COVID-19 and NIH-Funded Research

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I am an NIH employee. The opinions expressed are not necessary those of NHLBI or NIH
Discussion Points

- Effect of the COVID-19 pandemic on:
  - Previously NIH-funded research
  - New NIH-funded research on COVID-19
- Other COVID-19 related resources
- NHLBI-specific opportunities

https://coronavirus.jhu.edu/map.html
Working from Home. Together.
Preserving the Biomedical Enterprise
Patient Care and Researcher Safety is the First Priority

NIH is Open for Business
- The grant process continues as normal but with some flexibilities
- Working to provide funding opportunities to support COVID-19 research

Application Deadlines (NOT-OD-20-091)
- Late applications were accepted through May 1 for deadlines between March 9 and May 1.
- No justification for the late submission needed
- FOAs expiring within this time period will be extended

Human and Animal Research Affected by COVID-19 (NOT-OD-20-087; NOT-OD-20-088)
- Establish protective measures with IRB and institutions to ensure the safety of participants and staff
- Flexibility with project extensions and unanticipated costs

NIH is providing multiple administrative flexibilities to support the research community

Supporting NIH Grantees During Rapidly Evolving Circumstances

Salaries & Stipends (NOT-OD-20-086)
- Salaries and stipends may be charged to NIH grants if unable to work on grant/training activities
- Prior approval is not required to divert faculty from research to clinical work related to COVID-19 during this emergency period

Administrative Flexibilities (NOT-OD-20-086)
NIH is allowing:
- Pre-award costs to be incurred
- Extensions of post-award reporting
- Prior approval requirement waivers
- Numerous flexibilities regarding expenditures of funds

Accommodations for Loss of Research Time
- Extensions for early stage investigator eligibility
- Extend time constraints for fellowship, career development, and training awards

COVID-19 is an emerging, rapidly evolving situation.

Get the latest public health information from CDC: https://www.coronavirus.gov
Get the latest research information from NIH: https://www.nih.gov/coronavirus

SIGN UP for updates from NIH

https://www.nih.gov/health-information/coronavirus

Resources from NIH
- Information for NIH Applicants and Recipients (Grants & Funding)
- COVID-19 Social Media Resources
- Clinical Trials Related to COVID-19 listed on ClinicalTrials.gov
- Rising to the COVID-19 Challenge: Rapid Acceleration of Diagnostics (RADx) (NIH Director's Blog)
- Coping with the Crisis of Public Health Crises: COVID-19 and Substance Use Disorders
- The Challenge of Tracking COVID-19's Stealthy Spread (NIH Director's Blog)
- Building Safe and Effective Critical Tools for COVID-19

New NIH Funding Opportunities Related to COVID-19

- New COVID-19-related NIH Funding through competing supplements, administrative supplements, new awards – through many NIH ICs, NIH Common Fund

Many opportunities listed on Coronavirus Disease 2019 (COVID-19): Information for NIH Applicants and Recipients of NIH Funding website
NIH COVID-19 Knowledge Hub: Tracking the Most Recent Literature

LitCovid is a curated literature hub for tracking up-to-date scientific information about the 2019 novel Coronavirus. It is the most comprehensive resource on the subject, providing a central access to ~4000 (and growing) relevant articles in PubMed. The articles are updated daily and are further categorized by different research topics and geographic locations for improved access. You can read more at Chen et al. Nature (2020) and download our data here.

Comprehensive, freely available library of machine-readable coronavirus literature
Open-access Data and Computational Resources to Address COVID-19

<table>
<thead>
<tr>
<th>Resource</th>
<th>Description</th>
<th>Data Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Broad Terra cloud commons for pathogen surveillance</td>
<td>The Broad Terra cloud workspace for best practices with COVID-19 genomics data</td>
<td>genomics</td>
</tr>
<tr>
<td>ClinicalTrials.gov COVID-19 related studies</td>
<td>View listed clinical studies related to the coronavirus disease (COVID-19). Studies are submitted in a structured format directly by the sponsors and investigators conducting the studies. Submitted study information is generally posted on ClinicalTrials.gov within 2 days after initial submission and site content is updated daily. Full website content is also available through the API.</td>
<td>clinical studies</td>
</tr>
<tr>
<td>CORD-19: COVID-19 Open Research Dataset and AI Challenge</td>
<td>Freely available dataset of 45,000 scholarly articles, including over 33,000 with full text, on COVID-19, SARS-CoV-2, and related coronaviruses. This machine-readable resource is provided to enable the application of natural language processing and other AI techniques.</td>
<td>literature</td>
</tr>
</tbody>
</table>

- Sources include federal agencies, public consortia, private entities & other organizations.
- These resources are freely available and will expand as more information becomes available.

https://datascience.nih.gov/covid-19-open-access-resources

Comorbidities Driving COVID-19 Risk and Mortality are Relevant to the NHLBI Portfolio

Higher risk of severe COVID-19 disease correlates with underlying health conditions such as chronic lung disease, diabetes mellitus, and cardiovascular disease

<table>
<thead>
<tr>
<th>Underlying Condition</th>
<th>% Total #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>49.7</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>28.3</td>
</tr>
<tr>
<td>Chronic lung disease</td>
<td>34.6</td>
</tr>
<tr>
<td>Asthma</td>
<td>17.0</td>
</tr>
<tr>
<td>COPD</td>
<td>10.7</td>
</tr>
<tr>
<td>Cardiovascular disease</td>
<td>27.8</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>14.2</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>6.8</td>
</tr>
</tbody>
</table>

Adapted from https://www.cdc.gov/mmwr/volumes/69/wr/mm6913e2.htm

NHLBI Response to COVID-19

https://www.nhlbi.nih.gov/coronavirus

NHLBI Information & Resources on COVID-19

During this rapidly evolving situation and time of great uncertainty, the NHLBI shares concerns about the pandemic. We are working hard to support necessary research that will answer key questions aimed at keeping people healthy. For additional information on NHLBI’s efforts, read the blog from Gary H. Gibbons, M.D., director of NHLBI. Bookmark this page and return to it for updates on NHLBI COVID-19 activities. For questions and ideas regarding NHLBI’s COVID-19 related activities, email us at nhlbiformnhlbi.nih.gov.

FOR RESEARCHERS
FOR PRACTICING CLINICIANS
FOR THE PUBLIC

NHLBI’s COVID-19 Guidance for Researchers

What is NHLBI’s strategy for research in response to the COVID-19 crisis?

NHLBI’s mission is to support research that prevents, treats, and cures heart, lung, blood, and sleep disorders.

What kinds of NHLBI funding opportunities are available for COVID-19 research?

NHLBI has opened the following Notices of Special Interest:

- **NHLBI COVID-19 Research Opportunities:** NHLBI will fund studies that can be completed in a short period of time to address the COVID-19 pandemic.
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https://www.nhlbi.nih.gov/coronavirus

- **U.S. first case**
  - Jan 2020

- **NOT-HL-20-757**
  - NOSI for Administrative Supplements supporting COVID-19 research
  - March 17

- **RCT Roundtable**
  - Prioritize and identify candidate interventions
  - March 25

- **NOT-OD-20-097**
  - NOSI for Administrative Supplements and Urgent Competitive Revisions
  - Behavioral and Social Sciences
  - April 13

- **NOT-HL-20-782**
  - NOSI to support Phase I – III COVID-19 clinical trials
  - April 27

- **OTA-20-011**
  - Phase IIb – III Clinical Trials for COVID-19
  - April 29

- **April 3**
  - Acute Care & Longitudinal Studies Roundtable

- **May 2020**
Solicitations Cover the COVID-19 Research Domains

<table>
<thead>
<tr>
<th>Solicitation Mechanism</th>
<th>Type of Research</th>
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<tbody>
<tr>
<td><strong>NOSI Adm Supp/Comp Rev</strong></td>
<td>Supporting Basic → Preclinical → Clinical Research</td>
</tr>
<tr>
<td><strong>NOSI Adm Supp/Comp Rev</strong></td>
<td>Phase I – IIA Clinical Trials</td>
</tr>
<tr>
<td><strong>Other Transaction Authority (OTA)</strong></td>
<td>Phase IIb – III Clinical Trials</td>
</tr>
<tr>
<td><strong>NOSI Adm Supplements</strong></td>
<td>Behavioral and Social Sciences</td>
</tr>
<tr>
<td><strong>Upcoming</strong></td>
<td>Cohort and other Longitudinal Studies, Community-based Interventions</td>
</tr>
</tbody>
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Note: NHLBI Scientific Program Staff indicated in solicitations

Deadline: May 15, 2020
NHLBI COVID-19 Clinical Research Portfolio: Intervention Targeting the Spectrum of Clinical Presentations

Passive Immunization/Neutralizing Antibodies

Antithrombotic

Anti-Inflammatory/Immunomodulatory

RAAS Interventions

Anti-Viral

Observational

COVID-19+ Progression

Prevention → Outpatient Asymptomatic → Outpatient Symptomatic → Emergency Department → Hospital Vent / CPAP-free → Hospital ICU → Convalescence → Recovered

Prioritizing Coordinated Action: An NHLBI network of networks
Prioritizing NIH Support for Coordinated Action on COVID-19 Diagnostics and Therapeutic Interventions

NIH-funded Clinical Trials Recruiting
ORCHID Trial: Hydroxychloroquine
COLCORONA Trial: Colchicine

NIH Rapid Acceleration of Diagnostics (RADx) Initiative for COVID-19
NATIONAL CALL FOR INNOVATIVE TECHNOLOGIES
PHASE 0: "Dark tank": Use Rapid Selection Process
PHASE 1: Validation and Risk Review
PHASE 2: Clinical Tests, Regulatory Approval, and Scaling Up
END OF SUMMER/FALL 2020
Rolling Submissions and Selections Begin April 28, 2020

https://www.poctrn.org/radx
Be well, Stay well!

NIH nih.gov
NHLBI nhlbi.nih.gov

https://icite.od.nih.gov/covid19/search/
https://www.nih.gov/health-information/coronavirus
https://datascience.nih.gov/covid-19-open-access-resources