The Impact of COVID-19 on Conducting and Building a Career in Aging Research

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House Keeping

- All lines are muted
- Have a question? Enter in the Q&A box at the bottom of the screen
- Rolling – we will be recording...
The Impact of COVID-19 on Conducting and Building a Career in Aging Research

Clinician Scientists Transdisciplinary Aging Research (Clin-STAR) Program
2020 Annual Meeting - Virtual
November 17-18

Kenneth Santora, PhD
Director, Division of Extramural Activities
National Institute on Aging
COVID-19 and Older Adults

• Among adults, the risk for severe illness from COVID-19 increases with age, with older adults at highest risk.

• **8 out of 10 COVID-19 deaths** reported in the US have been in **adults 65 years old or older**.
  
  • **42 percent** of U.S. COVID-19 deaths have occurred in **nursing homes** and assisted living facilities

• Race and ethnicity are risk markers for other underlying conditions that impact health — including socioeconomic status, access to health care, and increased exposure to the virus due to occupation.
  
  • Black/African American: 2.6x cases/4.7x hospitalization/2.1x deaths
  • Hispanic/Latino: 2.8x cases/4.6x hospitalization/1.1x deaths
The COVID19 crisis has magnified the issues plaguing academic science, but it has also provided the scientific establishment with an unprecedented opportunity to reset. Shoring up the foundation of academic science will require a concerted effort between funding agencies, universities, and the public to rethink how we support scientists, with a special emphasis on early career researchers.
Congressional Response to the COVID-19 Crisis: Appropriations

• To date, NIH has received \textbf{$3.59$ billion} in supplemental appropriations for COVID-19 from the following:
  
  
  

• These funds are intended to facilitate a \textbf{rapid scientific response} to the COVID-19 emergency.
NIH’s Response to the COVID-19 Crisis: Funding Opportunities

• Across NIH, special funding announcements known as Notices of Special Interest (NOSIs) have been generated in response to the COVID-19 crisis.

• Goal is to expedite review of applications and distribution of funds to assist in COVID-19 research.


• NIA’s NOSI and other COVID-19-related funding opportunities and resources available here: https://www.nia.nih.gov/research/grants-funding/nia-covid-19-response
Stay Up to Date

• This is a rapidly evolving situation
• Keep Checking for updates:
  • Check for NIH and NIA Notices
  • Check the NIH and NIA Websites

• NIH: https://grants.nih.gov/policy/natural-disasters/corona-virus.htm
RADx-UP Notice of Special Interest

• RAPID ACCELERATION OF DIAGNOSTICS (RADX)
  https://www.nih.gov/research-training/medical-research-initiatives/radx

• bring their innovative ideas for new COVID-19 testing approaches and strategies
Rapid Acceleration of Diagnostics (RADx)

RADx Tech ($500M): Highly competitive, three-phase challenge to identify, at an accelerated pace, the best candidates for at-home or point-of-care tests for COVID-19.

RADx Underserved Populations (RADx-UP; $500M): Community-engaged projects focused on implementation strategies to enable and enhance COVID-19 testing in underserved and vulnerable populations.

RADx-Radical (RADx-Rad; $200M): Development and advancement of novel, non-traditional testing approaches or new applications of existing approaches.

RADx Advanced Technology Platforms (RADx-ATP; $230M): Rapid scale-up of advanced technologies to increase testing pace and enhance/validate throughput; creation of ultra-high throughput machines and facilities.

Data Management Support ($70M): Building an infrastructure to support coordination of the data management needs of COVID-19 efforts.
NIA NOSI: COVID-19 Supplements


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

- Awarded over 140 Administrative and Revision supplements
- Will expire soon (Dec 1, 2020)
- Still encourage to apply for COVID-related research via normal channels
  - (Parent FOAs)
  - Talk with your Program Officer!
NIA PAR: Multi-Site COVID Clinical Trials


Funding Opportunity Title
NIA Multi-site COVID-19 Related Clinical Trial Implementation Grant on Aging-Related Topics in at-risk Older Adult Populations (R01 Clinical Trial Required)

Activity Code
R01 Research Project Grant

Funding Opportunity Announcement (FOA) Number
PAR-20-234

Companion Funding Opportunity
PAR-19-302 - NIA Multi-site Clinical Trial Implementation Grant (R01 Clinical Trial Required)

Funding Opportunity Purpose
This Funding Opportunity Announcement (FOA) invites applications for implementation of investigator-initiated multi-site clinical trials (all phases or stages) of interventions focused on specific aging-related issues to reducing transmission, risk, morbidity, mortality, severity, or complications of Coronavirus Disease 2019 (COVID-19). Applications on the following priority topics are invited:

[Further details are provided but not transcribed here for brevity.]
## NIA participation FOAs/NOSIs

<table>
<thead>
<tr>
<th>Topic</th>
<th>FOA ID</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional)</td>
<td>RFA-OD-19-029</td>
<td>27-Nov-21</td>
</tr>
<tr>
<td>Notice of Special Interest (NOSI) regarding the Availability of Urgent Competitive Revisions and Administrative Supplements for Research on Coronavirus Disease 2019 (COVID-19) in Individuals with Down Syndrome for the INCLUDE Project</td>
<td>NOT-OD-20-129</td>
<td>1-Dec-20</td>
</tr>
<tr>
<td>Notice of Special Interest (NOSI): Competitive and Administrative Supplements for the Impact of COVID-19 Outbreak on Minority Health and Health Disparities</td>
<td>NOT-MD-20-019</td>
<td>1-Dec-20</td>
</tr>
<tr>
<td>Notice of Special Interest (NOSI) regarding the Availability of Administrative Supplements and Urgent Competitive Revisions for Mental Health Research on the 2019 Novel Coronavirus</td>
<td>NOT-MH-20-047</td>
<td>1-Dec-20</td>
</tr>
<tr>
<td>Notice of Special Interest (NOSI) regarding the Availability of Administrative Supplements and Urgent Competitive Revisions for Research on the 2019 Novel Coronavirus and the Behavioral and Social Sciences</td>
<td>NOT-OD-20-097</td>
<td>1-Dec-20</td>
</tr>
<tr>
<td>Digital Healthcare Interventions to Address the Secondary Health Effects Related to Social, Behavioral, and Economic Impact of COVID-19 (R01 - Clinical Trial Optional)</td>
<td>PAR-20-243</td>
<td>3-Mar-21</td>
</tr>
<tr>
<td>Notice of Special Interest (NOSI): Digital Healthcare Interventions to Address the Secondary Health Effects Related to Social, Behavioral, and Economic Impact of COVID-19</td>
<td>NOT-MH-20-053</td>
<td>1-Dec-20</td>
</tr>
<tr>
<td>Notice of Special Interest (NOSI): Competitive and Administrative Supplements for Community Interventions to Reduce the Impact of COVID-19 on Health Disparity and Other Vulnerable Populations</td>
<td>NOT-MD-20-022</td>
<td>1-Dec-20</td>
</tr>
<tr>
<td>Community Interventions to Address the Consequences of the COVID-19 Pandemic among Health Disparity and Vulnerable Populations (R01- Clinical Trial Optional)</td>
<td>PAR-20-237</td>
<td>2-Dec-20</td>
</tr>
</tbody>
</table>
COVID-19 and Older Adults

Related Policies to Mitigate COVID-Affected Grants
Patient Care and Researcher Safety is the First Priority

• The NIH is deeply concerned for the health and safety of people involved in NIH research, and about the effects of the COVID-19 public health emergency on the biomedical enterprise.

• NIH is providing many administrative flexibilities to help the research continue.

• Recipients must report any effects on the NIH funded research in their next RPPR submission.
Accommodations for Loss of Research Time

• Extensions for Early Stage Investigator eligibility due to COVID-19-related disruptions will be considered
  • ESI extension request: [ESI Extension Request online help](https://example.com)
• NIH will be flexible with extending time constraints for fellowship, career development, and training awards, including phased awards
• Temporary Extension of Eligibility for the NIH K99/R00 Pathway to Independence Award During the COVID-19 Pandemic [NOT-OD-20-158](https://example.com)
  • two-receipt cycle extension of eligibility
  • submission of a K99/R00 application from the June/July 2020 through the February/March 2021 due dates
• FAQs: [grants.nih.gov/faqs#/covid-19.htm](https://example.com)
Scientific Review

• Reviewers should assume that problems arising from the COVID-19 pandemic will be resolved and complications related to COVID-19 should not affect their scores.

• Contingency plans will not be considered in peer review but, if needed, COVID-19 contingency plans will be requested and carefully considered by NIH staff, before funding.

• NOT-OD-20-163 — Extending the Special Exception to the NIH/AHRQ/NIOSH Post-Submission Material Policy During the COVID-19 Pandemic
  • submit 1 page preliminary data as post-submission materials for applications submitted for the January 2021 council round has been extended to apply to the May 2021 council round

• Late Applications:
  • CSR reviewed applications; NO extensions due to COVID
  • IC reviewed applications: case by case; but NO extensions
Salaries & Stipends

- Recipients must exhaust other available funding sources to sustain its workforce and implement necessary steps to save operational costs to preserve Federal funds for grant supported activities.

- Considerations by ICs on a case by case basis:
  - Prior approval requests for delayed report submission
  - Second/third no-cost extensions
  - Carry over requests

- Effective October 1, 2020, the flexibility for recipients to continue charging salaries and benefits to active NIH awards has ended.
  - Any requests after that date will be considered by the funding IC on a case by case basis.
  - must maintain appropriate records and cost documentation in order to substantiate the charging of any salaries.
Related Policies to mitigate COVID-affected grants

• Exceptions to Use of a Single IRB During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency NOT-OD-21-006
  • ongoing or initially reviewed by the IRB may request an exception
  • Other Attachments section of the Research & Related Other Project Information form

• R13: Conference grants
  • Case by case: NCE for one year
  • re-budget costs for allowable grant activities within the scope of the award. This includes costs to support virtual meetings.

• Charging Personal Protective Equipment (PPE) to NIH Grants and Cooperative Agreements as Direct Costs https://nih-extramural-intranet.od.nih.gov/d/node/9884
  • allow for direct charging PPE costs on awards involving CT and CR
Guidance on Human Research Affected by COVID-19

• Ensure the safety of all human participants and research staff involved in clinical trials and human subject studies

• Consult with IRBs and institutions about protective measures, such as:
  • Limiting study visits to those needed for participant safety or coincident with clinical care
  • Conducting virtual study visits
  • Implementing flexibilities for required laboratory tests or imaging needed for safety monitoring

• NIH will be flexible regarding project extensions and accommodating unanticipated costs

• Learn more: NOT-OD-20-087
NIA Priority: Train up the next generation of Aging researchers
## Interim Pay Lines at the Continuing Resolution Funding Level

<table>
<thead>
<tr>
<th>CSR-Reviewed Research Applications</th>
<th>General Payline, &lt;$500K</th>
<th>General Payline, =&gt;$500K</th>
<th>AD/ADRD Payline, &lt;$500K</th>
<th>AD/ADRD Payline, =&gt;$500K</th>
</tr>
</thead>
<tbody>
<tr>
<td>All applications except as noted below</td>
<td>8%</td>
<td>5%</td>
<td>25%</td>
<td>25%</td>
</tr>
<tr>
<td>N.I. R01s</td>
<td>11%</td>
<td>8%</td>
<td>28%</td>
<td>28%</td>
</tr>
<tr>
<td>E.S.I. R01s</td>
<td>13%</td>
<td>10%</td>
<td>30%</td>
<td>30%</td>
</tr>
</tbody>
</table>

**New Investigator (N.I.):** An applicant who has not received a prior R01 award or its equivalent.

**Early-Stage Investigator (E.S.I.):** A new investigator who is within 10 years of finishing research training.

**AD/ADRD:** Research on Alzheimer's disease and Alzheimer’s disease-related dementias.
## Interim Pay Lines at the Continuing Resolution Funding Level

<table>
<thead>
<tr>
<th>NIA-Reviewed Applications (Impact Score)</th>
<th>General Pay Line</th>
<th>AD/ADRD Pay Line</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program projects</td>
<td>15</td>
<td>37</td>
</tr>
<tr>
<td>Other NIA-reviewed research</td>
<td>15</td>
<td>37</td>
</tr>
<tr>
<td>Career development awards</td>
<td>18</td>
<td>35</td>
</tr>
<tr>
<td>Fellowship awards</td>
<td>20</td>
<td>40</td>
</tr>
</tbody>
</table>
Definitions:

- **Early Stage Investigator (ESI):** A PD/PI who has completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years and who has not previously competed successfully as PD/PI for a substantial NIH independent research award.
  - R01-equivalent grants are defined as activity codes DP1, DP2, DP5, R01, R23, R29, R37, R56, RF1, RL1, U01
- **New Investigator (NI):** An investigator who has not previously competed successfully for substantial, independent funding from NIH.
- **Eligibility:** Always read the eligibility criteria in the FOA; especially in Career and Fellowship Grants (Ks/Fs)
NIA and NIH Opportunities

• Always Contact your Program Officer!! (Research Contact)
• List: NIA sponsored FOAs
  • 60+ NIA sponsored Active FOAs
  • 306 Active FOAs and NOSI NIA sponsor/signed on
  • https://www.nia.nih.gov/research/grants-funding
  • Check for RFA, PA, PAR, PAS and NOSI
• NACA Approved Concepts: (NIA Council)
  • https://www.nia.nih.gov/approved-concepts
• Search for FOAs by key word
  • https://grants.nih.gov/funding/index.htm
• Subscribe
  • Weekly NIH Guide to Grants and Contracts
  • https://grants.nih.gov/grants/guide/listserv_dev.htm
NIH Pathway to Independence Award (PA-20-188)

• **K99/R00:**
  • An attractive transition award which has the highest number of career development award applications at NIA.
  • Two phase award (2+3 years)
  • 4 years postdoctoral training eligibility window
  • R00 phase has specific requirements (tenure-track or equivalent position, start up package...)
  • R00 and K99 transition is not automatic and must be continuous. Submit transition application 2-6 months ahead of time.
Mentored Research Scientist Development Award (Parent K01 - Independent Clinical Trial Not Allowed)

• **K01:**
  • A five-year award, second most applied K award
  • Allow senior postdocs to apply
  • By the time of the award you must hold an academic position. Postdoc is not academic position.
  • Must be U.S. Citizen/Permanent resident by the time of the award.
Resources:

• **NIA Training and Career Development:**
  https://www.nia.nih.gov/research/training

• **NIA New and Early Stage Investigators**

• **NIA Grants & Funding**
  • https://www.nia.nih.gov/research/grants-funding

• **Sample Applications:**
  https://www.niaid.nih.gov/grants-contracts/sample-applications
NIA Diversity Initiatives:

• Aging Research Dissertation Awards to Increase Diversity (R36 Clinical Trial Not Allowed) PAR-19-394

• Examining Diversity, Recruitment and Retention in Aging Research (R24 Clinical Trial Not Allowed) PAR-18-749

• Research Supplements to Promote Diversity in Health-Related Research (Admin Supp - Clinical Trial Not Allowed) PA-20-222

• Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research (Parent F31 -Diversity) PA-19-196

• Butler-Williams Scholars Program
Ways to Stay Informed and Connected

Search all active NIA funding opportunities:  
https://www.nia.nih.gov/research/funding

Review the latest approved concepts:  
https://www.nia.nih.gov/approved-concepts

Subscribe to our blog and stay up to date on the latest NIA news:  
https://www.nia.nih.gov/research/blog
Questions?
Starting a Pragmatic Trial in a Pandemic

Karen P. Alexander MD
Professor Medicine/Cardiology
Duke University Medical Center/ DCRI
PI, PREVENTABLE Trail
PREVENTABLE

• NIA and NHLBI – U19 mechanism (Sept 20, 2019 NOA)
  – 60.2 million directs over 7 years
• 20,000 participants age 75+
• Site face to face only at baseline (no in-person site visits)
  – Follow patients by health records, phone, site-less follow up
    (Hawthorne Effect)
  – Mail Study drug direct to participant
Study Design

Participants will:
• Be followed through yearly phone calls for close to four years.
• Receive cognitive and physical function testing at screening, over the phone, and at home, if triggered.
• Have health records queried for outcomes
• Receive home delivery of study drug.

Randomization

Age 75+ without CVD, dementia or disability
(N = 20,000)

Atorvastatin 40mg

Placebo (4-year follow-up)

Survival w/o dementia or persisting disability

CV composite (CV death, MI, HF, Stroke/TIA) or MCI/dementia
Study Sites
Approximately 90 sites from PCORnet (non-VA) and BVARI (VA) will participate.
PREVENTABLE
Starting a Clinical Trial in a Pandemic

- Grant NOA
- DSMB Protocol #1
- IRB Protocol #1
- DSMB Protocol #2
- IRB Protocol #2
- COVID Admin Supplement
- 1st Site Activated
- 1st Participant Enrolled

- COVID
- Start Up
- Research Curtailed
- Focus on COVID

- 2019
- 2020

- Sept
- Dec
- Feb
- Mar
- April
- May
- June 10
- Sept
PREVENTABLE – Study Start Up Timeline

**JUNE**
- DSMB Approval of MOP, COVID admin supplement, mods based on COVID
- Site sIRB reliance begins
- V 0.1 Manual of Procedures (MOP) Launch
- Study Materials Translated

**JULY**
- Data Collection Forms (DCF) Reviewed
- CAQ Distributed to Sites
- V 1.0 Manual of Procedures (MOP)
- Site sIRB Approvals

**AUGUST**
- Data Collection Forms Final
- Site Contracts Executed
- Study Drug Ready
- Sites Activated
- Initial Site Training Early August

**SEPTEMBER**
- First Participant Enrolled
- Site Starter Kits Sent (IPAD, Barcode Scanner, Recruitment Material, Lab and Biorepository Supplies)

**Events**
- Early Sites Protocol Field Review
PREVENTABLE COVID-19 Contingency

COVID-19 Ready

- Direct Drug Shipment
- eConsent Enabled
- Remote Only Follow up
- Contract group in-home ready (HE)
- Good timing to address COVID-19
  - Statins – CV risk and anti-inflammatory

Watch List

- Clinical Care Still Virtual
- Site Limitations (IRB and start up)
- Hiring limitations?
- Drug Procurement delay
- Participants allow HE in their home
- Supply challenges - plastics for bottles, USPS continuance
COVID-19 Administrative Supplement Aims

Aim 1: *Epidemiology* Determine the prevalence and severity of SARS-CoV-2 infection among adults ≥75 years old in the PREVENTABLE study.
We will perform SARS-CoV-2 serological testing at enrollment and 3 months after enrollment to measure seropositive and seronegative status of participants to determine the prevalence of infection and immunological resilience. We will measure the severity of COVID-19 illness using a validated symptom severity questionnaire. Seropositive individuals will additionally have health records reviewed for hospitalization, length of stay, need for intensive unit care, non-invasive and invasive mechanical ventilation, and post-acute care. Among seropositive participants, we will use principal components analysis with these variables to generate a recovery score reflecting recovery from documented COVID-19 infection.

Aim 2: *Severity of illness* Identify clinical predictors of resilience to COVID-19 infection. Using regression analysis we will identify demographic factors, comorbidities, medication use (RAS inhibitors, Non-Steroidal Anti-Inflammatory Drugs), functional, and environmental factors associated with the recovery score. We will also determine associations between the recovery score and genetic variants, especially those that affect RAS activity and immune function.

Aim 3: *Recovery Differential* Identify biologic factors associated with higher or lower than expected resilience to COVID-19 infection. Using the regression model defined above, we will calculate the difference between each participant’s actual recovery score and expected recovery score derived from their individual clinical characteristics, to measure resilience as a continuous variable and to classify three groups of resilient older adults: expected, better than expected, and worse than expected. We will then identify genetic variants associated with resilience, including those that affect immunologic status, inflammation, RAS activity, metabolism and non-coding nucleic acids.
Research has never been easy

• Research Infrastructure is full of hurdles
  – IRB: Single IRB intention is good
    • Local IRBs still have responsibilities over their investigators
    • Not harmonized in understanding of sIRB
  – Contracts: Many people touch every contract

• Site teams are critically important
  – Need believers, those who want to do the work
  – Understand F&A and what is costs

• Pragmatic data-driven trial embedded in practice (totally new!)
Then COVID hit….

• Bright shiny projects
  – Pharma Vaccine Trials ($$$)
  – Operation Warp Speed (Dr. Collin’s letter to Health Systems and $$)

• Fatigue & Overload
  – Research staff (pulled to projects; WFH)
  – Potential Participants (one more thing; trust)

• Study awareness in a virtual world
  – Coordinators not in the clinic; asynchronous recruiting
Adaptations to pandemic from a bench/translational point of view

Clinician Scientists Transdisciplinary Aging Research (Clin-STAR) Program
2020 Annual Meeting - Virtual
November 17-18

Raymond Yung
Director, Geriatrics Center and Institute of Gerontology
Chief, Division of Geriatric and Palliative Medicine
University of Michigan
Disclosure

• No relevant financial disclosure.


• https://www.training.nih.gov/virtual_nih_activities_for_trainees_outside_the_nih

• https://www.sciencemag.org/news/2020/05/it-will-not-be-easy-labs-begin-reopen-enormous-challenges-remain

• https://www.nature.com/articles/d41586-020-01782-y


So many challenges.....

- Evolving institutional, County, State, and CDC guidelines for research closing/opening.
  - Ethical issues regarding older adult research
  - Bench research opens earlier than clinical research
  - Lab density – shifts
  - Reduced staffing in animal vivarium
  - PPE/sanitizing supplies
  - Graduate students – impact on research/graduation
So many challenges…..

• Changing clinical workload
• Virtual meetings……
• COVID fatigue and wellness
  – disproportionate burden on women faculty
• Impact on career trajectory/promotion
• Institutional finance
  – Hiring freeze
  – Discretionary (recruitment) funds
Some suggestions....

- Meet with your mentor/mentorship team frequently (mentors are not traveling)
- Support your research team
- Extensively lean on institutional resources!
• Develop a Disaster Preparedness Plan (what if a lab member comes down with COVID?)
  – Define the critical areas of your research e.g. techniques, equipment, databases, mice
  – Define the critical functions of each team member
  – Make sure protocols and data can be shared
  – Work out who can take over critical lab function(s)/cross-training
Some suggestions…. 

• Seek out new research/funding opportunities
• Keep yourself busy:
  – Write those papers you never got round to complete
  – Methodology papers
  – Put those interesting ideas on paper, and plan/submit that grant
  – Collaborating with those able to continue research
  – Database research to augment your research ideas
Breakout session