

# NIH COVID-19 Supplements and Revisions: How-to Guide

UAB Office of Research

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1. Available NIH COVID-19 Supplements and Revisions
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## THE MOST IMPORTANT TAKEAWAY:

**Contact the Program Officer listed on the FOA to discuss your ideas before writing the proposal.**

# Read the NOSI specific to the funding Institute of the parent grant carefully for detailed instructions

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Number	Title	Participating Organizations	Release Date
NOT-DK-20-020 <b>Slide: 14</b>	<a href="#">Notice of Special Interest (NOSI): Availability of Urgent Competitive Revision Supplements on Coronavirus Disease 2019 (COVID-19) Related to HIV Comorbidities, Coinfections, and Complications within NIDDK's Mission</a>	National Institute of Diabetes and Digestive and Kidney Diseases ( <a href="#">NIDDK</a> )	April 9, 2020
NOT-MD-20-019 <b>Slide: 17</b>	<a href="#">Notice of Special Interest (NOSI): Competitive and Administrative Supplements for the Impact of COVID-19 Outbreak on Minority Health and Health Disparities</a>	National Institute on Minority Health and Health Disparities ( <a href="#">NIMHD</a> )	April 9, 2020
NOT-TR-20-017 <b>Slide: 26</b>	<a href="#">Notice of Special Interest (NOSI) regarding the Availability of Emergency Competitive Revisions to Existing NIH Grants and Cooperative Agreements for Tissue Chips Research on the 2019 Novel Coronavirus</a>	National Center for Advancing Translational Sciences ( <a href="#">NCATS</a> )	April 9, 2020
NOT-MH-20-047 <b>Slide: 29</b>	<a href="#">Notice of Special Interest (NOSI) regarding the Availability of Administrative Supplements and Urgent Competitive Revisions for Mental Health Research on the 2019 Novel Coronavirus</a>	National Institute of Mental Health ( <a href="#">NIMH</a> )	April 9, 2020
NOT-TR-20-016 <b>Slide: 24</b>	<a href="#">Notice of Special Interest (NOSI) regarding the Availability of Administrative Supplements for Tissue Chips Research on the 2019 Novel Coronavirus</a>	National Center for Advancing Translational Sciences ( <a href="#">NCATS</a> )	April 9, 2020
NOT-CA-20-043 <b>Slide: 37</b>	<a href="#">Notice of Special Interest (NOSI): National Cancer Institute Announcement regarding Availability of Competitive Revision SBIR/STTR Supplements on Coronavirus Disease 2019 (COVID-19)</a>	National Cancer Institute ( <a href="#">NCI</a> )	April 9, 2020

# Read the NOSI specific to the funding Institute of the parent grant carefully for detailed instructions

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Number	Title	Participating Organizations	Release Date
NOT-ES-20-015 Slide: 39	<a href="#">Notice of Special Interest (NOSI): NIEHS Support for Understanding the Impact of Environmental Exposures on Coronavirus Disease 2019 (COVID-19)</a>	National Institute of Environmental Health Sciences ( <a href="#">NIEHS</a> )	April 9, 2020
NOT-DK-20-018 Slide: 43	<a href="#">Notice of Special Interest (NOSI): Availability of Urgent Competitive Revision Supplements on Coronavirus Disease 2019 (COVID-19) within the Mission of NIDDK</a>	National Institute of Diabetes and Digestive and Kidney Diseases ( <a href="#">NIDDK</a> )	April 9, 2020
NOT-DC-20-004 Slide: 47	<a href="#">Notice of Special Interest (NOSI) regarding the Availability of Urgent Competitive Revisions and Administrative Supplements for Research on Coronavirus Disease 2019 (COVID-19)</a>	National Institute on Deafness and Other Communication Disorders ( <a href="#">NIDCD</a> )	April 9, 2020
NOT-AG-20-022 Slide: 52	<a href="#">Notice of Special Interest (NOSI): NIA Availability of Administrative Supplements and Revision Supplements on Coronavirus Disease 2019 (COVID-19)</a>	National Institute on Aging ( <a href="#">NIA</a> ) National Institute of Mental Health ( <a href="#">NIMH</a> )	April 2, 2020
NOT-HG-20-030 Slide: 49	<a href="#">Notice of Special Interest (NOSI) regarding the Availability of Urgent Competitive Revisions for Research on the 2019 Novel Coronavirus</a>	National Human Genome Research Institute ( <a href="#">NHGRI</a> )	March 31, 2020

# Read the NOSI specific to the funding Institute of the parent grant carefully for detailed instructions

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Number	Title	Participating Organizations	Release Date
NOT-ES-20-014 <b>Slide: 59</b>	<a href="#">Notice of Special Interest: NIEHS Worker Training Program Coronavirus and Infectious Disease Response Training (Admin Supp Clinical Trial Not Allowed)</a>	National Institute of Environmental Health Sciences ( <a href="#">NIEHS</a> )	March 27, 2020
NOT-TR-20-012 <b>Slide: 61</b>	<a href="#">Notice of Special Interest (NOSI): Repurposing Existing Therapeutics to Address the 2019 Novel Coronavirus Disease (COVID-19)</a>	National Center for Advancing Translational Sciences ( <a href="#">NCATS</a> )	March 27, 2020
NOT-AI-20-034 <b>Slide: 63</b>	<a href="#">Notice of Special Interest (NOSI) regarding the Availability of Emergency Competitive Revisions for Research on Severe Acute Respiratory Syndrome</a>	National Institute of Allergy and Infectious Diseases ( <a href="#">NIAID</a> )	March 25, 2020
NOT-GM-20-025 <b>Slide: 67</b>	<a href="#">Notice of Special Interest (NOSI) regarding the Availability of Urgent Competitive Revisions for Research on Coronavirus Disease 2019 (COVID-19) and the Causative Virus SARS-CoV-2</a>	National Institute of General Medical Sciences ( <a href="#">NIGMS</a> )	March 25, 2020
NOT-TR-20-011 <b>Slide: 70</b>	<a href="#">Notice of Special Interest (NOSI) Clinical and Translational Science Award (CTSA) Program Applications to Address 2019 Novel Coronavirus (COVID-19) Public Health Need</a>	National Center for Advancing Translational Sciences ( <a href="#">NCATS</a> )	March 24, 2020

# Read the NOSI specific to the funding Institute of the parent grant carefully for detailed instructions

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Number	Title	Participating Organizations	Release Date
NOT-DA-20-047 <b>Slide: 72</b>	<a href="#">Notice of Special Interest (NOSI) regarding the Availability of Administrative Supplements and Urgent Competitive Revisions for Research on the 2019 Novel Coronavirus</a>	National Institute on Drug Abuse ( <a href="#">NIDA</a> )	March 19, 2020
NOT-HL-20-757 <b>Slide: 76</b>	<a href="#">Notice of Special Interest (NOSI): Availability of Administrative Supplements and Revision Supplements on Coronavirus Disease 2019 (COVID-19)</a>	National Heart, Lung, and Blood Institute ( <a href="#">NHLBI</a> )	March 17, 2020

# Supplement or Revision?

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**PA-18-591 Administrative Supplements** to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional)

- **In Scope** of parent grant

**PA-18-935 Urgent Competitive Revision** to Existing NIH Grants and Cooperative Agreements (Urgent Supplement - Clinical Trial Optional)

- **Out of Scope** of parent grant

- **NOTE:** Specific parent grant Institutes may require submission to FOAs other than PA-18-591 and PA-18-935. Further details below.

# What is “Out of Scope”?

- Introduction of a **new vertebrate species** (e.g., mice in parent grant and propose to study nonhuman primates in the supplement).
- Introduction of **human subjects research in the supplement when the parent grant does not already involve human subject research**, or the proposed introduction of human subjects research in children in the supplement when the parent grant only involves adult human subjects research, or vice versa.
- Introduction of a **clinical trial in the proposed supplement when the parent grant does not already include a clinical trial**, or
- Introduction of **new additional risks to human subjects** (e.g., change from minimal risk human subjects research to more than minimal risk research) such that a new Data and Safety Monitoring Plan or a Data and Safety Monitoring Board is now required.
- **Investigators should contact the research staff listed on the Institute-specific NOSI to discuss potential proposal prior to submitting an application.**



# Requirements

**To apply for either supplemental mechanism, the parent grant must:**

- Be actively funded; in some instances, must have 2 years remaining on the parent grant—discuss with program officer
- Propose a project that falls within the currently approved budget year of the parent grant
- *Institute-specific requirements covered below*

Investigators may submit more than one supplement request per the same parent grant as long as the projects are distinct.

# Requirements

## Further considerations:

- Discuss scope of the parent grant
- Include aims and strategy of the supplement and how it is *in or out of scope* of the parent grant
- Address how your proposal responds to the *research interest areas* of the specific NOSI

# Applying

**Step 1:** Enter the Appropriate FOA# on the ASSIST landing page.

- Step 2:**
- Enter the parent grant #
  - Enter the applicable NOSI#
  - Enter the title of your supplement proposal

## Welcome to the Application Submission System & Interface for Submission Tracking (ASSIST)



### INITIATE APPLICATION

Funding Opportunity Announcement #  
(Example: PA-XX-XXX or LITC-ABCD-XX-000)

PA-18-935

Go

The National Institutes of Health posts Funding Opportunity Announcements (FOAs) in the [NIH Guide for Grants & Contracts](#) and in [Grants.gov's Search Grants](#) . Each resource has robust search functionality to identify opportunities of interest. ASSIST can only be used to prepare and submit applications when explicitly stated in the FOA.

[Home](#) > [Initiate Application](#)

## Initiate Administrative Supplement Application ?

Parent Grant:  
(Example: Use CA987654 from 1R01CA987654-01)

Funding Opportunity Announcement: \*  
(Example: PA-XX-XXX)

Notice of Special Interest Reference:  
(Example: NOT-XX-XX-XXX)

Unique Supplement Label:

PA-18-935

NOT-AG-20-022

End COVID-19

Project/Performance Site Locations:

Senior/Key Persons:

☐ Check this to prepopulate all Project/Performance Site Locations from the parent grant

☐ Check this to prepopulate all Senior/Key Persons from the provided parent grant

Initiate Application

Cancel and Exit

# Applying – OSP Considerations

- Follow usual OSP guidelines
- Treated as a new submission, although the “Submission Type” will be “Supplement/Revision” and the parent grant OSP number should be listed on the Extramural Checklist

## Required Documents

### [UAB Extramural Support Checklist](#)

- Supplemental Application
- Budget
- RFA or PA# (provided on the checklist)

For more information regarding submitting to OSP, please review our [Federal](#) and [Industry](#) submission pages.

4	<b>Submission Type:</b>
	<input type="checkbox"/> Original/New *
	<input type="checkbox"/> Fee for Service *
	<input type="checkbox"/> Transfer In *
	<input type="checkbox"/> Study Startup Agreement
	<input type="checkbox"/> Resubmission *
	<input type="checkbox"/> Competing Continuation/Renewal *
	<input type="checkbox"/> Change in PI *
	<input type="checkbox"/> Amendment/Modification
	<input checked="" type="checkbox"/> Supplement/Revision
<input type="checkbox"/> Transfer Out	

# NIDDK – NOT-DK-20-020 (Urgent Competitive Revision Related to HIV Comorbidities, Coinfections, and Complications)

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## Research Objectives:

- Collection of biosamples that could yield pathophysiologic insights into the impact of COVID-19 on HIV-associated CCCs within the mission of the NIDDK; especially those related to the gastrointestinal, liver, renal/urological, and metabolic/endocrine systems.
- Studies to gather data from health care systems and ongoing cohort studies to elucidate whether PWH with CCCs within the mission of the NIDDK have different COVID-19 outcomes.

# NIDDK – NOT-DK-20-020 (Urgent Competitive Revision Related to HIV Comorbidities, Coinfections, and Complications)

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## Research Objectives:

- Studies that utilize nonhuman primate or ex vivo human models to characterize the effect of HIV-SARS-CoV-2 coinfection on gastrointestinal, liver, renal/urological, and metabolic/endocrine systems and processes.
- Studies to elucidate how HIV and SARS-CoV-2 coinfection impacts kidney or liver damage severity mediated by antiretroviral drugs.
- Pilot clinical studies designed to understand the natural history of COVID-19 related to either provoking or exacerbating HIV-associated CCCs within the mission of NIDDK, or to evaluate strategies for preventing or treating HIV-associated CCCs within the mission of NIDDK in the context of SARS-CoV-2 coinfection.

# NIDDK – NOT-DK-20-020 (Urgent Competitive Revision Related to HIV Comorbidities, Coinfections, and Complications)

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## Requirements:

- Revision applications **can support a significant expansion of the scope** and research protocol approved and funded for the “parent” award on which the revision application is based.
- The NIDDK will only accept applications in response to this Notice for the following activity codes: **R01, RC2, P01, U2C, UH3, U01, P50, U54, R41, R42, R43 and R44**
- Application budgets are limited to the current year direct cost budget, or \$500,000 direct costs (whichever is less), exclusive of consortium F&A costs, and must reflect the actual needs of the proposed project.
- Apply to:
  - [PA-18-935](#) Urgent Competitive Revision to Existing NIH Grants and Cooperative Agreements (Urgent Supplement - Clinical Trial Optional)

# NIMHD/NIA/NIMH – NOT-MD-20-019 (Supplements and Revisions)

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## Research Objectives:

- Examine the effects of the COVID-19 outbreak on disparities in healthcare utilization and health outcomes among medically vulnerable populations such as institutionalized and non-institutionalized elderly; persons with chronic conditions, mental health and/or substance abuse disorders, complex medical needs, and/or with compromised immune system function; and pregnant women.
- Examine the effects of the COVID-19 outbreak on disparities in healthcare utilization and health outcomes among socially vulnerable populations such as the homeless, the recently incarcerated, immigrants, persons with disabilities, and children.
- Examine the effects of the COVID-19 outbreak on disparities in access to care and quality of care for health disparity populations, taking into account how it impacts the structure and organization of different health care systems that serve disparity populations, including those living in rural areas.



# NIMHD/NIA/NIMH – NOT-MD-20-019 (Supplements and Revisions)

17

## Research Objectives:

- Examine how clinician and health care system biases affect health and health care disparities in relation to the COVID-19 outbreak.
- Examine the effects of the COVID-19 outbreak on the health outcomes of the health care workforce serving health disparity populations and factors alleviating or exacerbating these outcomes.
- Examine the geographic and place-based variations in social contexts and their influence on minority health and/or health disparities in relation to the COVID-19 outbreak.
- Examine how racism and other types of discrimination at multiple levels (structural, institutional, and personally mediated) influence minority health and/or health disparities in relation to the COVID-19 outbreak.

# NIMHD/NIA/NIMH – NOT-MD-20-019 (Supplements and Revisions)

18

## Research Objectives (NIMHD):

- Examine the role of state and local policies in different sectors (e.g., healthcare, labor, transportation, housing) in exacerbating or reducing the impact of COVID-19 on minority health and health disparities.
- Examine the effectiveness of existing health and social justice practices (policies geared towards low income and marginalized communities) such as paid sick leave for low-income jobs, ensuring access to food and other necessities, placing moratoriums on evictions, and increasing affordable housing, to minimize the health, financial and social impacts of the outbreak for health disparity population(s).
- Examine the effectiveness of best practices in health communication and social marketing, including the role of social media, on health promotion and prevention in relation to COVID-19 in health disparity populations.

# NIMHD/NIA/NIMH – NOT-MD-20-019 (Supplements and Revisions)

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## Research Objectives:

- Community engaged research studies examining community and culturally appropriate COVID-19 prevention methods.
- Modeling studies of the effects of the epidemic and the mitigation interventions on the health outcomes of health disparity populations including mental illness, substance use, exacerbation of chronic diseases and mortality.
- Examine how protective factors and factors that promote resilience at the individual, interpersonal, and contextual levels (e.g., social networks, and structural, neighborhood, and community resources) influence COVID-19 impact on minority health and/or health disparities.
- Documentation of COVID-19 natural history in an established health disparity study population.

# NIMHD/NIA/NIMH – NOT-MD-20-019 (Supplements and Revisions)

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## Research Objectives:

- Examine the role of genetic susceptibility and differential biological pathways with COVID-19 disease severity in health disparity populations, including epigenetic effects associated with social and environmental exposures.
- Examine the influence of self-reported chronic stress and/or biological markers of chronic stress on minority health and/or health disparities in relation to the COVID-19 outbreak.
- Examine the role of social determinants of health and cognitive and behavioral factors in influencing preventive health behaviors and practices related to the COVID-19 outbreak that may influence minority health and health disparities.
- Examine novel behavioral interventions leveraging digital technology to promote adherence with hand washing, social distancing, and self-quarantine recommendations?.

# NIMHD/NIA/NIMH – NOT-MD-20-019 (Supplements and Revisions)

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## Research Objectives:

- **NIMH:** Applications to describe the epidemiology of mental disorders and symptoms related to the COVID-19 pandemic are not a high priority; applications to examine how a disrupted workforce may adequately respond/adapt to and maintain services or provide additional care for new or worsening mental health needs where we anticipate health disparities will be most prominent will be seen as a high priority.
- **NIA:** Applications are encouraged that address the specific needs and circumstances of midlife and older adults, including, but not limited to, individuals with Mild Cognitive Impairment (MCI), Alzheimer's disease and Alzheimer's disease related dementias (AD/ADRD) and their healthcare providers and caregivers.

# NIMHD/NIA/NIMH – NOT-MD-20-019 (Supplements and Revisions)

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## Requirements:

- Individual requests can be no more than \$125,000 in direct costs.
- 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.
- The parent award must be active when the application is submitted. The project and budget periods must be within the currently approved project period for the existing parent award.
- Apply to:
  - [PA-18-935](#) Urgent Competitive Revision to Existing NIH Grants and Cooperative Agreements (Urgent Supplement - Clinical Trial Optional)
  - [PA-18-591](#) Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional)

# NCATS – NOT-TR-20-016 (Supplements for Tissue Chips Research)

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## Research Objectives:

- Use of microphysiological systems or tissue chips in collecting and examining data on the risks and outcomes for COVID-19 infection, and advance the translation of research findings into diagnostics, therapeutics, and vaccines.

## Requirements:

This Notice announces the availability of competitive revisions for investigators and institutions funded through:

- The NIH Microphysiological Systems (MPS) Program; or
- SBIR/STTR-supported investigators, provided the award involves tissue chips; or
- Microphysiological systems programs from across NIH.

# NCATS – NOT-TR-20-016 (Supplements for Tissue Chips Research)

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## Requirements:

- Requests may be for one year of support only.
- The Research Strategy section of the application is limited to 6 pages.
- Recipients of supplemental funds under this announcement will be expected to provide monthly updates to NIH program staff on funded projects.
- Applicant organizations may submit one application per parent grant.
- Apply to:
  - [PA-18-591](#) Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional)



# NCATS – NOT-TR-20-017 (Emergency Competitive Revisions for Tissue Chips Research)

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## Research Objectives:

- Incorporation of new and emerging data related to SARS-CoV-2 into ongoing research efforts to develop microphysiological systems/tissue chips models for COVID-19
- Use of microphysiological systems/tissue chips or evaluating, repurposing or modification of diagnostic tools to enable rapid detection of COVID-19 infection
- Use of microphysiological systems/tissue chips for the rapid development and assessment of potential therapeutic agents for COVID-19

# NCATS – NOT-TR-20-017 (Emergency Competitive Revisions for Tissue Chips Research)

26

## Requirements:

This Notice announces the availability of competitive revisions for investigators and institutions funded through:

- The NIH Microphysiological Systems (MPS) Program; or
- SBIR/STTR-supported investigators, provided the award involves tissue chips; or
- Microphysiological systems programs from across NIH.

# NCATS – NOT-TR-20-017 (Emergency Competitive Revisions for Tissue Chips Research)

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## Requirements:

- The Research Strategy section of the application is limited to 6 pages.
- Only existing UG3/UH3, R43/R44, R41/R42, R01, and U01 awardees of NCATS/NIH Microphysiological Systems program are eligible to apply.
- Applicant organizations may submit one application per parent grant.
- The Research Strategy should address the scope of the overall project and provide a description of the competitive revision's purpose with a clearly delineated timeframe to **complete the proposed project within 24 months.**
- Apply to: [PA-20-135](#); Emergency Competitive Revision to Existing NIH Awards (Emergency Supplement - Clinical Trial Optional)

# NIMH/NIA/NIAAA/NIMHD – NOT-MH-20-047 (Supplements and Revisions)

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## Research Objectives (NIMH):

- Research on alternatives to traditional services that rely on an available workforce to meet emergent psychiatric needs.
- Projects to develop and test tools that would enable health and social service workers to have real-time access to resources for case management and referral to medical/psychiatric treatment, as well as social support services, to meet the complex needs of persons with mental illness - who are in communities with cases, or have contracted SARS-CoV-2 themselves (needing e.g., in-patient beds, behavioral health crisis services, open brick and mortar and online pharmacies, the range of medication management and prescription access (e.g., out-patient opioid replacement therapy and antipsychotic medications, primary care medication access and management, shelter resources, food assistance).

# NIMH/NIA/NIAAA/NIMHD – NOT-MH-20-047 (Supplements and Revisions)

29

## Research Objectives:

- Research to determine the feasibility and utility of technology enabled screening to identify/triage those in immediate need of in-patient behavioral health, medications, and opioid replacement therapy. Higher priority research would include evaluation of participant follow through and outcomes related to pointofcare triage and referral to services (e.g., web-based or other self-care, and/or telephone counseling that supports individual brief CBT for distress, online group interventions, etc.).
- Development and testing of technology to leverage/build on the available response workforce to enable practical, scalable, and sustainable mental health screening, triage, and prevention/treatment interventions along a continuum of intensity for mental disorders across the lifespan, particularly for high risk populations. Interventions appropriate for mass trauma response are of interest (e.g., Psychological First Aid [PFA]; enhanced PFA; self-guided and professionally assisted skillsbased interventions, internetbased interventions for managing common posttraumatic symptoms and stressrelated symptoms and conditions; brief CBT-based approaches for distress, and Collaborative Care programs).

# NIMH/NIA/NIAAA/NIMHD – NOT-MH-20-047 (Supplements and Revisions)

30

## Research Objectives:

- Develop and test decision aides and evaluate utility for improving service access/engagement/outcomes.
- Research accessing and leveraging public and/or commercial mental health claims data and/or private EHR data to identify populations at high risk for functional impairment and health service interruption, and/or to target vulnerable populations for outreach and interventions.
- Research to understand and improve engagement and continuity of care including approaches to facilitate (re)connection to care for persons with serious mental disorders who experience disruption in services.
- Research focused on persons with pre-existing serious mental illness and their ability to maintain functioning, symptom stability, and implement their region's recommended or mandated safety measures to prevent transmission of SARS-CoV-2, e.g., staying at home except for essential business.

# NIMH/NIA/NIAAA/NIMHD – NOT-MH-20-047 (Supplements and Revisions)

## Research Objectives:

- Research on interventions to prevent suicide, especially among populations that may have less familiarity with or access to technologically-mediated means of social connection (e.g., older adults, individuals in rural communities).
- Research to identify potential intervention targets for modifying social connectedness, isolation, and/or loneliness via social media and/or electronic communication to prevent the development of clinically significant mental health symptoms.
- Studies on the impact (e.g., access, quality, and clinical outcomes) of state, local, federal, and guild-specific guidelines and policies around telehealth services, and of changes in those policies, with specific attention on the risks and benefits of relaxing those guidelines or policies.
- Research to test the feasibility and impact of programs that integrate testing for SARS-CoV-2 with HIV testing or other screenings, or which leverage existing HIV testing programs, strategies, and initiatives to expand access to SARS-CoV-2 testing among marginalized communities.

# NIMH/NIA/NIAAA/NIMHD – NOT-MH-20-047 (Supplements and Revisions)

## Research Objectives:

- Research on interventions such as those conducted through telemedicine that strengthen mental health and HIV prevention and care needs to advance COVID-19 prevention and mitigation efforts. This may include interventions that promote continuity of HIV prevention services, including mental health services, during the COVID-19 pandemic. Also, research to understand the impact of disrupted HIV care systems and/or social distancing on mental health, HIV care engagement, medication adherence, and viral suppression among people living with HIV in a manner that would directly inform future support interventions.
- Research that leverages existing cohorts to examine CNS complications including mental illness risk, onset, course as well as behavioral consequences due to SARS-CoV-2 immune responses and impact of SARS-CoV-2 co-infection with HIV on the CNS.



# NIMH/NIA/NIAAA/NIMHD – NOT-MH-20-047 (Supplements and Revisions)

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## Research Objectives:

- **NIA:** Applications are encouraged that address the specific needs and circumstances of midlife and older adults, including, but not limited to, individuals with Mild Cognitive Impairment (MCI), Alzheimer's disease and Alzheimer's disease related dementias (AD/ADRD) and their healthcare providers and caregivers.
- **NIAAA:** Encourages applications studying individuals with alcohol use disorder with and without comorbid psychiatric disorders, e.g., posttraumatic stress disorder, anxiety disorder, major depressive disorder, etc. Specific areas of interest include but are not limited to service delivery, telehealth, interactions between stress and social isolation on symptomatology, and increased risk for suicide as related to alcohol use in the general population and in under resourced communities, such as racial, ethnic and gender minorities; low socioeconomic, incarcerated, and homeless populations, etc.

# NIMH/NIA/NIAAA/NIMHD – NOT-MH-20-047 (Supplements and Revisions)

34

## Research Objectives:

- **NIMHD:** Examination of the onset and the course of anxiety and depression due to SDOH challenges (e.g., financial strain, housing insecurity, food insecurity, potential occupation-based exposure, etc.) exacerbated by COVID-19.
- Studies focused on point-of-care screening for COVID-19, brief mental health assessment, and referral for populations who are less likely to engage in mental health services.

# NIMH/NIA/NIAAA/NIMHD – NOT-MH-20-047 (Supplements and Revisions)

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## Requirements:

- The Research Strategy section of the application is limited to 6 pages.
- Apply to:
  - [PA-18-935](#) Urgent Competitive Revision to Existing NIH Grants and Cooperative Agreements (Urgent Supplement - Clinical Trial Optional)
  - [PA-18-591](#) Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional)

# NCI – NOT-CA-20-043 (Competitive Revision SBIR/STTR Supplements)

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## Research Objectives:

- Adapting the use of cancer diagnostics and diagnostic technologies and platforms for diagnosing the virus, infection, and potential immunity against the virus rapidly at the point of care setting;
- Repurposing or expanding use of cancer vaccines, vaccine candidates, and other technologies for prevention of, and/or protection from SARS-CoV-2 infection;
- Repurposing or expanding the use of cancer therapeutics and therapeutic candidates for the treatment of COVID-19 and the management of severe symptoms.

# NCI – NOT-CA-20-043 (Competitive Revision SBIR/STTR Supplements)

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## Requirements:

- Be an NCI-funded active SBIR/STTR (R41, R42, R43, R44 mechanisms) award (i.e., not be in an extension period) at the time the revision/supplement application is submitted.
- The Research Strategy section of the application is limited to:
  - 6 pages for R41 and R43 awards; and
  - 12 pages for R42 and R44 awards.
- The supplement project period will generally be limited to 1 year.
- Apply to:
  - [PA-18-935](#) Urgent Competitive Revision to Existing NIH Grants and Cooperative Agreements (Urgent Supplement - Clinical Trial Optional)

# NIEHS – NOT-ES-20-015 (Competitive Revisions and New R21s)

38

## Research Objectives:

- Examine the role of environmental exposures in impacting individual susceptibility to SARS-Cov-2 infection, or the development and severity of COVID-19 disease.
- Investigate the role of lifestyle factors (e.g. diet, physical activity) as modifiers of the effects of environmental exposures on the development or severity of COVID-19 disease.
- Leverage existing biological samples or data from human or animal research studies to test hypotheses examining the impact of environmental exposures on susceptibility to SARS-Cov-2 infection and COVID-19 disease severity or progression (e.g. detection of SARS-Cov-2 infection in an existing environmental epidemiology study).
- Utilize previously developed research tools or technology platforms that can be applied to understand how environmental exposures impact COVID-19 spread, or disease progression and severity (e.g. personal exposure monitoring, geospatial mapping, risk modeling tools, biomarkers to detect infection).

# NIEHS – NOT-ES-20-015 (Competitive Revisions and New R21s)

39

## Research Objectives:

- Apply multi-omics approaches that can accelerate identification of biomarkers/metabolic signatures of infection or disease progression using animal models as well as in study participants of existing environmental health studies.
- Understand the role of exposure-induced perturbations in respiratory microbiome and its contributions to COVID-19 susceptibility and disease progression.
- Assess the impact of COVID-19-related interventions (including social or physical distancing or public health messaging) on changes in the spread of COVID-19 as well as environmental exposures and related human health outcomes.
- Determine the potential health effects of increased personal/community use of disinfection products for COVID-19 control.

# NIEHS – NOT-ES-20-015 (Competitive Revisions and New R21s)

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## Research Objectives:

- Develop or apply educational, community-based, or other public health strategies that address the intersection between environmental exposures and COVID-19.
- Identify climate or weather-related factors that influence population susceptibility to SARS-Cov-2 infection and COVID-19 disease.
- Examine the potential impact of environmental health disparities on the spread of COVID-19 disease.



# NIEHS – NOT-ES-20-015 (Competitive Revisions and New R21s)

41

## Requirements:

- Requests may be for only one year of support for supplements, and up to two years for [RFA-ES-19-011](#) (R21).
- The Research Strategy section of the application is limited to 6 pages for PA-20-135. See [RFA-ES-19-011](#) for page limits.
- Apply to:
  - [PA-20-135](#) Emergency Competitive Revision to Existing NIH Awards (Emergency Supplement - Clinical Trial Optional)
  - [RFA-ES-19-011](#) Mechanism for Time-Sensitive Research Opportunities in Environmental Health Sciences (R21 Clinical Trial Not Allowed)

# NIDDK – NOT-DK-20-018 (Urgent Competitive Revisions)

42

## Research Objectives:

- Collection of biosamples that could inform the pathogenesis of COVID-19 associated kidney, gastrointestinal, or metabolic/endocrine diseases.
- Studies to gather data from health care systems and ongoing clinical trials to better understand whether patients with COVID-19 and diseases in the mission of NIDDK have different outcomes based on underlying disease factors or therapies for their condition.
- Studies to identify risk factors that could lead to modification of therapy in high risk individuals such as patients with acute kidney injury (AKI), organ transplantation, diabetes, inflammatory bowel disease, and other diseases within the mission of NIDDK that are treated with immunomodulators or biologic pathway inhibitors

# NIDDK – NOT-DK-20-018 (Urgent Competitive Revisions)

43

## Research Objectives:

- Studies to identify novel pathogenic pathways and potential translational targets for the development of kidney, gastrointestinal, endocrine and metabolic diseases associated with COVID-19 infection using relevant in vitro and in vivo studies of the kidney, gastrointestinal or endocrine/metabolism system.
- Pilot clinical studies designed to understand the natural history of COVID-19 related AKI, gastrointestinal or metabolic/endocrine diseases, or to evaluate interventions to prevent or treat COVID-19-induced AKI, digestive disorders, or metabolic/endocrine systems.

# NIDDK – NOT-DK-20-018 (Urgent Competitive Revisions)

44

## Requirements:

- Revision applications **can support a significant expansion of the scope** and research protocol approved and funded for the “parent” award on which the revision application is based.
- The NIDDK will only accept applications in response to this Notice for the following activity codes: **R01, RC2, P01, U2C, UH3, U01, P50, U54, R41, R42, R43 and R44**
- Application budgets are limited to the current year direct cost budget, or \$500,000 direct costs
- Be an active NIDDK award that is not in an extension period at the time the revision is awarded, and
- Have enough time left in the award to complete the studies proposed after the revision has been awarded.

# NIDDK – NOT-DK-20-018 (Urgent Competitive Revisions)

45

## Requirements:

- Apply to:
  - [PA-18-935](#) Urgent Competitive Revision to Existing NIH Grants and Cooperative Agreements (Urgent Supplement - Clinical Trial Optional)

# NIDCD – NOT-DC-20-004 (Supplements and Revisions)

46

## Research Objectives:

- Address the pathology, prevention, diagnosis, sequelae, or treatment of COVID-19 directly related to NIDCD's mission areas.

## Requirements:

- The Research Strategy section of the application is limited to 6 pages.
- The project period of the supplement must not exceed one year.
- Application budgets cannot exceed \$125,000 direct costs.
- The parent award (**R01 or U01 only**) must be active when the application is submitted. The parent award cannot be in a no cost extension.

# NIDCD – NOT-DC-20-004 (Supplements and Revisions)

47

## Requirements:

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

# NIGRI – NOT-HG-20-030 (Supplements and Revisions)

48

## Research Objectives:

- Develop novel methods using genomic techniques to identify signatures of infection, prognosis, and/or severity of disease in a medical setting.
- Development of novel genomic-based tools, kits or reagents to track and monitor SARS-CoV-2 itself and infected individuals.
- Computational approaches to integrate human or animal model genomic data with data from SARS-CoV-2 infection, replication, pathogenesis and transmission to inform models of host-pathogen interactions and predict infection outcomes.



# NIGRI – NOT-HG-20-030 (Supplements and Revisions)

49

## Research Objectives:

- Development of visualization, curation and analysis platforms for human and animal model genomic data related to SARS-CoV-2 infection, replication, pathogenesis and transmission studies.
- Use of electronic health information, or other relevant clinical, environmental, demographic and social determinants of health data, and accompanying genomic data to aid in tracking and understanding the genetic epidemiology of SARS-CoV-2, and the individual susceptibility and resistance to infection and disease severity.
- Studies addressing the ethical, legal and social implications of the use of genetic and genomic information and technologies to diagnose, track, monitor, treat and triage SARS-CoV-2 and COVID-19 infected patients and populations in clinical and public health settings.

# NIGRI – NOT-HG-20-030 (Supplements and Revisions)

- The Research Strategy section of the application is limited to **6 pages**.
- The project period for the supplement will generally be limited to **1 year**. Project periods of up to 2 years will be considered only with strong justification.
- Application budgets are limited to no more than \$250,000 per year in direct costs and must reflect the actual needs of the proposed project.
- **One page about the proposed project, including:**
  - Goals and specific aims
  - Summary of the project's significance, innovation, and generalizability
  - Summary of the approaches to be used
- No more than **one page budget justification** including direct and total costs
- Apply to:
  - [PA-18-935](#) Urgent Competitive Revision to Existing NIH Grants and Cooperative Agreements (Urgent Supplement - Clinical Trial Optional)
  - [PA-18-591](#) Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional)

# NIA/NIMH – NOT-AG-20-022 (Supplements and Revisions)

51

## Division of Aging Biology (DAB) Research Interests:

- Studies of the role of inflammation and immunesenescence in older populations with increased susceptibility to SARS-CoV-2 infection and subsequent progression to more severe disease, including lung pathology and acute respiratory distress syndrome (ARDS).
- Development of aged animal models (including non-human primates) or *in vitro* models suitable for studies on pathogenesis of the virus and/or pre-clinical testing of therapeutics and vaccines against SARS-Cov-2.
- Studies of how cellular and molecular mechanisms identified as pillars of aging impact the treatment, recovery, and repair of tissue and organ systems in older individuals infected with SARS-CoV-2. Studies of the identification of predictive biomarkers derived from clinical specimens and data collected from patients are also encouraged.
- Studies of how host factors, including existing co-morbidities such as respiratory, cardiac, and other conditions, predispose older individuals to acquire SARS-CoV-2 infections and/or develop more severe COVID-19 disease, such as ARDS.

# NIA/NIMH – NOT-AG-20-022 (Supplements and Revisions)

52

## Division of Neuroscience (DN) Research Interests:

- Studies of neurological and neurocognitive symptoms in COVID-19 and sequelae of SARS-CoV-2 infection related to the development or aggravation of such symptoms in older adults, e.g., delirium or early alterations in sensory function; studies of the susceptibility of people with Alzheimer's disease or Alzheimer's disease-related dementias (AD/ADRD) to COVID-19.
- Studies of mechanisms of underlying SARS-CoV-2 neurological symptoms and pathology in older adults with COVID-19; research on the role of brain barriers in preventing SARS-CoV-2 from gaining access to the neural tissues and mechanisms through which SARS-CoV-2 compromises such barriers and propagates in the central nervous system (CNS); neuropathological studies of COVID-19 and the contribution of brain tissue damage by SARS-CoV-2 to the morbidity and mortality in COVID-19 in older adults.

# NIA/NIMH – NOT-AG-20-022 (Supplements and Revisions)

53

## Division of Neuroscience (DN) Research Interests:

- Studies aimed at discovery and development of novel drugs, as well as repurposing and repositioning existing drugs, for preventing and treating COVID-19, particularly drugs that are specific for COVID-19 related CNS targets and CNS mechanisms related to or driving the viral-mediated pathophysiology; studies on blood-brain-barrier penetrant drugs to treat potential SARS-CoV-2 reservoirs in the CNS.
- Development of computational and informatics methods, e.g., machine learning or artificial intelligence integrating with emerging multi-modal data for COVID-19 diagnosis, prevention, and treatment.

# NIA/NIMH – NOT-AG-20-022 (Supplements and Revisions)

54

## Division of Geriatrics and Clinical Gerontology (DGCG) Research Interests:

- Relationships of individual factors, including co-existing conditions and medications, to resilient or adverse outcomes to SARS-CoV-2 exposure in older adults and comparisons with younger adults.
- Evaluation of pharmacological or health care delivery intervention strategies in older adults after exposure to SARS-CoV-2 to prevent or mitigate morbidity and/or improve post-infection health and function.
- Studies in pre-hospital, emergency, or critical care settings to improve screening, risk stratification, care delivery decisions, resource allocation, and clinical outcomes for older adults exposed to SARS-CoV-2.
- Evaluation of strategies to minimize spread of COVID-19 among older adults and their care providers, particularly within facilities housing older adults, including telemedicine and remote medicine strategies.

# NIA/NIMH – NOT-AG-20-022 (Supplements and Revisions)

55

## Division of Behavioral and Social Research (DBSR) Research Interests:

- Leveraging longitudinal studies to elucidate how COVID-19-related changes in the social, economic, institutional, and policy environments differentially impact the health and welfare of people across the life course and in vulnerable social groups; comparative studies of regional and national approaches are encouraged.
- Studies of prevention practices (hand washing, effectively covering a cough, social distancing, etc.) and factors that influence adherence, including individual and age differences and social network effects.
- Studies of how social distancing requirements impact the care and well-being of vulnerable older adult populations, including individuals with Mild Cognitive Impairment (MCI) and AD/ADRD.
- Evaluating strategies used by health systems to reallocate resources, rapidly train practitioners, communicate preventative practices, and maintain adherence to public health and clinical guidelines, with a particular interest in those that serve high-risk groups (e.g. nursing homes) and resulting racial, ethnic, or regional disparities in access/care.

# NIA/NIMH – NOT-AG-20-022 (Supplements and Revisions)

## **The National Institute of Mental Health (NIMH)**

- Will accept and consider support for applications for supplements and revisions to NIMH projects that fall within the scope of this announcement and are relevant to the mission and strategic priorities of the NIMH. Applications to describe the epidemiology of mental disorders and symptoms related to the COVID-19 pandemic are not a high priority; applications to examine how a disrupted workforce may adequately respond/adapt to and maintain services or provide additional care for new or worsening mental health needs and/or suicide risk in midlife and older age adults will be seen as a high priority.



# NIA/NIMH – NOT-AG-20-022 (Supplements and Revisions)

## Requirements:

- The project period will generally be limited to 1 year. Project periods up to 2 years will be considered only with strong justification.
- Page limitations and document requirements should follow guidelines of the parent grant
- Apply to:
  - [PA-18-935](#) Urgent Competitive Revision to Existing NIH Grants and Cooperative Agreements (Urgent Supplement - Clinical Trial Optional)
  - [PA-18-591](#) Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional)

# NIEHS – NOT-ES-20-014 (Revisions: Worker Training Program)

58

## Specific Areas of Training:

- Develop safety and health training for those workers supporting the national Coronavirus response. Applicants should develop targeted pilot training for those at high risk of accepting or potentially being closely exposed (such as transport cabin crew) to Coronavirus-exposed patients and waste and bodily fluid through air transport, medical treatment, environmental services, waste handling, and cleanup. They break up blocks of text.
- Using our hazmat trainers understanding of worker safety and health protection issues, knowledge of PPE usage, and experience in training disaster workers, WTP would coordinate with CDC, Health and Human Services Assistant Secretary for Preparedness and Response (ASPR), OSHA and NIOSH to develop an evidence-based curriculum that addresses the science of Coronavirus (clinical symptoms, mode of transmission, persistence in the environment, treatment); infection control and worker protection (isolation/quarantine, PPE); working in the contaminated environment (sampling and decontamination); and behavioral health resiliency .

# NIEHS – NOT-ES-20-014 (Revisions: Worker Training Program)

59

## Specific Areas of Training:

- Train-the-Trainer (TTT) Model.
- WTP Direct Training Model.

## Requirements:

- Requests may be for one to three years of support only.
- The Research Strategy section of the application is limited to 6 pages.
- Apply to: [PA-20-135](#) - Emergency Competitive Revision to Existing NIH Awards (Emergency Supplement - Clinical Trial Optional)

# NCATS – NOT-TR-20-012 (Repurposing Existing Therapeutics)

60

## Research interest areas:

- Testing a publicly posted therapeutic candidate for use to treat COVID-19. Examples include clinical candidate therapeutics in documents publicly posted by the World Health Organization ([types/classes of candidate therapeutics](#)) and ([candidates for clinical evaluation](#)).
- Testing a candidate therapy to treat COVID-19 that was already identified with a publicly available computational approach.
- Testing of existing therapeutic candidates that work on mechanistic targets shared among other viruses that may be relevant to SARS-CoV-2.

# NCATS – NOT-TR-20-012 (Repurposing Existing Therapeutics)

**Must apply to and follow guidelines of the following FOAs:**

Activity Codes	FOA Title	Applicable Dates
UG3/UH3	<a href="#">PAR-17-465</a> : Bench Testing Therapeutic/Indication Paring Strategies (UG3/UH3)	Applicable Receipt Date: •June 26, 2020
U34	<a href="#">PA-18-462</a> :Clinical Trial Planning: Therapeutic/Indication Pairing Strategies (U34) (Clinical Trial Not Allowed)	Applicable Receipt Date: •June 16, 2020 •October 16, 2020
U01	<a href="#">PAR-18-332</a> : Clinic Testing Therapeutic/Indications Pairing Strategies (U01 Clinical Trial Required)	Applicable Receipt Dates: •June 5, 2020 •October 5, 2020

# NIAID – NOT-AI-20-034 (Emergency Competitive Revisions)

62

## Research Objectives

- Studies to identify optimal *in vitro* culture requirements and conditions;
- Development of reagents and assays for virus characterization;
- Studies to understand critical aspects of viral infection, replication, pathogenesis, and transmission;
- Studies to identify viral epitopes critical for binding neutralization;
- Studies to examine virus stability and persistence;
- Production of molecular clones of SARS-CoV-2, reporter viruses and recombinant viral proteins;

# NIAID – NOT-AI-20-034 (Emergency Competitive Revisions)

63

## Research Objectives

- Development of animal models of SARS-CoV-2 infection suitable for screening vaccine and therapeutic candidates and/or pathogenesis studies;
- Studies on the evolution and emergence of SARS-CoV-2 viruses including the identification of factors that affect viral host-range and virulence;
- Virologic and serologic surveillance studies of the distribution and natural history of SARS-CoV-2 viruses in animal populations and in humans at the human/animal interface with particular emphasis on host reservoirs and understanding cross-species transmission events;
- Development of sensitive, specific, and rapid clinical diagnostic tests for SARS-CoV-2;

# NIAID – NOT-AI-20-034 (Emergency Competitive Revisions)

64

## Research Objectives

- Development of SARS-COV-2 therapeutic candidates; broad-spectrum therapeutics against multiple coronavirus strains; examination of SARS-CoV-2 antiviral activity of existing or candidate therapeutics initially developed for other indications;
- Identification and evaluation of the innate, cellular and humoral immune responses to SARS-CoV-2 infection and/or candidate vaccines, including, but not limited to: cross-reactive antibodies from individuals exposed to SARS-CoV-2 and other coronaviruses; viral epitopes critical for antibody binding and neutralization; immune-mediated pathology or host factors that might predispose to severe infection; and
- Development of SARS-CoV-2 vaccine candidates that include emerging antigen design strategies, novel platforms or delivery approaches, adjuvants, or assessing cross-neutralization potential of SARS-CoV vaccine candidates.



# NIAID – NOT-AI-20-034 (Emergency Competitive Revisions)

## Requirements:

- The Research Strategy section of the application is limited to 6 pages.
- The award project period of the Competitive Revision must not exceed two years.
- Application budgets should not exceed the annual amount of the current parent award and should reflect the actual needs of the proposed project. Exceptions will be considered on a case-by-case basis.
- The parent award must be active when the application is submitted. The project and budget periods should generally be within the currently approved project period for the existing parent award. Exceptions will be considered on a case-by-case basis.
- Apply to: [PA-20-135](#); Emergency Competitive Revision to Existing NIH Awards (Emergency Supplement - Clinical Trial Optional)

# NIGMS – NOT-GM-20-025 (Urgent Competitive Revisions)

## Research Objectives

- NIGMS will accept the submission of applications for Competitive Revisions to active grants to address only the following research areas of interest:
- Incorporation of data related to SARS-CoV-2 into ongoing research efforts to develop predictive models for the spread of SARS-CoV-2 and other related infectious agents (all relevant grants).
- Repurposing or modification of diagnostic tools currently under development to enable rapid detection of SARS-CoV-2 infection (SBIR/STTR grants only).
- Rapid development of potential therapeutic agents for COVID-19 (SBIR/STTR only).

# NIGMS – NOT-GM-20-025 (Urgent Competitive Revisions)

## Requirements:

- The Research Strategy section of the application is limited to 6 pages.
- The award project period of the Competitive Revision must not exceed one year.
- Application budgets are limited to no more than the amount of the current parent award, and must reflect the actual needs of the proposed project.
- Apply to: [PA-18-935](#) "Urgent Competitive Revision to Existing NIH Grants and Cooperative Agreements (Urgent Supplement - Clinical Trial Optional)"

# NIGMS – NOT-GM-20-025 (Urgent Competitive Revisions)

68

## Considerations:

- Urgency and significance of research: How will successful completion of the aims contribute to or complement public health efforts for the control of SARS-CoV-2 infection and related pathogenic processes? Does the proposed research fit within the mission of an urgent response to provide critical expertise, resources or activities?
- Feasibility of research: Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Is the urgent time frame feasible for the proposed research? Are the PD/PIs, collaborators, and other researchers well suited and appropriate to carry out the project?

# NCATS – NOT-TR-20-011 (CTSAs to Address COVID-19 Public Health Need)

69

## Research Interest Areas:

- Use of informatics solutions to diagnose cases and the use of CTSA-supported core resources (e.g., advanced scientific instruments, highly-specialized facilities, and regulatory expertise) to facilitate research on COVID-19 and advance the translation of research findings into diagnostics, therapeutics, and vaccines.

# NCATS – NOT-TR-20-011 (CTSAs to Address COVID-19 Public Health Need)

70

**Must apply to and follow guidelines of the following FOAs:**

Activity Codes	FOA Title	Applicable Dates
UL1, U01, R21	<a href="#">PA-18-591</a> - Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional)	Applicable Receipt Dates: <ul style="list-style-type: none"><li>•May 4, 2020</li><li>•November 2, 2020</li></ul>
U01	<a href="#">PAR-19-099</a> - Limited Competition: Clinical and Translational Science Award (CTSA) Program: Collaborative Innovation Award (U01 Clinical Trial Optional)	Applicable Receipt Dates: <ul style="list-style-type: none"><li>•July 10, 2020</li><li>•November 9, 2020</li><li>•March 8, 2021</li><li>•July 9, 2021</li></ul>
R21	<a href="#">PAR-19-100</a> - Limited Competition: Clinical and Translational Science Award (CTSA) Program: Exploratory Collaborative Innovation Awards (R21 Clinical Trial Optional)	Applicable Receipt Dates: <ul style="list-style-type: none"><li>•July 10, 2020</li><li>•November 9, 2020</li><li>•March 8, 2021</li><li>•July 9, 2021</li></ul>
UL1	<a href="#">PAR-19-337</a> - Limited Competition: Competitive Revision Awards for the Clinical and Translational Science Award (CTSA) Program (U54 Clinical Trial Optional).	Applicable Receipt Date: <ul style="list-style-type: none"><li>•September 25, 2020</li></ul>

# NIDA – NOT-DA-20-047 (Supplements and Revisions)

71

## Research Objectives:

- Research to determine whether substance use (especially smoking tobacco or marijuana, vaping, opioids and other drug use) is a risk factor for the onset and progression of COVID-19.
- Research on how HIV among persons who use substances may impact the onset and progression of COVID-19.
- Research to understand system-level responses to COVID-19 prevention and risk mitigation in secure settings such as prisons and jails, with a particular emphasis on detainees with substance use disorder (SUD). For example:
  - Interactions of COVID-19 treatment with SUD treatments, including medications for opioid use disorders
  - Strategies for integrating COVID-19 and other infectious disease screening, prevention, and treatment protocols with SUD treatment and other health services.

# NIDA – NOT-DA-20-047 (Supplements and Revisions)

72

## Research Objectives:

- Research to understand the respiratory effects of SARS-CoV-2 infection among individuals with substance use disorders (SUD); in particular those with nicotine, marijuana, opioid, and methamphetamine use disorders.
- Research to understand how the respiratory effects of COVID-19 influences the rate of opioid overdoses both in pain patients as well as patients with an opioid use disorders and also to assess how it influences the outcomes for naloxone interventions for overdose reversal
- Research to develop therapeutic approaches for comorbid SARS-CoV-2 infection and SUDs.
- Research to evaluate drug-drug interaction of medications to treat SARS-CoV-2 and substances of abuse or medications to treat SUDs.



# NIDA – NOT-DA-20-047 (Supplements and Revisions)

73

## Research Objectives:

- Research to understand system- or organizational-level responses to identify, prevent, or mitigate the impact of COVID-19 in service settings that serve vulnerable populations, including people who are homeless or unstably housed.
- Research to understand and mitigate the impact of COVID-19 in methadone treatment programs and syringe exchange services.
- Research on how potential overcrowding of emergency departments and health services will impact the treatment of opioid overdoses and of opioid use disorder
- Research using ongoing studies to understand the broad impacts of COVID-19 (e.g., school closures, food insecurity, anxiety, social isolation, family loss) on neurodevelopment, substance use, substance use disorders, and access to addiction treatment.

# NIDA – NOT-DA-20-047 (Supplements and Revisions)

74

## Requirements:

- The Research Strategy section of the application is limited to 6 pages.
- The award project period of the submission must not exceed two years.
- Application budgets are generally limited to no more than \$100,000 direct costs per year.
- Apply to:
  - [PA-18-935](#) Urgent Competitive Revision to Existing NIH Grants and Cooperative Agreements (Urgent Supplement - Clinical Trial Optional)
  - [PA-18-591](#) Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional)

# NHLBI – NOT-HL-20-757 (Supplements and Revisions)

75

## Research Interest Areas:

- 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

# NHLBI – NOT-HL-20-757 (Supplements and Revisions)

76

## Research Interest Areas:

- 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

# NHLBI – NOT-HL-20-757 (Supplements and Revisions)

77

## Research Interest Areas:

- 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

# NHLBI – NOT-HL-20-757 (Supplements and Revisions)

78

## Requirements:

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

## Questions?

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