NATIONAL INSTITUTES OF HEALTH (NIH), PART OF THE US DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health (NIH) R34 Clinical Trial Planning Grants

Le NIGMS (National Institute of General Medical Sciences) s'intéresse particulièrement à l'intégration des données du Covid-19 dans les efforts de recherche en cours visant à élaborer des modèles prédictifs pour la propagation des coronavirus et des pathogènes connexes.

Le NIAID (National Institute of Allergy and Infectious Diseases) s'intéresse particulièrement aux projets portant sur l'histoire naturelle virale, la pathogénicité, la transmission, ainsi qu'aux projets de développement de contre-mesures médicales et de modèles animaux appropriés pour les essais précliniques de vaccins et de produits thérapeutiques contre le Covid-19.

Notice of Special Interest (NOSI): Availability of Administrative Supplements and Revision Supplements on Coronavirus Disease 2019 (COVID-19)

Notice Number: NOT-HL-20-757

Key Dates
Release Date: March 17, 2020
First Available Due Date: March 17, 2020
Expiration Date: October 06, 2020

Related Announcements
NOT-AI-20-030
NOT-OD-20-077
PA-18-591 Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional)
PA-18-935 Urgent Competitive Revision to Existing NIH Grants and Cooperative Agreements (Urgent Supplement - Clinical Trial Optional)

Issued by

National Heart, Lung, and Blood Institute (NHLBI)

Purpose

NHLBI is issuing this Notice of Special Interest (NOSI) to highlight the urgent need for research on Coronavirus Disease 2019 (COVID-19) and on biological effects of its causative agent, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Topics of specific interest to NHLBI include host response, associations with heart, lung, and blood (HLB) diseases, potential impacts on transfusion safety, and clinical outcomes of infected individuals.

Background
As of March 16, 2020, more than 169,000 cases of COVID-19 and 6,500 deaths have been reported worldwide, with more than 3700 cases and 60 deaths in the United States. The virus binds to the angiotensin-converting enzyme 2 (ACE2) receptor in humans, which is highly expressed in the kidney, endothelium, lung, and heart.

Patients diagnosed with this illness have reported symptoms such as fever, cough, shortness of breath, fatigue,

myalgias, headache, sore throat, abdominal pain, and diarrhea. Patients admitted to the hospital generally have pneumonia and abnormal chest imaging, and complications include acute respiratory failure, acute respiratory distress syndrome (ARDS), and acute myocardial injury. ARDS appears to be a significant predictor of mortality. The severity of illness and course of the infection is heterogenous and appears to be more severe in the elderly and in individuals with underlying comorbidities, including cardiovascular and chronic respiratory diseases. To date, SARS-CoV-2 and COVID-19 disease has not caused significant morbidity in infancy and early childhood, a pattern atypical for most viral respiratory diseases.

Research Objectives

To better understand the host response, associated HLB disease, impact on transfusion safety, and short- and long-term clinical outcomes of individuals infected with SARS-CoV-2, the NHLBI encourages the submission of applications for Administrative Supplements and Competitive Revisions to active NHLBI grants to support research on SARS-CoV-2 and HLB COVID-19 disease. Of particular interest are studies that take advantage of human research or unique model systems to study the consequences of SARS-CoV-2 infection. Supported research is expected to inform future efforts to diagnose, prevent, mitigate, or treat this viral infection and associated HLB manifestations.

Possible research interests include but are not limited to the following:

- Host factors, including the microbiome or existing cardiac, respiratory, or hematologic conditions, that predispose persons to acquire SARS-CoV-2 or to develop severe COVID-19 disease, or that confer resistance to severe disease as in infants and young children
- Manifestations, complications, and long-term consequences of SARS-CoV-2 infection, including identification of predictive biomarkers derived from imaging, clinical data, and biospecimens collected across organ systems
- Time course and features of virus-host interactions, including the impact of SARS-CoV-2 infection on innate and adaptive immune responses
- Prevalence and mechanisms of lung and cardiac injury with SARS-CoV-2 infection
- Host factors and biological pathways that impact recovery and repair of the cardiopulmonary and vascular systems after SARS-CoV-2 infection
- Development of animal or in vitro models of SARS-CoV-2 infection suitable for pathogenesis and therapeutic studies or transfusion transmission experiments such as, but not limited to, macaque and ACE-2 receptor murine models
- Use of artificial intelligence or machine learning approaches to understand the biological pathways of COVID-19 disease, its comorbidities, and potential prevention strategies
- Prevalence of RNAemia in symptomatic and asymptomatic people found to test positive for SARS-CoV-2 using respiratory tract samples
- Dynamics of SARS-CoV-2 viremia and antibody response, and implications on screening and diagnostic assay development
- Development of GMP quality hyper immune globulin from convalescent plasma collected from patients who have recovered from documented SARS-CoV-2 infection
- Development and testing of strategies at the healthcare system level to address barriers and facilitators in the treatment of high-risk populations, particularly rural residents and underserved individuals

Supplementary funds may be used for the collection of blood or lung samples from human cohorts of individuals with COVID-19 or evidence of SARS-CoV-2 infection or controls, and/or development of novel model systems to expose animals and cells to SARS-CoV-2.

Application and Submission Information

Applications in response to this NOSI must be submitted using one of the following target opportunities or subsequent reissued equivalent.

- PA-18-591 - Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional)
- PA-18-935 Urgent Competitive Revision to Existing NIH Grants and Cooperative Agreements (Urgent Supplement - Clinical Trial Optional)

Administrative supplement work that is proposed through PA-18-591 Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) must be within the general scope of the research or training that is already supported. Eligible activity codes for applications to PA-18-591 are limited to the mechanisms listed in PA-18-591.

Applications that involve a change in scope (e.g., the addition of human subjects or children to a grant that has not been previously so coded and approved, the addition of vertebrate animals to a grant that has not been previously so coded and approved) mustapply through PA-18-935 Urgent Competitive Revision to Existing NIH Grants and Cooperative Agreements (Urgent Supplement - Clinical Trial Optional). Eligible activity codes for applications to PA-18-935 are

limited to the following mechanisms: P01, R00, R01, R03, R15, R21, R33, R35, R41, R42, R43, R44, R61, U01, U24, U54, UG3, UH3, UM1.

To be eligible for either an Administrative Supplement or Urgent Competitive Revision, the parent award on which the supplement or revision application is based must:

be an active NHLBI award (i.e., not be in an extension period) at the time the supplement or revision is awarded, and
have sufficient time left to complete the studies proposed after the supplement or revision has been awarded within the existing project period.
All instructions in the SF424 (R&R) Application Guide and in the target funding opportunity announcement (PA-18-591 or PA-18-935) must be followed, with the following additions:
The Research Strategy section of the application is limited to 6 pages.
The project period will generally be limited to 1 year. Project periods up to 2 years will be considered only with strong justification.
Applications will be accepted on a rolling basis from March 17, 2020 through October 5, 2020 by 5:00 PM local time of the applicant organization. This NOSI expires on October 6, 2020. An application submitted in response to this NOSI that is received on October 6, 2020 or later will be withdrawn.
Specific to applications that target PA-18-591 (Administrative Supplements): The process for Streamlined Submissions using the eRA Commons cannot be used for PA-18-591.
IMPORTANT: For funding consideration, all applicants must designate NOT-HL-20-757 in the Agency Routing Identifier field (Box 4b) of the SF424 (R&R) Form. Applications without this information in Box 4b will not be considered for this initiative.
Applications nonresponsive to the terms of this Notice will not be considered for this initiative
All applications (including those for multi-project activity codes) must be submitted electronically using a single-project application form package
Administrative supplement applications to PA-18-591 must use the application form package with the Competition ID of “FORMS-E-ADMINSUPP-RESEARCH". This FOA will be reissued with a “FORMS-F-ADMINSUPP-RESEARCH” package on May 25, 2020. Submissions to PA-18-591 must be completed by June 25, 2020 (see NOT-OD-20-026 for details.) Submissions to the reissued FOA will be accepted on or after May 25, 2020 through the expiration date of this Notice.
Competitive revision applications to PA-18-935 must use the application form package with the Competition ID of “NOT-HL-20-757-FORMS-E." This FOA will be reissued with a “NOT-HL-20-757-FORMS-F” package on May 25, 2020. Submissions to PA-18-935 must be completed byJune 25, 2020. Submissions to the reissued FOA will be accepted on or after May 25, 2020 through the expiration date of this Notice.
Applications must specifically address issues of potential biohazards, and all research must be conducted in compliance with the health and safety requirements found in the NIH Grants Policy Statement.

Investigators planning to submit an application in response to this NOSI are strongly encouraged to contact and discuss their proposed research/aims with Program staff listed on this NOSI well in advance of the grant receipt date to better determine appropriateness and interest of the NHLBI.

Inquiries

Please direct all inquiries to:

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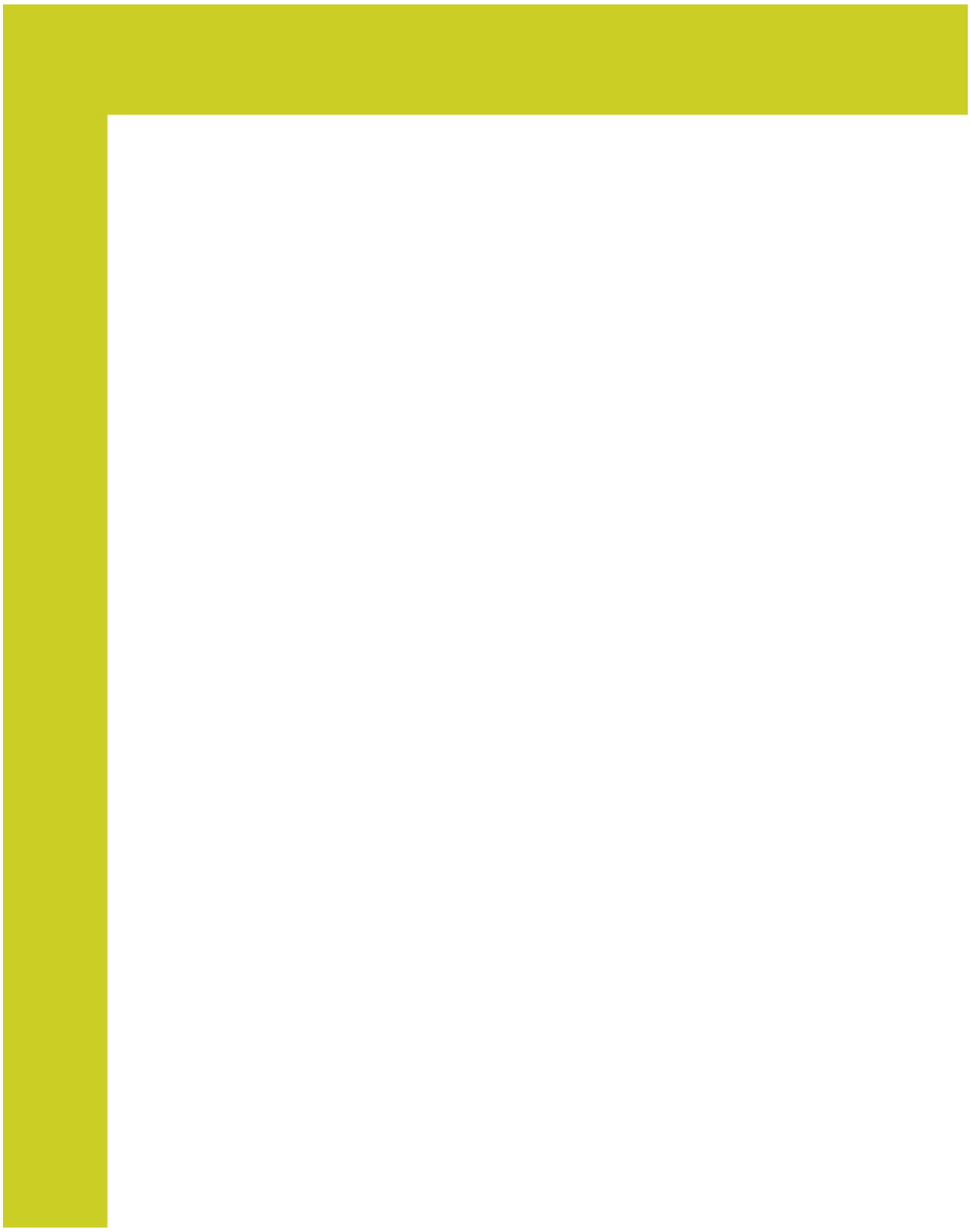
Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files.



17 mars 2020
7 septembre 2020

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