Questions and Answers

CDC-RFA-IP22-2203

Tracking the burden, distribution, and impact of Post COVID-19 conditions in diverse populations for children, adolescents, and adults (Track PCC)

Eligibility, Applications, and Funding

What are the deadlines for the application submission for CDC-RFA- IP22-2203, Tracking the burden, distribution, and impact of Post COVID-19 conditions in diverse populations for children, adolescents, and adults (Track PCC) funding opportunity?

This Notice of Funding Opportunity (NOFO) CDC-RFA-IP22-2203 was posted on Grants.gov on January 5, 2022 and will remain open for 60 days.

The CDC has requested that interested candidates submit a letter of intent (LOI). Submission of an LOI is optional, non-binding, and is intended to allow CDC to plan for the number of objective reviewer staff needed. Letter of Intents are due January 24, 2022.

The application due date is March 8, 2022 at 11:59 AM EST.

Can an organization apply for both component A and component B of this funding opportunity?

From the NOFO page 11, an applicant can apply to component A, component B, or both component A and component B. Separate applications are required for each component.

Does the ceiling amount in the NOFO include funding for both direct and indirect cost?

The ceiling amount for each component represents a total funding amount for both direct and indirect cost for the applicant's budget.

What is the page limit for the NOFO application?

As stated in the funding opportunity on page 27, the multi component NOFO may have a maximum of 15 pages, and up to 4 additional page per component for the project narrative section. This page limit is for all areas of the Project Narrative. This includes Background, Approach, Purpose, Outcomes, Strategies/Activities, Collaborations, Target Population/Health disparities, Evaluation and Performance Plan, Organizational Capacity to Implement and the Work Plan (included in the Project Narrative's page limit).

What is the expected period of performance for this NOFO?

The number of years for which federal support has been planned is 60 months (5-year project period) the project period for this NOFO is June 1, 2022, through May 31, 2027. The total

period of performance comprises the initial competitive segment (first 12-month budget period) and subsequent non-competitive continuation award(s) (four additional 12-month budget periods).

General NOFO Questions

Does CDC have any specific geographical areas of the country they are targeting for the cohort population?

The intent of the NOFO is to have cohort populations included from different parts of the country. As indicated on page 36 of the NOFO, applicants' geographical location of surveillance may be taken into consideration to ensure surveillance representation for different areas in the United States.

Which age groups for should be included in the NOFO cohort population?

The target population for this funding opportunity is United States population for children (0-11 years), adolescents (12-17 years) and/or adults (≥18 years).

As stated in the NOFO on page 10, each site applying for component A must demonstrate ability to include two or more of the target age populations and/or two or more populations disproportionately affected by SARS-CoV-2 infections.

For this funding opportunity can an applicant submit more than one Principal Investigator in their application given the population age-range?

Organization must have at least one PI identified on their funding application. It may be reasonable for applicants to list multiple PIs to support the surveillance activities of this project.

Should the workplan in the application include information for the first year of the cooperative agreement or all years of the cooperative agreement?

As stated in the NOFO announcement on page 17, applicants must provide a detailed work plan for the first year of the project and a high-level work plan for subsequent years. Plan should provide detailed timeline including realistic and measurable milestones for the proposed activities and include detailed budget plan that is linked to the activities and milestones.

Will CDC require all Component A sites to use a standard data system for this project?

CDC is not specifying a standard data system that all Component A sites will be required to use. However, we do request that all applicants describe methods for data collection and coordination. As an example, on page 10 for Component A "To describe methods for study-wide coordination. Include plans for development and maintenance of central data system or data base, data management and coordination with sites."

Related to the Component A project, is the cohort of 1,000 people for one of the defined populations of interest (0-11yrs, 12-17yrs, 18+, or some other disproportionately impacted population) or can it be 1,000 people across all or multiple characteristics?

There are a variety of ways to identify the cohort population and to assess the prevalence of post COVID-19 conditions. In the application, the organization should determine how they will identify their proposed population and describe a surveillance design and approach to address the required activities of the NOFO. This includes describing the target source population by age, sex, race/ethnicity, and sociodemographic factors. This should also include describing the surveillance approach details and the ability of the design to provide reliable estimates by these groups.

For this project, is there an expectation that applicants have a comparison or control group for the 1000-person cohort or is having a cohort of people diagnosed with Sars-Cov-2 sufficient?

There is no expectation to have a comparison or control group of persons without evidence of SARS-CoV-2 infection.

Will each Component A award recipient manage their own system, or will that be managed by the Component B Data Coordinating Center?

Each Component A award recipient will be required to describe their methods for data collection and management. Component B, as the coordinating center, will develop study wide central data system or data base or data management. From page 9 of the NOFO, for Component B Advance electronic information/data exchange. Describe methods for study-wide coordination. Include plans for development and maintenance of central data system or data base, data management and coordination with sites. Describe expected work with funded site partners and CDC programs to address data collection processes. Describe readiness/ preparation to coordinate with other sites/recipients on data base development, data management, data sharing, development of data reports, data analysis, and protocol development.

Will CDC require all Component A award recipients to provide data according to a specific standard, or will harmonizing the data be solely the task of the Component B Data Coordinating Center?

CDC, Component A and Component B award recipients will work together to develop a harmonized data collection and analysis approach.

Will Component B award recipient be responsible for tracking specimens collected by Component A award recipient and/or tracking shipment of these specimens to any reference labs?

The Coordinating Center award recipient is expected to be responsible for management of data and will not be expected to be responsible for the collection of or processing of specimens for this NOFO.

For an applicant interested in component B of this project, is enrollment of the 1000 population mean the ability to collect specific samples from patients or is this project a secondary data effort to Track PCC across a population?

Component B is the coordinating center as noted on page 7 of the NOFO, (Coordinating Center provides infrastructure for standardized approaches and analytic methods for consolidate estimates) and is not expected to enroll participants.

From page 11 of the NOFO, each site applying for component A must demonstrate ability to include two or more of the target age populations and/or two or more populations disproportionately affected by SARS-CoV-2 infections. Component B is not included in this expectation.

Can an applicant organization data mine through their electronic health records or use other existing cohorts from their organization to identify the required cohort of 1,000 participant for this surveillance project?

There are a variety of ways to identify the cohort population and to assess the prevalence of post COVID-19 conditions. An organization can use existing cohorts or electronic health records with the understanding that one of the objectives of the NOFO is the on-going monitoring and tracking of incidence and prevalence of post-COVID conditions. In the application, the organization should determine how they will identify their proposed population and describe a surveillance design and approach to address the required activities of the NOFO. This includes describing the target source population by age, sex, race/ethnicity, and sociodemographic factors. This should also include describing the surveillance approach details and the ability of the design to provide reliable estimates by these groups.

Can client/patient follow up care cost such as lab work and x-rays be support by the cooperative agreement funding?

This is non-research surveillance funding opportunity. The intention of the project is track and investigate the burden and impact of post COVID-19 conditions (PCC) through surveillance and long-term follow-up of cohorts with PCC in collaboration with public health, academic, or healthcare partners for follow up of routine clinical care. It is not expected that funding from this project would be routinely used to support follow up care cost.

Is there an expectation for this NOFO that applicants collect additional clinical and biological assessments of cohort participants beyond routine health care?

There is no expectation for additional clinical and biological assessments of the cohort participants beyond routine care. This is non-research surveillance funding opportunity. The

intention of the project is track and investigate the burden and impact of post COVID-19 conditions (PCC) through surveillance and long-term follow-up of cohorts with PCC in collaboration with public health, academic, or healthcare partners for follow up of routine clinical care.

While a definition for a SARS-Cov-2 infection was given (i.e., CSTE definition), there was no guidance on a definition or method for determining long COVID. Is each applicant expected to provide their own definition/method? Will there be a standardized definition/method established among selected sites?

There is a recognition that the standardized definition and method for determining post-COVID conditions is evolving. Applicants are encouraged to reference and use available definitions for post-COVID conditions. It is expected that award recipient for Component A and Component B will work collaboratively to provide consolidated estimates.

Is CDC anticipating looking at a sub-sample of the larger cohort to look at specific PPC outcomes?

Based on reliability of the surveillance estimates submitted by the four surveillance sites, CDC is anticipating looking at sub-samples of the larger cohort. It is expected that submitted data will support samples for specific demographic groups and for specific post COVID-19 conditions and outcomes.

What is the expectation of the applicant to collaborate the state or local health department or community partners to support this project?

There are a variety of approaches applicants could present to meet the requirement of this NOFO. Applicants must provide details in their application that describe access to surveillance data to meet the requirements of the NOFO, their expected collaboration with public health, academic, or healthcare partners, their approach to the surveillance project, and the advantages to their proposed approach.

Is the expectation that surveillance data will be available at the end of Year 1? Or can Year 1 be used to establish infrastructure, methods, and standardization across selected sites?

CDC recognizes that a portion of the time during year 1 of the cooperative agreement will be used to establish infrastructure, data collection methods, and standardized study protocols. As stated on page 11, both Component A and Component B award recipients should include plans for quarterly reports to CDC, including the first year of the study.

On page 15 of the NOFO, performance monitoring, “To ensure that the activities have been implemented as expected and that the intended project period outcomes have been achieved and CDC will keep track of some performance measures to demonstrate the effectiveness and/or to suggest ways to improve the program as follows: % Activities producing preliminary

findings within 3 months of data collection, % Activities producing project report within 3 months of preliminary findings"

It appears that equipment purchase is not allowable through this cooperative agreement for example using a mobile unit to conduct follow up surveillance activities. Is this correct?

Large equipment purchase would not be allowable related to this funding opportunity. The intention of the project is track and investigate the burden and impact of post COVID-19 conditions (PCC) in diverse populations through surveillance and long-term follow-up of cohorts with PCC in collaboration with public health, academic, or healthcare partners.

Our organization works with international partners on other projects. Can we use these our international partners to support this project?

The target population for this funding opportunity is United States population for children (0-11 years), adolescents (12-17 years) and/or adults (≥18 years). It is not clear how work with international partner would support this US population surveillance project.

Related to letter of support, can an applicant submit one collaborative letter of support that is signed by all our partners?

The purpose of letters of support is to include specifics activities that partners support. It is not clear if a summary document will reflect how each partnering organization is working with the applicant organization to support the activities for this NOFO.

Regarding the Workforce Capacity and describing training for investigators on page 9 of the NOFO, would this area be appropriate to involve doctoral or nursing school students to support their area of study?

The intent for the area of the applications is to describe engagement of the applicant organization in training programs. CDC would like to allow for this project to encourage the development of junior investigators and trainees.

There appears to be an emphasis on use and dissemination of the surveillance findings as intermediate outcomes in the logic model. In the NOFO document, there do not appear to be any evaluation/scoring criteria for this for Component A applicants. Where will public health reporting, data dissemination, and use be scored within the application review?

For Component A, these criteria are captured under the evaluation and performance measurement area page 34 of the NOFO.

The extent to which the applicant describes an approach to provide monthly dashboards on study metrics and disseminate results on an on-going basis within 4 months of data collection?

How will applications be reviewed by CDC for responsiveness to the requirement of this NOFO?

It is important that applicants understand the Review and Selection Process as outlined in Section E of the NOFO starting on page 33. This describes the review criteria that will be used by an Objective Review Panel to determine each applicant's responsiveness to the NOFO.

Who can applicants reach out to if there are questions about components of the IP22-2203 NOFO?

Applicants should submit questions via email to Elizabeth Sullivan, Project Officer, for this NOFO. EMB1@CDC.gov