



Inaugural Annual Meeting

November 17, 2020

2:55-3:55 p.m. ET

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

Kenneth Santora, PhD, Director, Division of Extramural Activities (National Institute on Aging)

Karen Alexander, MD, Professor Medicine/Cardiology (Duke University Medical Center/ DCRI)

Raymond Yung, MB, ChB, Director, Geriatrics Center and Institute of Gerontology and Chief, Division of Geriatric and Palliative Medicine (University of Michigan)



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

Cell Commentary: How Support of Early Career Researchers Can Reset Science in the Post-COVID19 World

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.

Cell 181, June 25, 2020 © 2020 Elsevier Inc.

Congressional Response to the COVID-19 Crisis: Appropriations

- To date, NIH has received **\$3.59 billion** in supplemental appropriations for COVID-19 from the following:
 - **Coronavirus Preparedness and Response Supplemental Appropriations Act** (P.L. 116-123, 3/6/2020)
 - **Coronavirus Aid, Relief, and Economic Security “CARES” Act** (P.L. 116-136, 3/27/2020)
 - **Paycheck Protection Program and Health Care Enhancement Act** (P.L. 116-139, 4/23/2020)
- These funds are intended to facilitate a **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.
- **Full NIH list available here:** <https://grants.nih.gov/policy/natural-disasters/corona-virus.htm>.
- **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
- [NIA: https://www.nia.nih.gov/research/grants-funding/nia-covid-19-response](https://www.nia.nih.gov/research/grants-funding/nia-covid-19-response)
- [NIH: https://grants.nih.gov/policy/natural-disasters/corona-virus.htm](https://grants.nih.gov/policy/natural-disasters/corona-virus.htm)
- [CDC: https://www.cdc.gov/coronavirus/2019-ncov/index.html](https://www.cdc.gov/coronavirus/2019-ncov/index.html)

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

- <https://grants.nih.gov/grants/guide/notice-files/NOT-AG-20-022.html>

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

<https://grants.nih.gov/grants/guide/pa-files/PAR-20-234.html>

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:

NIA participation FOAs/NOSIs

		NIA expire
The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional)	RFA-OD-19-029	27-Nov-21
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	NOT-OD-20-129	1-Dec-20
Notice of Special Interest (NOSI): Competitive and Administrative Supplements for the Impact of COVID-19 Outbreak on Minority Health and Health Disparities	NOT-MD-20-019	1-Dec-20
Notice of Special Interest (NOSI) regarding the Availability of Administrative Supplements and Urgent Competitive Revisions for Mental Health Research on the 2019 Novel Coronavirus	NOT-MH-20-047	1-Dec-20
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	NOT-OD-20-097	1-Dec-20
Digital Healthcare Interventions to Address the Secondary Health Effects Related to Social, Behavioral, and Economic Impact of COVID-19 (R01 - Clinical Trial Optional)	PAR-20-243	3-Mar-21
Notice of Special Interest (NOSI): Digital Healthcare Interventions to Address the Secondary Health Effects Related to Social, Behavioral, and Economic Impact of COVID-19	NOT-MH-20-053	1-Dec-20
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	NOT-MD-20-022	1-Dec-20
Community Interventions to Address the Consequences of the COVID-19 Pandemic among Health Disparity and Vulnerable Populations (R01- Clinical Trial Optional)	PAR-20-237	2-Dec-20

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](#)
- 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](#)
 - 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

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

CSR-Reviewed Research Applications				
	General Payline, <\$500K	General Payline, =>\$500K	AD/ADRD Payline, <\$500K	AD/ADRD Payline, =>\$500K
All applications except as noted below	8%	5%	25%	25%
N.I. R01s	11%	8%	28%	28%
E.S.I. R01s	13%	10%	30%	30%

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.

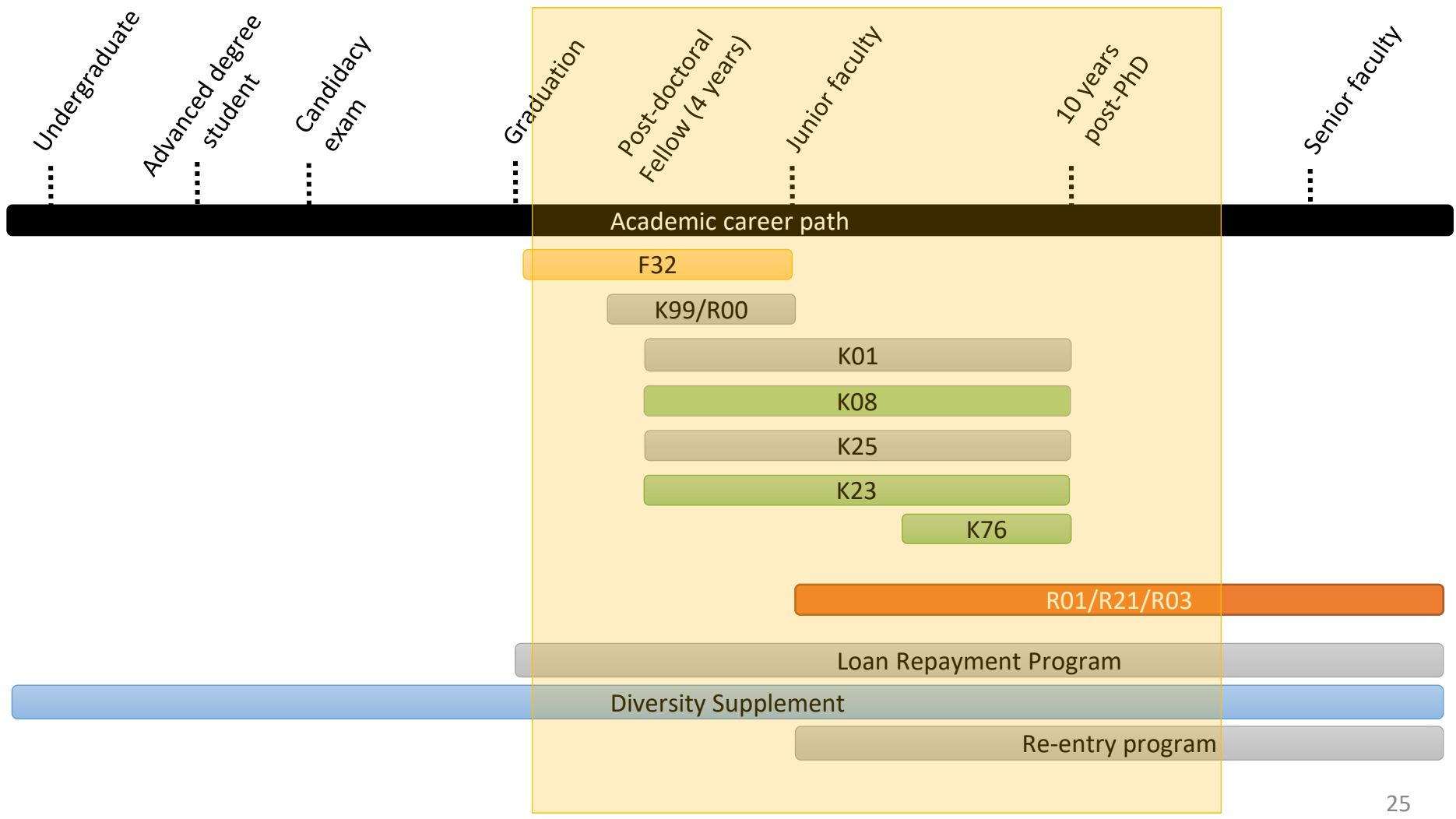
AD/ADRD: Research on Alzheimer's disease and Alzheimer's disease-related dementias.

Interim Pay Lines at the Continuing Resolution Funding Level

NIA-Reviewed Applications (Impact Score)		
	General Pay Line	AD/ADRD Pay Line
Program projects	15	37
Other NIA-reviewed research	15	37
Career development awards	18	35
Fellowship awards	20	40

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:**

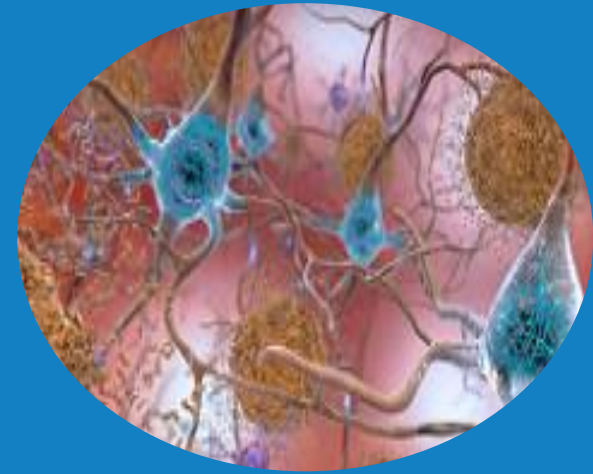
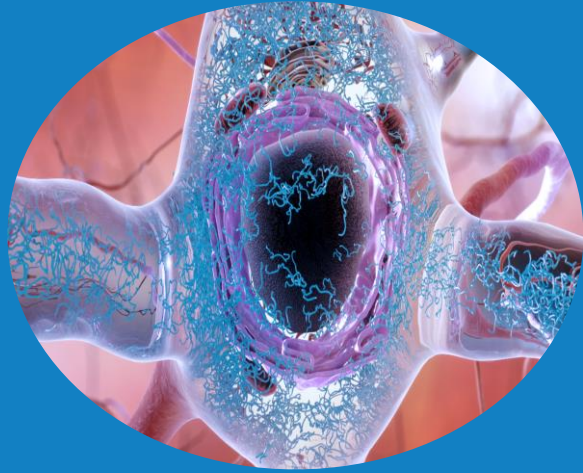
- A five-year award, second most applied K award
- Allow senior postdocs to apply
- By the time of the award you must hold an academic position. Postdoc is not academic position.
- Must be U.S. Citizen/Permanent resident by the time of the award.

Resources:

- **NIA Training and Career Development:**
<https://www.nia.nih.gov/research/training>
- **NIA New and Early Stage Investigators**
 - <https://www.nia.nih.gov/research/grants-funding/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](#)



NIA

The Leader in Aging Research



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



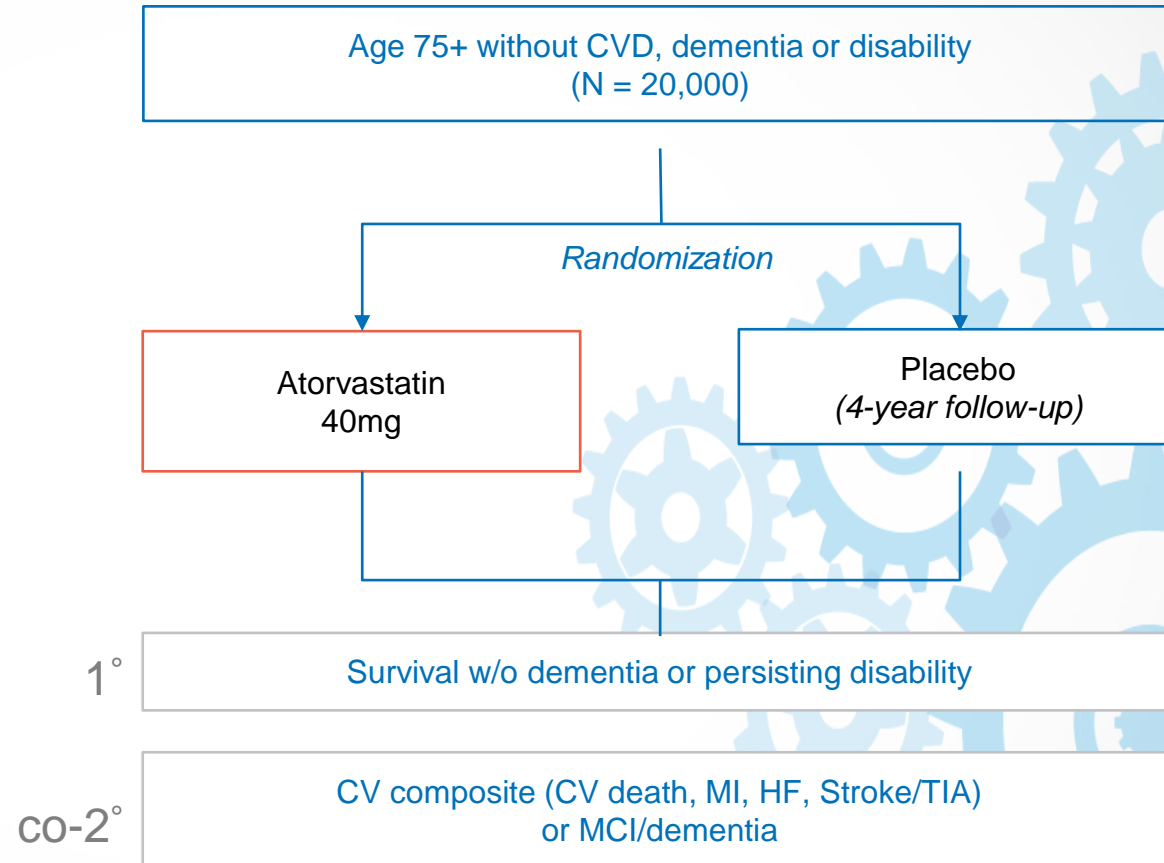
PREVENTABLE

- 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

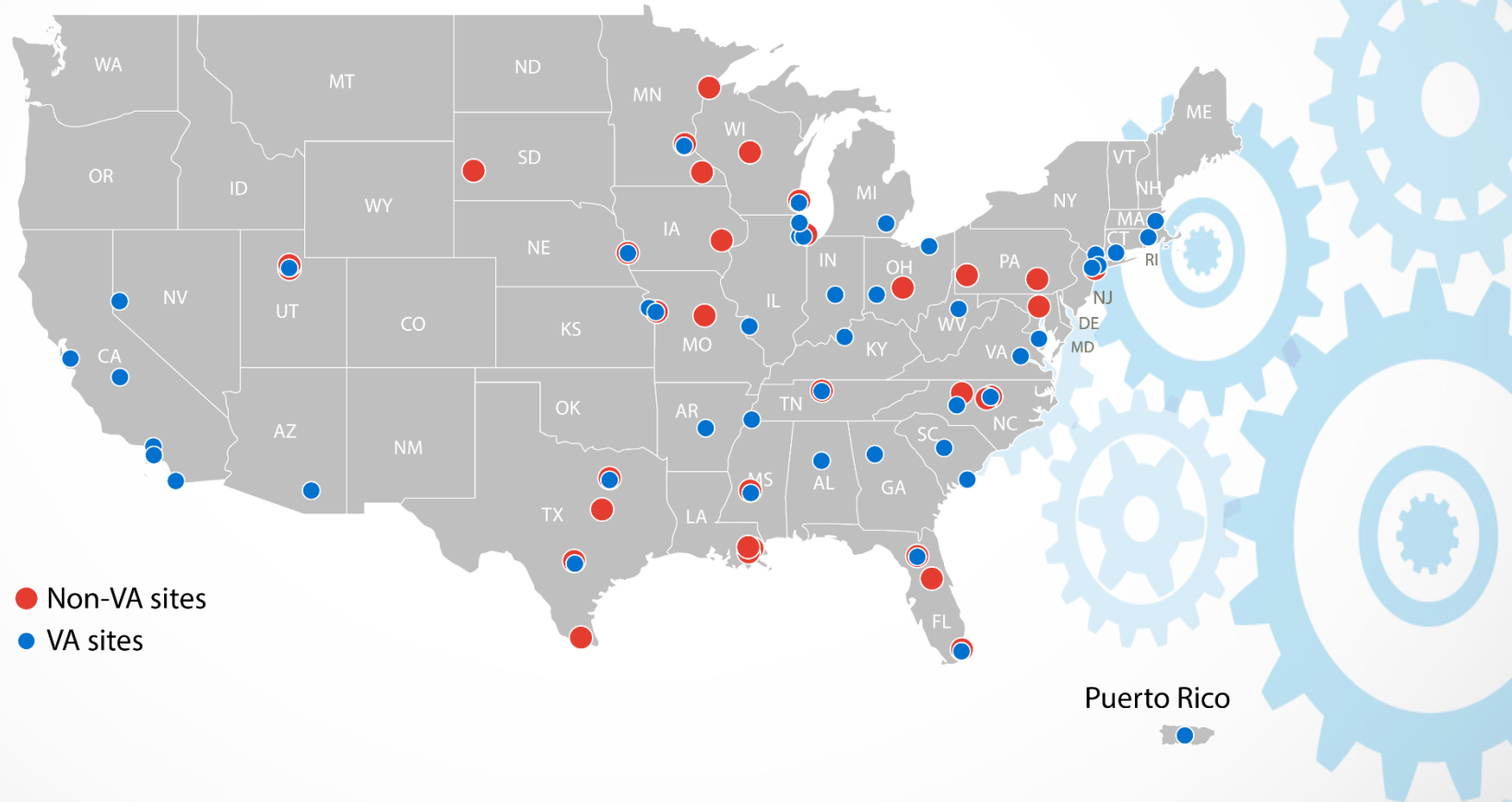
Participants will:

- 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.



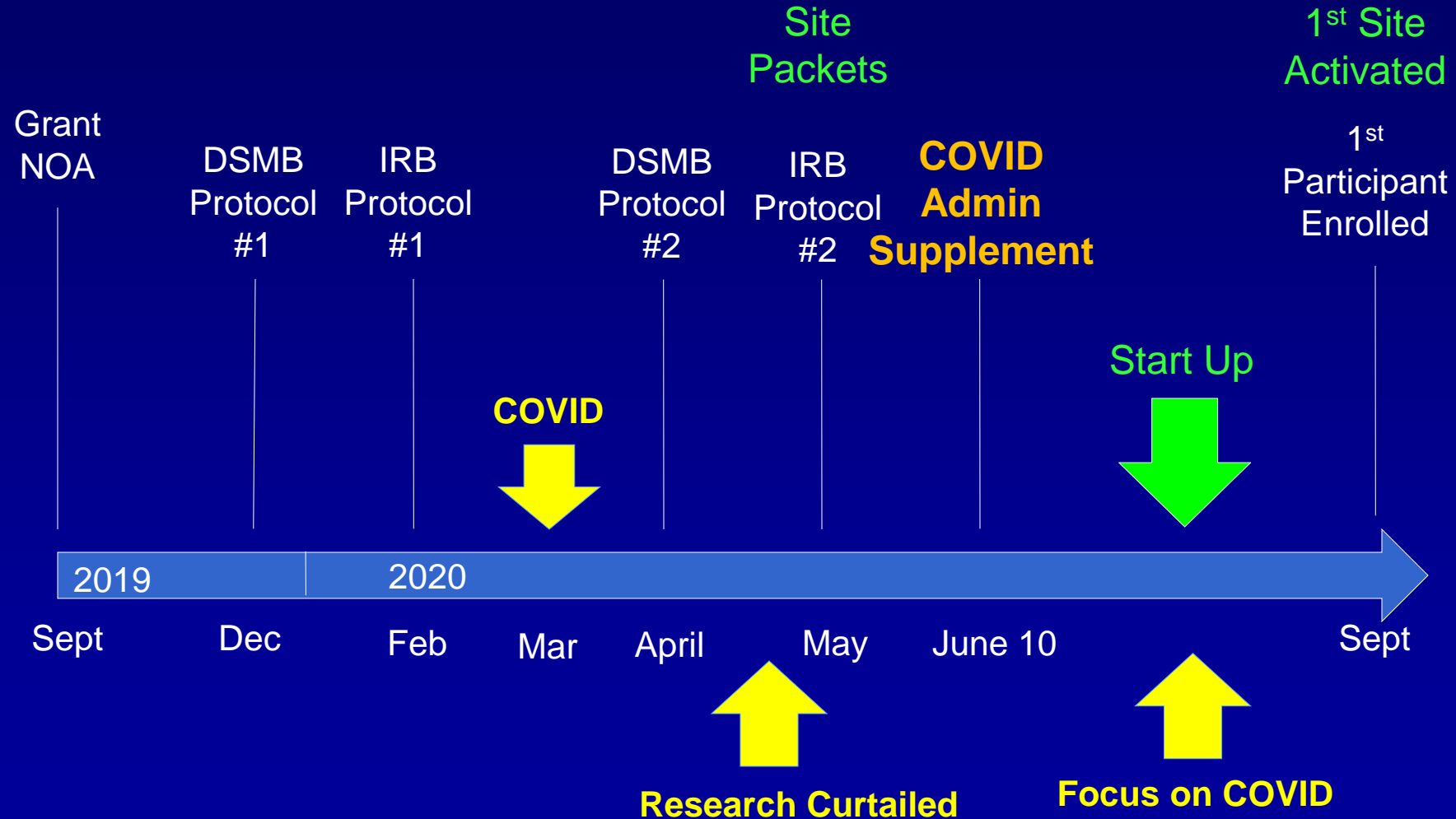
Study Sites

Approximately 90 sites from PCORnet (non-VA) and BVARI (VA) will participate.

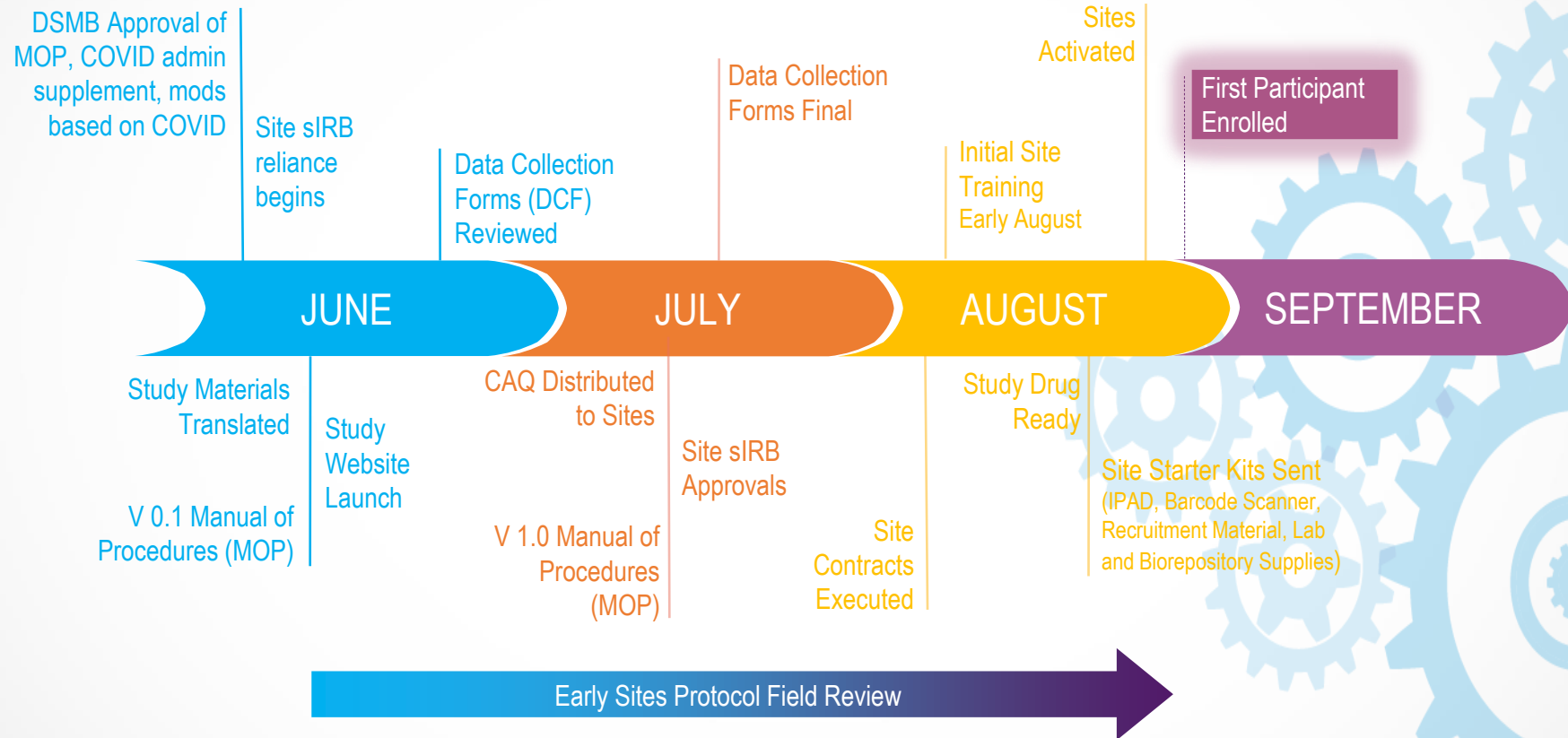


PREVENTABLE

Starting a Clinical Trial in a Pandemic



PREVENTABLE – Study Start Up Timeline



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.

Resources

- Nicol GE, Piccirillo JF, Mulsant BH, Lenze EJ. Action at a distance: geriatric research during a pandemic. *J Am Geriatr Soc.* 2020;68:922–925.
- Goh EF, Tan CN, Pek K, Leong S, Wong WC, Lim WS. Not Wasting a Crisis: How Geriatrics Clinical Research Can Remain Engaged During COVID-19. *J Am Geriatr Soc.* 2020;68(8):1676-1677. doi:10.1111/jgs.16569
- Cohen AB, Parks AL, Whitson HE, Zieman S, Brown CJ, Boyd C, Covinsky KE, Steinman MA. Succeeding in Aging Research During the Pandemic: Strategies for Fellows and Junior Faculty. *J Am Geriatr Soc.* 2020 <https://doi.org/10.1111/jgs.16868>
- 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>
- <https://www.nationalacademies.org/news/2020/07/reopening-us-research-universities-weathering-the-pandemic-and-looking-beyond-it>
- <https://rethinkingclinicaltrials.org/news/june-30-2020-special-issue-of-jags-features-nia-impact-collaboratorys-work-on-embedded-pragmatic-trials-and-dementia-care/>

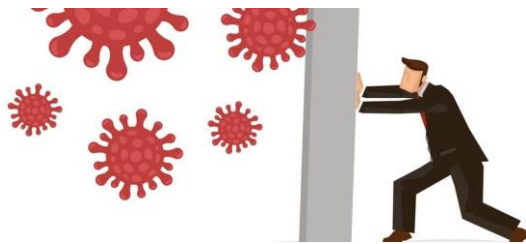
So many challenges.....

- 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!



Some suggestions....

- 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