical merit of the proposed project through expanded inclusivity. The PEDP should provide a holistic and integrated view of how enhancing diverse perspectives is viewed and supported throughout the application and can incorporate elements with relevance to any review criteria (significance, investigator(s), innovation, approach, and environment) as appropriate. Where possible, applicant(s) should align their description with these required elements within the research strategy section. The PEDP will vary depending on the scientific aims, expertise required, the environment and performance site(s), as well as how the project aims are structured. The PEDP may be no more than 1-page in length and should include a timeline and milestones for relevant components that will be considered as part of the review. Examples of items that advance inclusivity in research and may be part of the PEDP can include, but are not limited to:

- Discussion of engagement with different types of institutions and organizations (e.g., research-intensive, undergraduate-focused, minority-serving, community-based).
- Description of any planned partnerships that may enhance geographic and regional diversity.
- Plan to enhance recruiting of women and individuals from groups traditionally under-represented in the biomedical, behavioral, and clinical research workforce.
- Proposed monitoring activities to identify and measure PEDP progress benchmarks.
- Plan to utilize the project infrastructure (i.e., research and structure) to support career-enhancing research opportunities for diverse junior, early- and mid-career researchers.
- Description of any training and/or mentoring opportunities available to encourage participation of students, postdoctoral researchers and co-investigators from diverse backgrounds.
- Plan to develop transdisciplinary collaboration(s) that require unique expertise and/or solicit diverse perspectives to address research question(s).
- Publication plan that enumerates planned manuscripts and proposed lead authorship.
- Outreach and planned engagement activities to enhance recruitment of individuals from diverse groups as research participants including those from under-represented backgrounds.

For further information on the Plan for Enhancing Diverse Perspectives (PEDP), please see https://braininitiative.nih.gov/about/plan-enhancing-diverse-perspectives-pedp.

Project/Performance Site Locations (Overall)

Enter primary site only.

A summary of Project/Performance Sites in the Overall section of the assembled application image in eRA Commons compiled from data collected in the other components will be generated upon submission.

Research and Related Senior/Key Person Profile (Overall)

Include only the Project Director/Principal Investigator (PD/PI) and any multi-PDs/PIs (if applicable to this FOA) for the entire application.

- Within the biosketches describe how the PD(s)/PI(s) have the leadership, scientific, and managerial experience required to develop, manage, and direct a program of this size and complexity, including the time commitment and demonstrated ability to establish and manage collaborations.

A summary of Senior/Key Persons followed by their Biographical Sketches in the Overall section of the assembled application image in eRA Commons will be generated upon submission.

Budget (Overall)

The only budget information included in the Overall component is the Estimated Project Funding section of the SF424 (R&R) Cover.

PEDP implementation costs:

- Applicants may include allowable costs associated with PEDP implementation (as outlined in the Grants Policy Statement section 7).

A budget summary in the Overall section of the assembled application image in eRA Commons compiled from detailed budget data collected in the other components will be generated upon submission.

PHS 398 Research Plan (Overall)

Specific Aims: List in priority order the broad, long-range objectives and goals of the proposed Program. Describe the hypothesis or hypotheses to be tested.

Research Strategy:

- Summarize the overarching theme of the proposed GCID Program, and explain how, in the long-term, the work proposed can address critical gaps, longstanding obstacles, or key biomedical questions in infectious disease research, while highlighting the innovation, significance, and emerging concepts of the proposed research and technology development.
- Describe how the individual projects and cores relate to the overall goals of the GCID and provide a cohesive and synergistic whole that is more beneficial than pursuing each project separately.
- Describe how the GCID will significantly contribute to and advance the infectious disease genomics field for each of the group of organisms selected, including a description of the GCID's goal as it relates to research addressing multiple strains and isolates of specific microbial species, populations, and communities.
- Describe how the GCID applies large-scale sequencing technologies to address important questions in infectious diseases.
- Explain ongoing, planned, and potential future collaborations, nationally and internationally, to conduct basic and clinical research.

Resource Sharing Plan:
Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide.

The following modifications also apply:

- All software developed within the GCID must be released under the Open Source Initiative-approved, non-viral, open-source license. The terms of the software availability should permit others to freely use, modify, and include as components of other software, as well as to commercialize enhancements of the software. Recipients are encouraged to manage and disseminate their source code through an open revision control and source code management system such as GitHub.
- For reagents, investigators are encouraged to consult with NIAID program officers to determine which reagents should be deposited at the BEI Resources Repository or other approved public repositories. Resources and reagents to be shared should be released rapidly and no later than the time of publication or the end of the award, whichever comes first.
- The resources must be disseminated using NIH or NIAID repositories or existing public repositories whenever possible. A list of potential data repositories, including NIAD-specific ones can be found on the NIH Scientific Data Sharing website.

Other Plan(s):

Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing Plan will be attached in the Other Plan(s) attachment in FORMS-H application forms packages. If required, the Data Management and Sharing (DMS) Plan must be provided in the Overall component.

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

- All applicants planning research (funded or conducted in whole or in part by NIH) that results in the generation of scientific data are required to comply with the instructions for the Data Management and Sharing Plan. All applications, regardless of the amount of direct costs requested for any one year, must address a Data Management and Sharing Plan. The Data Management and Sharing (DMS) Plan must be provided in the Overall component.
- Additionally, the plan should address the following data and reagents sharing and release guidelines:
  - For Genomic Data Sharing, all pathogen and vector raw genome or metagenome data generated using sequencing approaches should be submitted to public repositories as rapidly as possible and no later than 45 calendar days after quality control. These data should also include relevant metadata. Full or partial genome and metagenome assemblies and their annotations should be submitted to the appropriate database (e.g., GenBank) either as individual samples or for defined cohorts of samples as rapidly as possible and no later than 45 calendar days after being generated and validated. For infectious disease emergency response research, pathogen genomic information should be released as soon as possible to effectively inform public health and outbreak mitigation responses. GenBank records for genome assemblies and annotation should contain language to acknowledge the funding source in addition to the data generators and sample providers, as applicable.
  - Other data types including expression data, immunological data, proteomic data, other omics data, unpublished primary and secondary data, and models and other digital work products are expected to be released within nine months of generation and validation or upon publication, whichever comes first.

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Overall)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered “Yes” to the question “Are Human Subjects Involved?” on the R&R Other Project Information form, there must be at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or a **Delayed Onset Study** record within the application. The study record(s) must be included in the component(s) where the work is being done, unless the same study spans multiple components. To avoid the creation of duplicate study records, a single study record with sufficient information for all involved components must be included in the Overall component when the same study spans multiple components.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the SF424 (R&R) Application Guide must be followed.

Delayed Onset Study

Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).All instructions in the SF424 (R&R) Application Guide must be followed.

PHS Assignment Request Form (Overall)

All instructions in the SF424 (R&R) Application Guide must be followed.

Administrative Core

When preparing your application, use Component Type 'Admin Core.'

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Administrative Core)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Administrative Core)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Administrative Core)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Administrative Core)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Administrative Core)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Core Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.
- The Administrative Core must be headed by the contact PD/PI of the application. Include details of the experience, expertise, and ability of the Administrative Core Lead and key personnel to manage all aspects of the Core and Program successfully.
- The Administrative Core Lead provides leadership and guidance in fulfilling the objectives of the GCID, is responsible for promoting cross-discipline interactions among all Cores and Research Projects and provides oversight and governance over fiscal and resource management.

Budget (Administrative Core)

Budget forms appropriate for the specific component will be included in the application package.

- Development of Collaborative Pilot Projects: include a maximum of $50,000 direct costs per year (beginning in Year 1) for a maximum of one CRP per year, with each award not to exceed two years
- Include travel funds for the PD(s)/PI(s), Research Project Leaders and Core Leaders, and Project presenters to attend one programmatic meeting, to be held in Year 3 in the Rockville, MD area.
- Include travel funds and per diem costs for the PD(s)/PI(s), Research Project Leaders and Core Leaders to attend the Kick-off Meeting in the Rockville, MD area in Year 1 of the award.
- Funds to support deposition of research reagents such as clones, strains, etc. into existing public repositories to ensure access to these resources to the broad research community.
- Funds to support publications for the Center.
- Include costs associated with training and outreach activities.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Administrative Core)

Specific Aims: List in priority order, the broad, long-range objectives and goals of the proposed Administrative Core.

Research Strategy: Describe plans and procedures for establishing and managing an Administrative Core that provides the organizational capacity for the following:

- Coordinating, supervising, and managing all Center activities.
- Establishing and monitoring overall Center progress including timelines, milestones, and implementation of the PEDP and Data Management and Sharing Plan.
- Assisting Core and Research Project Leaders with administrative aspects of their projects, such as gathering of annual progress reports, and monitoring progress.
- Organizing annual programmatic meetings, site visits, and teleconference calls.
- Developing, designing, establishing, and monitoring Collaborative Pilot and Emergency Response Projects.
- Communicating with other Centers regarding collaboration and coordination of activities and projects.
- Communicating and interacting with NIAID staff.

Management and Staffing Plan

The Management and Staffing plan should include:

- A description of how the organization of the proposed Program and its management structure will form a cohesive Center that provides scientific and administrative oversight of the Research Project and Core(s).
- A description of the structure and roles of the administrative and scientific staff
- A description of how GCID resources will be prioritized, allocated and managed.
- A conflict resolution plan.

Collaborative Pilot Project Plan

The Collaborative Pilot Project Plans should include:

- A description of the process to identify and develop collaborative pilot projects across the GCIDs
- A description of the review process and evaluation criteria that will be used to select the most promising pilot projects for funding
- Plans for managing progress and monitoring the success/productivity of funded pilot projects
- A discussion of how funds associated with each Collaborative Pilot will be managed

Emergency Response Project Plan

The Emergency Response Project Plan would be executed only in the case of a Public Health Emergency that requires a rapid research response. The plan should include:

- A description of the process to identify and develop emergency response projects within the Center.
- A description of the review process and evaluation criteria that will be used to select the most promising emergency response project for funding.
- Plans for managing progress and monitoring the success/productivity of funded emergency response projects.
- A discussion of how funds associated with each emergency response project will be managed.
- A discussion about how funds for Emergency Response Projects, which may be up to 20% of the annual program budget, may be allocated from existing Projects.

Note: The CPP and ERP sections should only include information about the establishment and management of the projects and should not include any CPP or ERP proposed research projects.

Milestones and Timelines

A section of the Administrative Core entitled "Milestones and Timelines" should be provided. The section should include milestones and timelines and a plan describing how they will be met, addressing all Research Project and Core activities.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide.

Appendix:

Only limited items are allowed in the Appendix.Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Administrative Core)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information**form or a **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the SF424 (R&R) Application Guide must be followed

Delayed Onset Study

Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).All instructions in the SF424 (R&R) Application Guide must be followed.

Technology and Data Core

When preparing your application, use Component Type 'Core.'

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Technology and Data Core)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Technology and Data Core)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Technology and Data Core)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Technology and Data Core)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Technology and Data Core)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Core Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.
- Include details about the experience, expertise and ability of the Core Lead and key personnel to manage the Technology and Data Core.

Budget (Technology and Data Core)

Budget forms appropriate for the specific component will be included in the application package.

Note: Investigators can request funds toward data management and sharing in the budget and budget justification sections of their applications as part of the Data Sharing and Management Plan.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Technology and Data Core)

Specific Aims: Describe the broad, long-range objectives and goals of the proposed Technology and Data Core.

Research Strategy: Describe plans and procedures for establishing and effectively managing a Technology and Data Core, including the following:

- Describe how Core activities will contribute to meeting the Center's goals and objectives and explain the rationale for selection of the general methods, technologies, and approaches proposed to accomplish the specific aims of the Center's Research Projects.
- Describe the genomic technologies that will support the Research Projects, including innovative plans to evaluate, develop, and incorporate potential modifications and improvements to existing technologies, platforms, pipelines, and resources to increase efficiency and decrease cost.
- Without duplicating information in the biosketches, highlight the capabilities of the team to meet the goals of the Technology and Data Core.
- Describe how the Core will develop, enhance, establish, and maintain innovative bioinformatics and computational tools for analysis of diverse data sets generated by the Research Projects, and how these resources may benefit the scientific community.
- Describe the process for the management of project data, including the tracking of samples and sequencing activities.
- Describe the processes and systems used for data upload and sharing to ensure public access and sharing per NIH guidelines.
- Describe the development and maintenance of a public website that provides an overview of the Center and its resources that are available to the broad scientific community, including protocols, methods, and reference datasets or reagents.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide.

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Technology and Data Core)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or a **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the SF424 (R&R) Application Guide must be followed

Delayed Onset Study

Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).All instructions in the SF424 (R&R) Application Guide must be followed

Scientific Core (Optional)

When preparing your application, use Component Type 'FOA Specific.'

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Scientific Core)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Scientific Core)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Scientific Core)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Scientific Core)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Scientific Core)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Core Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.
- Include details of experience, expertise, and ability of the Core Lead and key personnel to manage the Scientific Core.

Budget (Scientific Core)

Budget forms appropriate for the specific component will be included in the application package.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Scientific Core)

Specific Aims: List in priority order, the broad, long-range objectives and goals of the proposed Scientific Core.

Research Strategy: Provide details of the services or resources provided by the scientific core to support at least two Research Projects, and how the core is relevant to the primary theme of the application.

- Clarify how the scientific core is not duplicative of other services or facilities provided by the other cores.
- Describe how the proposed core activities will contribute to meeting the Center's goals and objectives.
- For each technology, explain the rationale for selection of the general methods and approaches proposed to accomplish the specific aims.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide.

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Scientific Core)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or a **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the SF424 (R&R) Application Guide must be followed

Delayed Onset Study

Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).All instructions in the SF424 (R&R) Application Guide must be followed

Research Projects

When preparing your application, use Component Type 'Project.'

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Research Projects)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Research Projects)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Research Projects)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Research Projects)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Research Projects)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Project Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.
- The biosketch should describe the Project Leader's relevant expertise in each thematic area.

Budget (Research Projects)

Budget forms appropriate for the specific component will be included in the application package.

Note: Do not budget for costs associated with prospective human sample collection. If samples for the proposed studies are to be provided from an independently funded clinical research project, you may include the following costs: costs for preparation and shipping.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Research Projects)

Specific Aims: Describe the broad objectives and goals of the proposed Research Project. Concisely and realistically describe the hypothesis or hypotheses to be tested. State the Projects' relationship to the Center's goals and how they relate to the other Research Projects and the Cores.

Research Strategy: Preliminary studies for projects should be included as part of the Approach section, and include the following:

- Discussion of relevant knowledge gaps including descriptions of how the research will advance scientific knowledge, technical capabilities, or how it might influence clinical practices.
- The availability of and the rationale for selecting pathogens, samples, methods, and technologies for accomplishing project's aims. As applicable, include descriptions of new methodologies, their advantages, and limitations over existing ones, including alternative approaches.
- A description of the prior research that serves as the key support for the proposed project.
- Discussion about innovative aspects of the research projects, including state-of-the-art genomic technology platforms and bioinformatics analyses tools and pipelines.
- Milestones and timelines for each Research Project that address all research activities and includes data generation, analysis, integration, and timelines for receiving samples from collaborators.
- Highlight of the institutional support, equipment, and other resources that are available to achieve the goals of the project.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide.

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Research Projects)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or a **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the SF424 (R&R) Application Guide must be followed

Delayed Onset Study

Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).All instructions in the SF424 (R&R) Application Guide must be followed.

Foreign Institutions

Foreign (non-U.S.) institutions must follow policies described in the *NIH Grants Policy Statement*, and procedures for foreign institutions described throughout the SF424 (R&R) Application Guide.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

Part I. Overview Information contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday, the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (the online portal to find and apply for grants across all Federal agencies) using ASSIST or other electronic submission systems. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons, NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the *NIH Grants Policy Statement*.

Pre-award costs are allowable only as described in the *NIH Grants Policy Statement*.

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

For information on how your application will be automatically assembled for review and funding consideration after submission go to: http://grants.nih.gov/grants/ElectronicReceipt/files/Electronic_Multi-project_Application_Image_Assembly.pdf.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply – Application Guide. If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) and component Project Leads must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile form**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH.

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

See more tips for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review and responsiveness by NIAID, NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Applications must include a PEDP submitted as Other Project Information as an attachment. Applications that fail to include a PEDP will be considered incomplete and will be withdrawn before review.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the NIH mission are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact - Overall

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the Genomic Center for Infectious Disease to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the Genomic Center proposed)

Scored Review Criteria - Overall

Reviewers will consider each of the review criteria below in the determination of scientific merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the Center address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the Center are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Specific to this FOA:

- Does the GCID and its individual Projects and Core(s) provide a cohesive and synergistic whole?
- Will the GCID significantly contribute to and advance the genomics field for each of the four groups of organisms selected?
- Does the proposed GCID address human pathogens and vectors, including an emphasis on studying multiple strains and isolates of specific microbial species, populations, and communities?
- To what extent do the efforts described in the Plan for Enhancing Diverse Perspectives further the significance of the project?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Specific to this FOA:

- Do the PD(s)/PI(s) demonstrate the ability to develop, manage, and direct a scientific program of this size and complexity, including the time commitment and demonstrated ability to establish and manage collaborations?
- To what extent will the efforts described in the Plan for Enhancing Diverse Perspectives strengthen and enhance the expertise required for the project?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Specific to this FOA:

- To what extent will the efforts described in the Plan for Enhancing Diverse Perspectives meaningfully contribute to innovation?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the Center? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the Center involves human subjects and/or NIH-defined clinical research, are the plans to address:

1) the protection of human subjects from research risks, and
2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

Specific to this FOA:

- Does the GCID apply large-scale sequencing technologies to address important questions in studying infectious diseases with a focus on the pathogen and host?
- Are the plans for implementation of a genomics-focused approach well justified, and will the GCID generate valuable genomic and bioinformatic resources to advance the field?
- Are the plans describing ongoing, planned, and potential future collaborations nationally and internationally to conduct basic and clinical research appropriate?
- Are the timeline and milestones associated with the Plan for Enhancing Diverse Perspectives well-developed and feasible?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Specific to this FOA:

- To what extent will features of the environment described in the Plan for Enhancing Diverse Perspectives (e.g., collaborative arrangements, geographic diversity, institutional support) contribute to the success of the project?

Overall Impact - Research Projects

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the research project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria – Research Projects

Reviewers will consider each of the review criteria below, as appropriate for the individual project, in the determination of merit and will give an overall impact score for each project but will not give separate scores for each criterion.

- Are the experience, level of commitment, and expertise of the Project Leader and key personnel adequate to manage and advance the aims of the Project?
- Does the project address relevant infectious disease knowledge gaps? If the aims are accomplished, will the project advance scientific knowledge, technical capabilities, or influence clinical practice?
- Is the prior research that serves as the key support for the proposed project rigorous?
- Are the proposed pathogens, samples, and technologies available and adequate to address the hypotheses of the Research Project?
- Are alternative approaches and limitations to new methodologies described and reasonable?
- Does the project incorporate innovative aspects and state-of-the art genomic technology platforms and bioinformatics analysis tools and pipelines to study infectious diseases?
- Are the timelines and milestones provided well-justified and appropriate for the scope of the research project?
- Are the institutional support, equipment, and other resources available to the investigators and adequate for the project proposed?

Overall Impact – Individual Cores

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the Core activities to meet the needs of individual Research Projects or other Cores, and to contribute to Center goals and objectives, in consideration of the following points (as applicable to the Core proposed).

Scored Review Criteria – Individual Cores

Reviewers will consider each of the review criteria below, as appropriate for the individual core, in the determination of scientific merit and provide an overall impact score but will not give separate scores for these items.

Administrative Core

- Are the experience, level of commitment, and availability of the Administrative Core Director adequate to manage the overall Center?
- Is the administrative and organizational structure clearly defined and is it appropriate and adequate to coordinate, supervise, and manage activities and accomplish the objectives of the Center?
- Are the proposed milestones, timelines and objectives for the overall Center adequate, including the plans for overseeing the PEDP and Data Management and Sharing Plan?
- Is the Management and Staffing Plan appropriate to facilitate attainment of the objectives of the proposed GCID?
- Are the plans for coordination, problem identification and resolution and the establishment of a strong collaborative environment for the Program appropriate?
- Are plans for organizing programmatic meetings, site visits, and teleconference calls appropriate?
- Are the plans for Collaborative Pilot and Emergency Response Projects adequately described and appropriate?

Technology and Data Core

- Are the experience, level of commitment, and expertise of the Core Leader and key personnel adequate to manage and advance the aims of the Core?
- Will the Core activities contribute to meeting the Center's goals and objectives?
- Is the rationale for selecting methodologies, technologies, and approaches appropriate to support the Research Projects?
- Will the proposed genomic technologies support meeting Research Projects' goals? Will the plans to evaluate, develop, and incorporate potential modifications and improvements to existing technologies, platforms, pipelines, and resources increase efficiency of sequencing and data analysis, and decrease costs?
- Does the Core plan to develop, enhance, establish, and maintain innovative bioinformatics and computational tools to analyze diverse data sets? Will these tools be beneficial to the scientific community?
- Are the described data management activities, including sample tracking and sequencing activities appropriate?
- Are the processes and systems used for data upload and sharing appropriate for ensuring public data access and sharing?
- Is the plan for developing and maintaining a public website appropriate?

Scientific Core

- If present, is the optional Scientific Core justified and relevant to the theme of the overall Center?
- Is adequate justification provided that the Scientific Core will support at least two Research Projects?
- Is provision of resources and core services to the Research Projects critical and justified?
- Are the experience, level of commitment, and expertise of the Core Leader and key personnel adequate to manage the Core?

Additional Review Criteria - Overall, Administrative Cores, And Research Projects

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects.

Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animals Section.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

Not Applicable

Renewals

For Renewals, the committee will consider the progress made in the last funding period.

Revisions

Not Applicable

Additional Review Considerations - Overall, Administrative Cores, And Research Projects

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Applications from Foreign Organizations

Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the Resource Sharing Plan(s) (e.g., Sharing Model Organisms) or the rationale for not sharing the resources, is reasonable.

Authentication of Key Biological and/or Chemical Resources:

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the National Institute of Allergy and Infectious Diseases, in accordance with NIH peer review policy and procedures, using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications will receive a written critique.

Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.

Appeals of initial peer review will not be accepted for applications submitted in response to this FOA

Applications will be assigned to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the National Advisory Allergy and Infectious Diseases Council. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities including the PEDP.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons. Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the NIH Grants Policy Statement.

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the recipient's business official.

Recipients must comply with any funding restrictions described in Section IV.6. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

Institutional Review Board or Independent Ethics Committee Approval: Grantee institutions must ensure that protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the recipient must provide NIH copies of documents related to all major changes in the status of ongoing protocols.

Prior Approval of Collaborative Pilot and Emergency Response Projects

Collaborative pilot and emergency response projects require prior approval by NIH prior to initiation.

For any Collaborative Pilot or Emergency Response Project, the recipient institution will comply with the NIH Guidance on Changes That Involve Human Subjects in Active Awards and That Will Require Prior NIH Approval.

The recipient institution will provide NIH with specific plans for data and safety monitoring, and will notify the IRB and NIH of serious adverse events and unanticipated problems, consistent with NIH Human Subjects Research policies.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement as part of the NoA. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities, including of note, but not limited to:

- Federal wide Research Terms and Conditions
- Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment
- Acknowledgment of Federal Funding

If a recipient is successful and receives a Notice of Award, in accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Should the applicant organization successfully compete for an award, recipients of federal financial assistance (FFA) from HHS will be required to complete an HHS Assurance of Compliance form (HHS 690) in which the recipient agrees, as a term and condition of receiving the grant, to administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, age, sex and disability, and agreeing to comply with federal conscience laws, where applicable. This includes ensuring that entities take meaningful steps to provide meaningful access to persons with limited English proficiency; and ensuring effective communication with persons with disabilities. Where applicable, Title XI and Section 1557 prohibit discrimination on the basis of sexual orientation, and gender identity. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html

HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.htmlandhttps://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see https://www.hhs.gov/civil-rights/for-individuals/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html or call 1-800-368-1019 or TDD 1-800-537-7697.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 and 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships."

Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Part 75 and 2 CFR Part 200, and other DHHS, PHS, and NIH grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the recipients is anticipated during the performance of the activities. Under the cooperative agreement, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the recipients for the project as a whole, although specific tasks and activities may be shared among the recipients and the NIH as defined below.

The PD(s)/PI(s) will have the primary responsibility for:

- Coordinating the Projects and Cores within the overall Program.
- Defining the research objectives, approaches, and details of the projects within the guidelines of the RFA, and retaining primary responsibility for the planning, directing, and executing the proposed scientific activities.
- Organizing, participating, and chairing one of the Annual Programmatic Meetings of all GCIDs funded under this FOA; these meetings will be held in-person once at NIAID in year 3, and virtual in years 2, 4, and 5 of the awards. The organization of the virtual meetings will rotate among the Programs' GCIDs. The programmatic kick-off meeting will be held shortly after award and will be organized by the NIAID Project Scientist in coordination with all funded GCIDs.
- Organizing and chairing annual site visit activities.
- Managing the Collaborative Pilot and Emergency Response Projects as applicable.
- Making sure that the NIAID Data Release Guidelines (see below) are properly implemented by the personnel of the Research Projects and Cores.
- Ensuring that results obtained from the Program are analyzed and published in a timely manner.
- Provide updates at least annually on implementation of the PEDP.

Program Generated Data, Software and Other Resources

Recipients will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and NIH policies.

Program-generated data and software include, for example:

- all research data (both experimentally and computationally generated) and associated metadata.
- database schema and specifications.
- experimental protocols and Standard Operating Procedures (SOPs).
- data analysis tools, models and algorithms generated under this cooperative agreement, including source code, complete use documentation, and tutorials.
- Program-generated novel reagents (e.g., expression vectors, mutant strains, libraries, protein clones), should be made available through NIAID-supported repositories, such as the NIAID BEI Resources (http://www.beiresources.org/) or in other repositories in consultation with the NIAID.

NIH staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

- The role of the NIAID Project Scientist in the cooperative agreement is to support and encourage the recipient's activities by substantial involvement as partners and facilitators in the process without assuming responsibilities that remain with the PDs/PIs. The NIAID Project Scientist will work closely with the PD(s)/PI(s) and other Program member scientists to facilitate collaborations and to leverage the resources available to the Program.
- The NIAID Project Scientist will monitor the progress of the Program, help coordinate research approaches among all GCIDs funded through the FOA and contribute to the shaping of Research Projects or approaches as warranted. The NIAID Project Scientist will support and facilitate this process but will not direct it.
- The NIAID Project Scientist will keep the Program informed about other ongoing studies supported by NIAID to avoid duplication of effort and encourage sharing/collaboration in infectious diseases research. The NIAID Project Scientist will coordinate access for the Program to other NIAID resources, as well as assist the research efforts of the Program by facilitating access to fiscal and intellectual resources provided by industry, private foundations, NIH intramural scientists and other federal government agencies as appropriate.

Additionally, a NIAID program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

Areas of Joint Responsibility include:

The NIAID Project Scientist will provide overall coordination across all funded GCIDs, will coordinate with the PD(s)/PI(s), and will hold regular GCID Program-wide discussions to facilitate the achievement of GCID Program goals. In the event that some members of the GCID Program develop common research interests working groups may be formed to pursue collaborative activities.

In addition, PD(s)/PI(s), Research Project and Core Leaders and the NIAID Project Scientist will discuss potential projects to be funded through the Collaborative Pilot and Emergency Response Project Program.

Bimonthly Teleconferences

These teleconferences will be held to discuss progress, problems, proposed solutions and any matter that is relevant to the scientific and financial administration of the Center and future activities. The schedule for those meetings will be established by the PD(s)/PI(s) and the NIAID Project Scientist.

Dispute Resolution:
Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) between recipients and the NIH may be brought to Dispute Resolution. A Dispute Resolution Panel composed of three members will be convened. It will have three members: a designee of the Steering Committee chosen without NIH staff voting, one NIH designee, and a third designee with expertise in the relevant area who is chosen by the other two; in the case of individual disagreement, the first member may be chosen by the individual recipient. This special dispute resolution procedure does not alter the recipient's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulation 42 CFR Part 50, Subpart D and DHHS regulation 45 CFR Part 16.

3. Data Management and Sharing

Note: The NIH Policy for Data Management and Sharing is effective for due dates on or after January 25, 2023.

Consistent with the NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the NIH Grants Policy Statement. Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described. If additional Data Management and Sharing requirements need to be added, please insert what requirements are desired.

- For Genomic Data Sharing, all pathogen and vector raw genome or metagenome data generated using sequencing approaches should be submitted to public repositories as rapidly as possible and no later than **45 calendar days** after quality control. These data should also include relevant metadata. Full or partial genome and metagenome assemblies and their annotations should be submitted to the appropriate database (e.g., GenBank) either as individual samples or for defined cohorts of samples as rapidly as possible and no later than 45 calendar days after being generated and validated. For infectious disease emergency response research, pathogen genomic data should be released as quickly as possible to effectively inform public health and outbreak mitigation responses. GenBank records for genome assemblies and annotation should contain language to acknowledge the funding source in addition to the data generators and sample providers, as applicable.
- Other data types including expression data, immunological data, proteomic data, other omics data, unpublished primary and secondary data, and models and other digital work products are expected to be released within nine months of generation and validation or upon publication, whichever comes first.

4. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR) annually and financial statements as required in the NIH Grants Policy Statement.

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the NIH Grants Policy Statement. NIH FOAs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 45 CFR Part 75.301 and 2 CFR Part 200.301.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over the threshold. See the NIH Grants Policy Statement for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and 2 CFR Part 200.113 and Appendix XII to 45 CFR Part 75 and 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 and 2 CFR Part 200 – Award Term and Condition for Recipient Integrity and Performance Matters.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)

Finding Help Online: https://www.era.nih.gov/need-help (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)
Email: GrantsInfo@nih.gov (preferred method of contact)
Telephone: 301-637-3015

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov

Scientific/Research Contact(s)

Inka Sastalla, Ph.D.
National Institute for Allergy and Infectious Diseases (NIAID)
Telephone: 301-761-6431
Email: inka.sastalla@mail.nih.gov

Peer Review Contact(s)

Mohammed Aiyegbo, Ph.D.
National Institute for Allergy and Infectious Diseases (NIAID)
Telephone: 301-761-7106
Email: mohammed.aiyegbo@nih.gov

Financial/Grants Management Contact(s)

Annie Grimes
National Institute for Allergy and Infectious Diseases (NIAID)
Telephone: 301-761-7315
Email: Annie.grimes@nih.gov

Section VIII. Other Information

Recently issued trans-NIH policy notices may affect your application submission. A full list of policy notices published by NIH is provided in the NIH Guide for Grants and Contracts. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement.

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75 and 2 CFR Part 200.