

Notice of Intent to Publish a Research Opportunity Announcement (ROA) for Clinical Trials for the Prevention and/or Treatment of Post-Acute Sequelae of SARS CoV2 infection (PASC)

Related Announcements

The National Institutes of Health (NIH) published several relevant Research Opportunity Announcements (ROAs) in support of its Post-Acute Sequelae of SARS-CoV-2 (PASC) infection Initiative, including OTA-21-015A for the Clinical Science Core, Data Resource Core, and PASC Biorepository Core, and OTA-21-015B on SARS-CoV-2 Recovery Cohort Studies. Potential applicants are encouraged to review these ROAs to understand the role and function of these key elements of the PASC Initiative.

Purpose

The purpose of this Notice is to alert the community that the NIH intend to publish a ROA to solicit applications proposing clinical trials in those over 18 years old in the prevention and/or treatment of PASC as part of the [NIH RECOVER initiative](#).

Background

Recovery from SARS-CoV-2 infection is extremely variable, with many patients recovering quickly while for others there are clinically significant post-acute sequelae. Reported symptoms among persons who have been infected with SARS-CoV-2 range from mild to incapacitating, may persist after recovery from acute disease, may involve multiple organs and systems, and can adversely affect overall quality of life. In some cases, new symptoms and findings are reported that appear linked to the timing of acute infection but emerge subsequently and evolve over time. The magnitude of the public health impact of these sequelae is currently unknown but potentially large given the numbers of individuals across the age spectrum who have been and will be infected with SARS-CoV-2. It is a public health priority that we better understand and develop strategies to prevent and treat PASC and that these strategies enable rapid innovation, evolution, and adaptation as more is learned about PASC and its potential impact on public health over time. The goal of the RECOVER Initiative is to rapidly improve understanding of recovery after SARS-CoV-2 infection and to prevent and treat PASC.

Research Opportunity Details

With the uncertain etiology or etiologies and the multiple clinical manifestations underlying PASC, NIH is seeking trials testing interventions across multiple domains and using diverse methods to test different therapeutic and/or prevention strategies. Trials considered in scope for this ROA include exploratory Phase IIb trials as well as trials that provide adequate statistical power to support informed clinical decision making (Phase III), and as appropriate, sub-group analyses; pragmatic trials; trials with Bayesian designs, and adaptive platform protocols that could be modified to add and drop interventions as indicated. Trials that allow seamless transition from phase II to phase III would also be in scope. Acceptable interventions could include, but are not limited to, registration and non-registration pharmacologic (e.g., anti-virals, immunomodulators), non-pharmacologic (e.g. biologics, complementary and integrative approaches), devices, as well as behavioral health and lifestyle intervention strategies. Interventions may include leveraging strategies for which there is already an evidence base for addressing other relevant conditions. Acceptable outcomes include, but are not limited to, those assessing intervention effects on general well-being, specific signs and/or symptoms, and underlying pathobiology. NIH strongly encourages the use of NIH COVID-19 common data elements (CDEs).

Submitted protocols will undergo review and modifications may be necessary to meet the priorities of the program. Successful applicants may be asked to work collaboratively with other awardees to develop a protocol that integrates several proposed intervention strategies.

An important component of the RECOVER Initiative is the active engagement and contribution of people suffering with PASC, as well as their caregivers, in the development of the research program. Trials proposals should reflect community and patient engagement.

The RECOVER Clinical Trial Data Coordinating Center will provide administrative, data management, and statistical support across all RECOVER clinical trials.

This Notice is being provided for informational purposes to allow potential applicants additional time to develop responsive applications. NIH reserves the right to modify the scope and objectives as described in this Notice. Final scope, objectives, and requirements will be set forth in the published ROA.

Funding information

Funding of the projects will utilize NIH's Other Transaction Authority (OTA), which offers flexibility and the ability to engage partners in collaborative innovation and problem solving.

Eligibility

The following entities are eligible to receive an award under this ROA:

Higher Education Institutions

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

Foreign Institutions

- Non-domestic (non-U.S.) Entities (Foreign Institutions) are not 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.

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)

Inquiries

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