JENNIFER GUIDA

BASIL ELDADAH

DIANE ST. GERMAIN

FUNDING ENVIRONMENT AND COLLABORATIONS

(45 MINS)







Jennifer Guida, Ph.D., M.P.H.
Program Director
Basic Biobehavioral and Psychological
Sciences Branch of the Behavioral
Research Program (BBPSB)





Basil Eldadah MD, PhD
Supervisory Medical Officer
Division of Geriatrics and
Clinical Gerontology (DGCG)





Diane St Germain, RN, MS, CRNP
Community Oncology and Prevention
Trials Research Group





National Cancer Institute Funding Opportunities

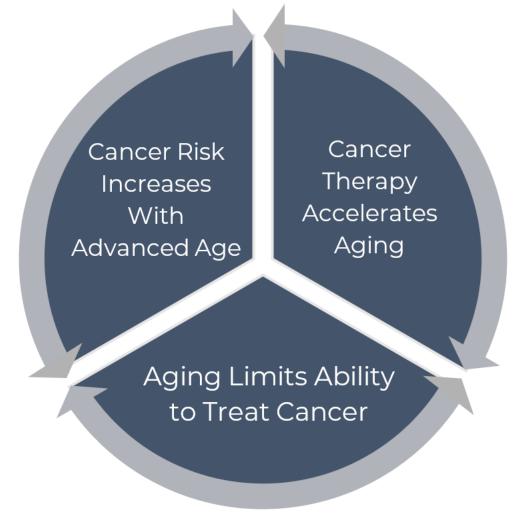
2023 CARG Annual Meeting

Jennifer Guida, PhD, MPH
Program Director
Division of Cancer Control and Population Sciences

<u>Jennifer.Guida@nih.gov</u>



"It is becoming increasingly clear that time itself is a potential mutagen."



"Many cancer drugs contribute directly to aging."

"Therapies that are beneficial in young adults can be difficult to use in older adults because of the age-associated reduced resilience of the host."

Dr. Sharpless, 2020 CAIG virtual conference

New Goals for Cancer Moonshot 2.0

- Cut today's age-adjusted death rate from cancer by at least 50 percent.
- Improve the experience of people and their families living with and surviving cancer.



Perspective FREE PREVIEW

Treatment of Older Adults with Cancer — Addressing Gaps in Evidence

Monica M. Bertagnolli, M.D., and Harpreet Singh, M.D.

<

Older adults with cancer are underrepresented in clinical research. Because of insufficient data, such patients and their physicians must make life-altering treatment decisions without adequate evidence-based guidance.

September 16, 2 N Engl J Med 20 DOI: 10.1056/NE

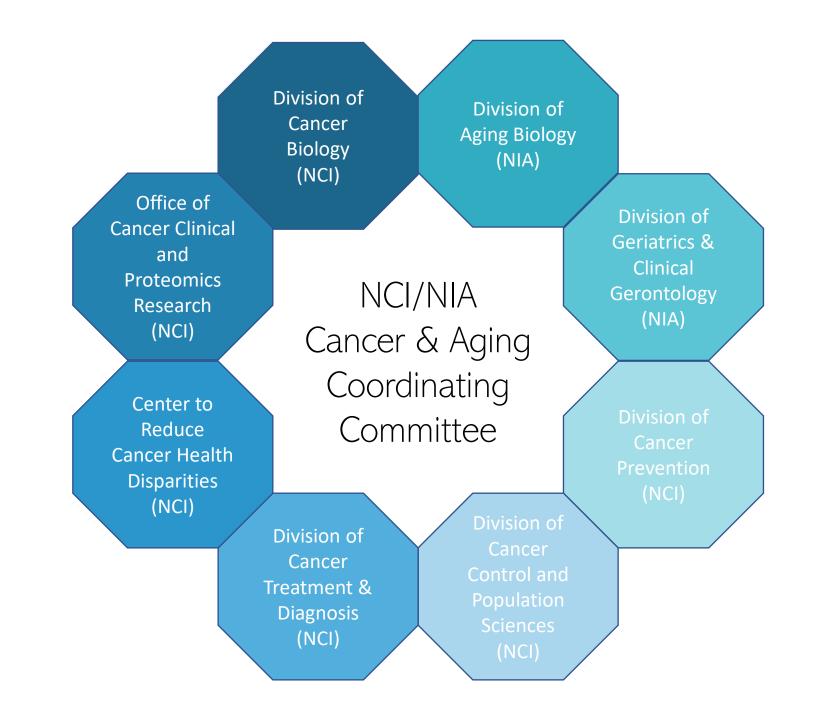


Dr. Monica Bertagnolli, 16th NCI Director

Trans-NCI Cancer & Aging Coordinating Committee (CACC)

Purpose:

- To integrate and coordinate all cancer and aging extramural program activities by enhancing communication about those efforts, and promoting collaboration, among NCI extramural program staff
- Founded in 2019
- Founding chair: Paige Green (DCCPS)
- Current co-chairs: Lisa Gallicchio (DCCPS), Chamelli Jhappan (DCB)



Trans-NCI Cancer & Aging Coordinating Committee (CACC)

CACC Goals:

- To coordinate all trans-NCI cancer and aging extramural activities (e.g., meetings, workshops, webinars)
- To promote collaboration by establishing working groups and conducting strategic planning focused on cancer and aging
- To facilitate extramural program interactions, collaborations, and meetings conducted with the National Institute on Aging (NIA)
- To support NCI participation in and establish robust communication with the Trans-NIH GeroScience Interest Group (GSIG) through the designated NCI liaison

Trans-NCI Cancer & Aging Coordinating Committee (CACC)

CACC Working Groups:

- Aging and Sex Disparities (Gosia Kaluzinska and Konstantin Salnikow)
- Cancer and Accelerated Aging Biomarkers (Jen Guida)
- Cancer and Comorbidities (Weiwei Chen)
- Health and Aging Trajectories (Gabriela Riscuta and Anil Wali)
- Scientific Coding (Linnia Mayeenuddin)





Dr. Arti Hurria 1970-2018

Building Infrastructure for Cancer and Aging Research

Supriya Mohile & William Dale

Canaries in the Coal Mine: What we can Learn about Aging from Survivors of Childhood Cancer Kiri Ness & Monica Gramatges

Cancer and Aging: Biological and Phenotypic Measures of Aging Luigi Ferrucci & Morgan Levine

Geriatric Assessment in Oncology: Yesterday, Today, & Tomorrow Hyman Muss & Grant Williams

Harnessing the Power of the WHI Life and Longevity after Cancer (WHI-LILAC) Study to Better Understand Cancer and Aging

Garnet Anderson & Elizabeth Cespedes Feliciano

Cancer and Aging: Microenvironmental Impact on Oncogenesis and Immunity James DeGregori & Curtis Henry

Targeting Aging to Transform Human HealthNathan LeBrasseur & Jessica Scott

Measuring Patient's Pace of Biological Aging Through Life-Course Research Daniel Belsky & Terrie Moffit

Cellular Senescence and Cancer Therapy: Mechanisms and Strategies to Improve Health During Survivorship

Judith Campisi & Marco Demaria

Research to Understand and Address the Survivorship Needs of Individuals Living with Advanced/Metastatic Cancer

This RFA is intended to solicit applications proposing:

- 1) Observational studies to understand the trajectory of physical and psychological symptoms, patterns of care, and unmet needs; and/or
- 2) The development and testing of interventions to improve the delivery of comprehensive survivorship care in this group of cancer survivors.

- FOA Number: RFA-CA-22-027
- Expiration Date: September 30, 2023
- Program Contacts: Michelle Mollica, Ph.D., M.P.H., R.N., O.C.N., Lisa Gallicchio, Ph.D.

Cannabis and Cannabinoid Use in Adult Cancer Patients During Treatment: Assessing Benefits and Harms (U01 Clinical Trial Not Allowed)

This RFA is intended to solicit applications proposing:

- Cooperative Agreement (U01) applications that propose prospective research studies to assess the benefits and harms of cannabis and cannabinoid use among adult cancer patients during active treatment. NCI is seeking well-designed prospective cohort studies of cancer patients with solid or hematologic tumors currently receiving treatment. Studies are expected to compare cancer patients who use cannabis/cannabinoids with cancer patients that do not use cannabis and/or cannabinoids.
- FOA Number: <u>RFA-CA-22-052</u>
- Expiration Date: February 18, 2023
- Program Contacts: Kelly Filipski, Ph.D., M.P.H and Andrew Freedman, Ph.D.

Understanding the Effects of Cancer and Cancer Treatment on Aging Trajectories and Aging Outcomes

- To solicit investigator-initiated applications that aim to better understand the effects of a cancer diagnosis and subsequent cancer treatment on aging trajectories and aging outcomes.
- FOA Number: NOT-CA-21-031
- Expiration Date: January 08, 2024
- Program Contacts: <u>Lisa Gallicchio</u>, Ph.D., NCI & <u>Basil Eldadah</u>, M.D., NIA

Advancing Research to Develop Improved Measures and Methods for Understanding Multimorbidity (Clinical Trial Optional)

- Measurement and methods research to understand and promote primary, secondary, and tertiary prevention of multimorbidity for cancer survivors and the prevention of cancer among those diagnosed with other chronic conditions
- FOA Number: <u>PAR-20-179</u> (R01)
- Expiration Date: September 08, 2023
- Program Contact: <u>Bryan Kim</u>, Ph.D.

Identifying Innovative Mechanisms or Interventions that Target Multimorbidity and Its Consequences (Clinical Trial Optional)

- NCI is interested in observational and intervention research to understand and promote primary, secondary, and tertiary prevention of multimorbidity for cancer survivors and the prevention of cancer among those diagnosed with other chronic conditions (e.g., diabetes, hypertension, obesity).
- FOA Number: <u>PAR-20-180</u> (R01)
- Expiration Date: September 08, 2023
- Program Contact: <u>Bryan Kim</u>, Ph.D.

Clinical Characterization of Cancer Therapy-induced Adverse Sequelae and Mechanism-based Interventional Strategies

(R01 Clinical Trial Optional)

- Applications should focus on cancer therapy-induced adverse sequelae that persist and become chronic comorbidities or develop as delayed posttreatment effects. These adverse sequelae include, but are not limited to, therapy-induced peripheral neuropathy, neurocognitive impairments, cardiovascular toxicity, pulmonary fibrosis, fatigue, nephrotoxicity, ototoxicity, and various immune system-related AEs.
- FOA Number: <u>PAR-21-329</u>
- Expiration Date: November 06, 2024
- Program Contacts: <u>Kelly Filipski</u>, Ph.D., M.P.H and <u>Alexis Bakos</u>, Ph.D., M.P.H., R.N.

^{*}Program Announcement with special receipt, referral, and/or review considerations

Improving Outcomes in Cancer Treatment-Related Adverse Sequelae

Funding Opportunity Purpose:

 Focus is on mitigating cardiovascular dysfunction while optimizing cancer outcomes by understanding the mechanisms of cancer treatment-related cardiotoxicity and translating the findings to improve risk stratification, early detection, prevention, and management.

■ FOA Number: NOT-CA-22-001

Expiration Date: November 06, 2024

Program Contacts: <u>Nonniekaye Shelburne</u>, M.S., C.R.N.P., A.O.C.N., NCI and <u>Bishow B. Adhikari</u>,
 Ph.D., NHLBI

- PAR*: Basic Research in Cancer Health Disparities (Clinical Trial Not Allowed)
 - Innovative studies designed to investigate biological/genetic bases of cancer health disparities, such as
 - Mechanistic studies of biological factors associated with cancer health disparities
 - Development and testing of new methodologies and models
 - Secondary data analyses
- FOA Number: <u>PAR-21-322</u> (R01), <u>PAR-21-323</u> (R21), <u>PAR-21-324</u> (R03)
- Expiration Date: September 8, 2024
- Program Contacts: <u>Anu Sharman</u>, Ph.D., <u>Asad Umar</u>, D.V.M., Ph.D., <u>Tiffany Wallace</u>, Ph.D.

- PAR*: Health Care Models for Persons with Multiple Chronic Conditions from Populations that Experience Health Disparities: Advancing Health Care towards Health Equity (R01 - Clinical Trials Optional)
 - To support innovative, multidisciplinary, and multi-level and/or multi-component research through existing or newly proposed health care models designed to optimize the care of persons with multiple chronic conditions from U.S. populations that experience health disparities through the adaption, integration, and implementation of evidence-based or recommended guidelines of care for different and coexisting chronic conditions with a holistic perspective, and focused on attaining optimal health outcomes.
- FOA Number: <u>PAR-22-092</u>
- Expiration Date: September 8, 2024
- Program Contacts: Priscilla Novak, Ph.D., NIA, Sallie Weaver, Ph.D., M.H.S., NCI

- Notice of NCI Participation in PAR-22-064, "Patient-Clinician Relationship: Improving Health Outcomes in Populations that Experience Health Care Disparities (R01 Clinical Trial Optional)"
 - To support innovative multi-disciplinary and multi-level (e.g., patient, clinician, interpersonal, health care system, community) research designed to understand how optimizing patient-clinician communication and relationship affects health care outcomes in patients from populations with health care disparities.
- FOA Number: <u>NOT-CA-22-048 / PAR-22-064</u>
- Expiration Date: January 08, 2025
- Program Contacts: <u>Sallie J. Weaver</u>, Ph.D., M.H.S., <u>Amanda Acevedo</u>, Ph.D., <u>Diane St.</u>
 <u>Germain</u>, R.N., M.S., C.R.N.P.

- Risk and Protective Factors of Family Health and Family Level Interventions (R01 - Clinical Trial Optional)
 - The purpose of this initiative is to advance the science of minority health and health disparities by supporting research on family health and well-being and resilience. The NIMHD Research Framework recognizes family health, family well-being, and family resilience as critically important areas of research to decrease disparities and promote equity.
- FOA Number: <u>PAR-21-358</u>
- Expiration Date: May 08, 2025
- Program Contacts: Rebecca Ferrer, Ph.D., Anil Wali, Ph.D.

Selected Cancer and Aging Extramural Program Points of Contact

| National Cancer Institute | Division of Cancer Biology | Chamelli Jhappan | jhappanc@mail.nih.gov |
|--------------------------------|--|------------------------|---------------------------|
| | | Konstantin Salnikow | salnikok@mail.nih.gov |
| | Division of Cancer Control and Population Sciences | <u>Lisa Gallicchio</u> | lisa.gallicchio@nih.gov |
| | | <u>Paige Green</u> | paige.green@nih.gov |
| | | <u>Jennifer Guida</u> | jennifer.guida@nih.gov |
| | Division of Cancer Prevention | Gabriela Riscuta | gabriela.riscuta@nih.gov |
| | | Diane St. Germain | dstgermain@mail.nih.gov |
| | | Matthew Young | matthew.young@nih.gov |
| | Division of Cancer Treatment and Diagnosis | Weiwei Chen | weiwei.chen@nih.gov |
| | | Richard Little | littler@mail.nih.gov |
| | | Ana I. Robles | roblesa@intra.nci.nih.gov |
| | Center to Reduce Cancer Health Disparities | <u>Nelson Aguila</u> | aguilah@mail.nih.gov |
| | | <u>Anil Wali</u> | walia@mail.nih.gov |
| National Institute on Aging | Division of Geriatrics and Clinical Gerontology | <u>Basil Eldadah</u> | eldadahb@mail.nih.gov |
| | Division of Aging Biology | <u>Max Guo</u> | max.guo@nih.gov |



www.cancer.gov/espanol

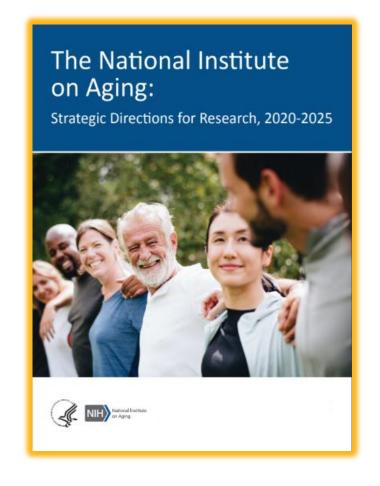
Working with NIA and beyond

Basil Eldadah, MD, PhD
Chief, Geriatrics Branch
Division of Geriatrics and Clinical Gerontology
National Institute on Aging

CARG Virtual Conference February 15, 2023

NIA Mission

- Support and conduct genetic, biological, clinical, behavioral, social, and economic research on aging.
- Foster the development of research and clinician scientists in aging.
- Provide research resources.
- Disseminate information about aging and advances in research to the public, health care professionals, and the scientific community, among a variety of audiences.



NIA Organization

Office of the Director/Deputy Director

Richard Hodes / Amy Kelley

- Office of Special Populations
- Office of Legislation/Policy/International Activities
- Office of Communications and Public Liaison
- Office of Planning, Analysis, and Evaluation

Division of Extramural Activities

Director: Ken Santora

- Scientific Review Branch
- Grants/Contracts Management Branch
- Office of Small Business Research
- NIA Training Office

Intramural Research Program

Director: Luigi Ferrucci

Division of Aging Biology

Director: Ron Kohanski

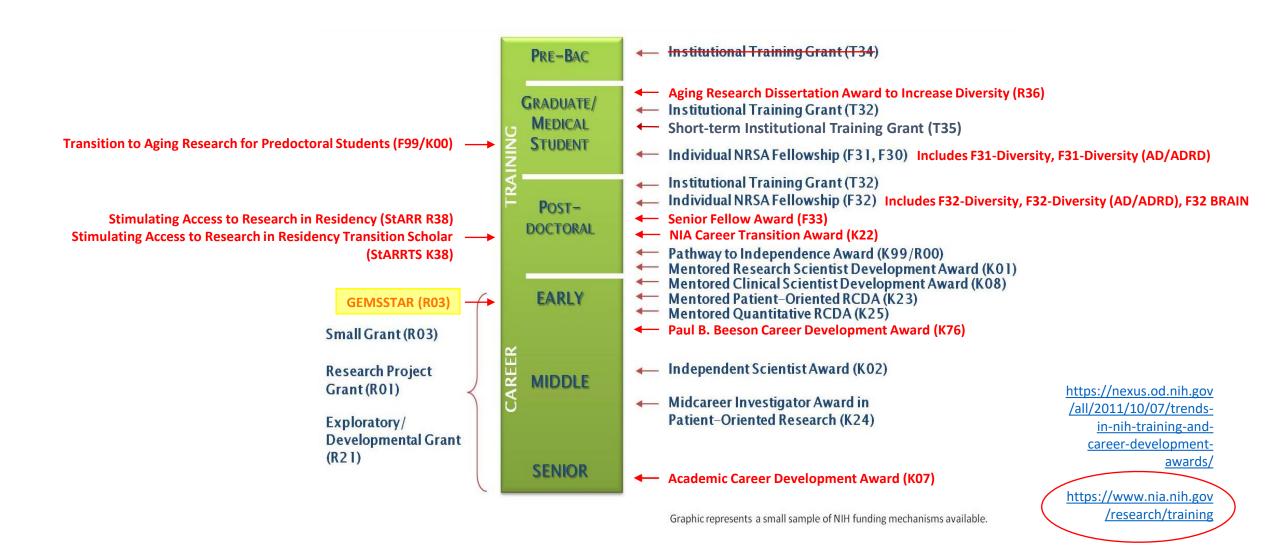
Division of Behavioral and Social Research Director: Lisbeth Nielsen Division of Geriatrics and Clinical Gerontology

Director: Evan Hadley

Division of Neuroscience

Director: Eliezer Masliah

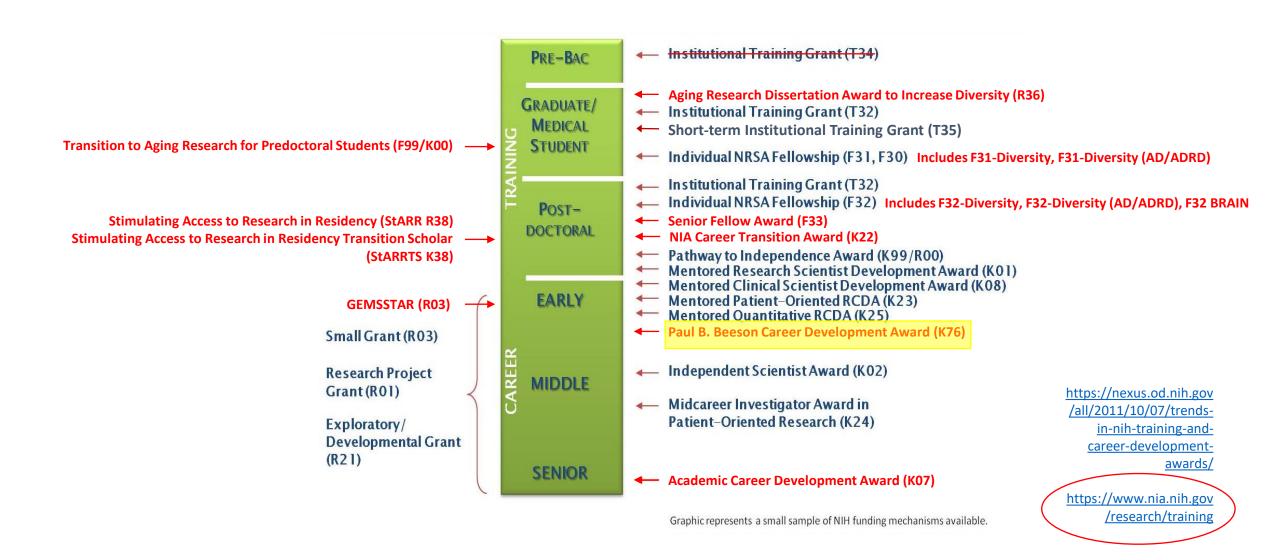
NIA Training, Fellowship, and Career Development Awards



Grants for Early Medical/Surgical Specialists' Transition to Aging Research (GEMSSTAR)

- An NIA "pre-K" award program for junior faculty physicians or dentists interested in a research career bridging their specialty and aging
- R03 mechanism (\$100,000/y DC for 2 years) plus evidence of a supportive research career environment (Professional Development Plan)
- Regular GEMSSTAR scholar conferences
- Yearly announcement with receipt date typically in Fall
- Most recent competition: RFA-AG-23-031

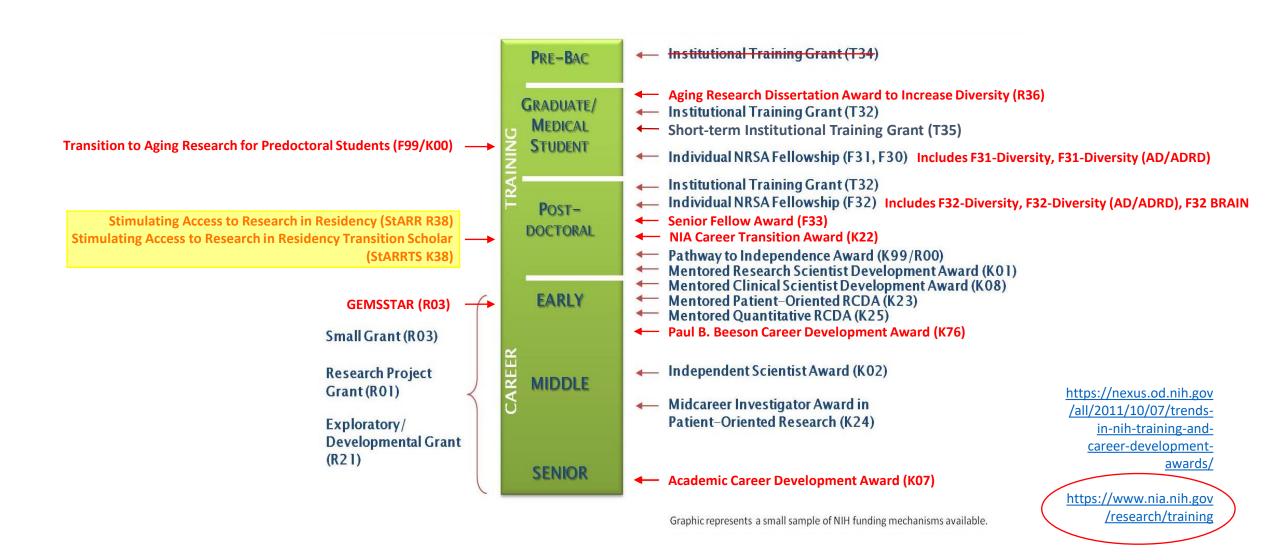
NIA Training, Fellowship, and Career Development Awards



Paul B. Beeson Emerging Leaders Career Development Award in Aging (K76)

- RFA-AG-21-021 (clinical trial) and RFA-AG-21-020 (no clinical trial)
- Eligibility
 - Early-Stage Investigator status (no R01-type funding and within 10 years of terminal degree) at time of award
 - Current/prior research support expected
 - Research or clinical doctoral degree (e.g., PhD, MD, DO, DMD, DDS, OD, DC, PharmD, ND, DVM)
 - Prior evidence of leadership in clinical duties or research activities
- Up to \$225,000/y (direct costs)
- Annual Beeson scholars meeting

NIA Training, Fellowship, and Career Development Awards



Stimulating Access to Research in Residency (StARR) (R38) Stimulating Access to Research in Residency Transition Scholar (StARRTS) (K38)

- RFA-HL-23-006: Stimulating Access to Research in Residency (StARR) (R38)
 - Institutional awards to support 1-2 years of research in clinical residency (physicians, dentists, or veterinarians)
 - Support for 2-3 residents at 80% of PGY salary + research costs
 - Regular investigators meetings
 - Yearly receipt dates on March 15 in 2022, 2023, and 2024
 - Number and scope of awards vary by participating ICs (NHLBI, NCI, NIAID, NIA)
- RFA-HL-23-007: Limited Competition: Stimulating Access to Research in Residency Transition Scholar (StARRTS) (K38)
 - Individual mentored awards to StARR residents for continued research and career development support in clinical fellowship or early faculty position
 - 1-2 year support for 75% of base PGY salary (fellows) or up to 50% of base salary ≤ \$60k/y (early career faculty) + ≤ \$20k/y research costs + ≤ \$3 k/y travel costs
 - Yearly receipt dates on October 13, 2022; October 13, 2023; and October 11, 2024
 - Number and scope of awards vary by participating ICs (NHLBI, NCI, NIAID, NIA)
 - NIA supports only fellowship through this award; early career faculty are supported through GEMSSTAR









ABOUT ~ **CORES** Y **FUNDING OPPORTUNITIES** CAREER & RESEARCH RESOURCES

NEWS & **EVENTS**

A National Platform to Advance Transdisciplinary Aging Research





The Clinician-Scientists Transdisciplinary Aging Research (Clin-STAR) Coordinating Center provides a national platform for clinicians focusing their careers on aging research in order to improve patient-centered care for older adults across specialties and disciplines.

Clin-STAR Coordinating Center initiatives include:

- Clin-STAR Database
- Pilot Grants
- Outreach Funds
- Webinars
- Mentoring & Collaboration:
 - · Career and Research Advice Opportunities
 - Special Interest Groups
 - Office Hours
 - Peer Support
- Career, Mentoring and Research Resources



Join the "Who's Who" in Aging Research

Joining is free and without any commitments. The Clin-STAR

Database features unique functions to search and visualize
how the broad aging research community is connected with
clinician-investigators from any discipline or level of
seniority, starting as early as medical students. The database
allows users to easily identify and contact investigators for
transdisciplinary research collaborations and mentoring
opportunities.



Get started on the Clin-STAR Database here!



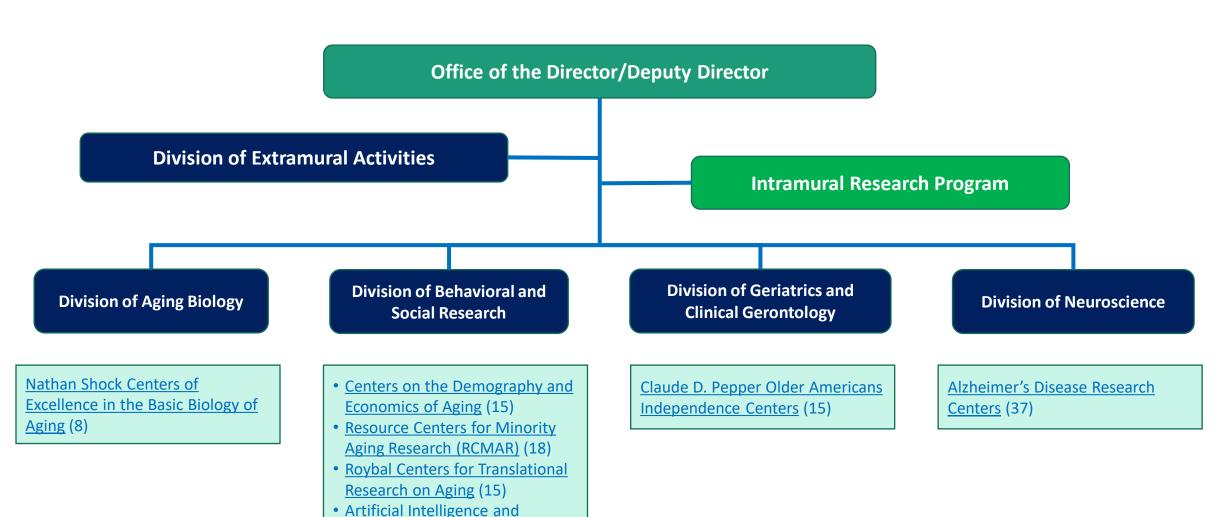
- Establishment: January 2019
- Continues to expand its collections of biospecimen and associated data to:
 - Better serve the scientific community
 - Provide a wide array of research opportunities
 - Advance science and improve the health of older adults
- Study collections currently available:
 - Biospecimens and related data: LIFE, SWAN, SOF, MrOS, T-trials, MOST, ENRGISE, CALERIE, SAGES
 - Data: STRIDE
- For further information please visit <u>https://agingresearchbiobank.nia.nih.gov/</u> or contact <u>Rosaly.correa-de-araujo@nih.gov</u>

| | | | | Español | |
|---|---|-------------------|-----------|---------|--|
| NIH National Institute on Aging | 5 | Search | | Q | |
| Health Information Y Research & Funding Y | News & Events | ~ | About NIA | * | |
| Home / Research & Funding | | | | | |
| Research Resources | | | | | |
| Use the NIA Research Resources database to find NIA-support datasets, informatics resources, and more. Search by keyword Division or IRP. | | | | | |
| Keywords | | | | | |
| - Any - | | | | | |
| Resource Type | | | | | |
| - Any - | | | | | |
| Divisions | | | | | |
| - Any - | | | | | |
| Apply | | | | | |
| Health Databases | | | | | |
| Advanced Cognitive Training for Independent (ACTIVE) | and Vital Elde | erly | | | |
| With 2,832 participants, the <u>ACTIVE Study</u> is the largest study ever performed. Funded by the National Institutes of Health a the University of Alabama at Birmingham, the National Instituturies University School of Medicine, Penn State University, and other | nd led by research te on Aging, the In | ners at ndiana | | | |

proves that healthy older adults can make significant cognitive improvements with

https://www.nia.nih.gov/ research/resources

NIA Centers Programs



Technology Collaboratories for

Aging Research (3)

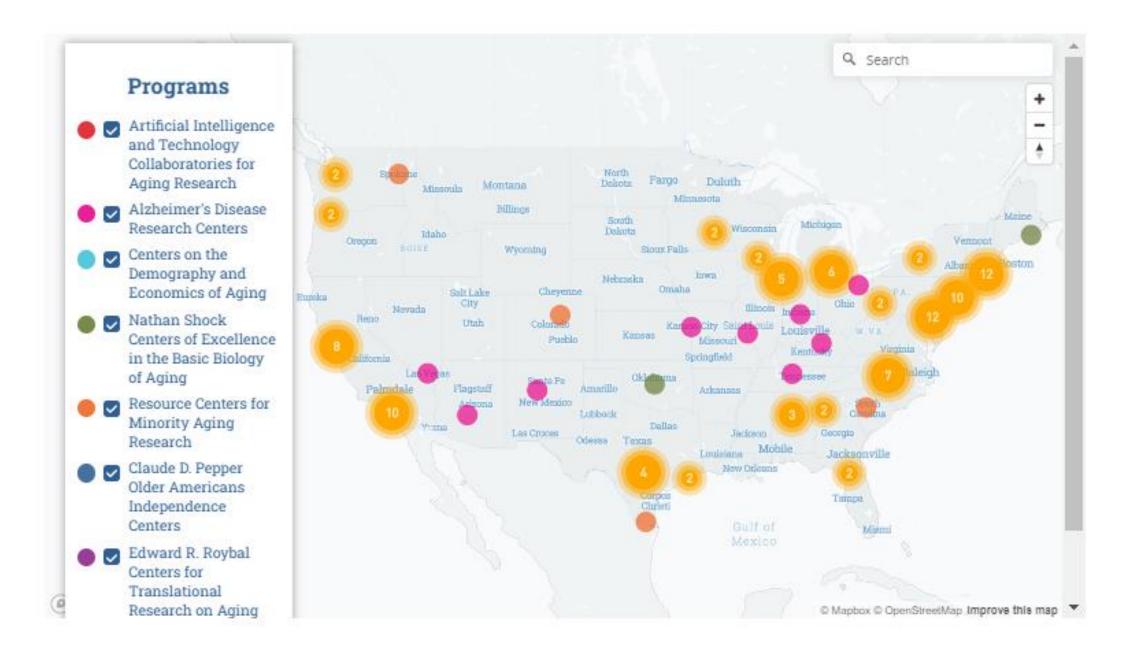


The problems associated with an aging society transcend the boundaries of any specific discipline and play out across multiple biologic and societal domains ranging from individual cells, to organs and organ systems, to persons, to communities, to national and world economies. The six National Institute on Aging (NIA) Center programs address important topics in aging but typically from a specific disciplinary perspective.

The objective of the Research Centers Coordinating Network (RCCN) is to initiate new cross-disciplinary collaborative networks that bring together key thought leaders from each of the six NIA center programs to align approaches across programs that will uncover synergies and insights that lead to novel collaborations.

The RCCN website supports linkages between the six NIA center programs and shares center-related resources, funding and meetings opportunities, and webinars.

Managed by Wake Forest School of Medicine and the American Federation for Aging Research (AFAR), the RCCN will spur multi-disciplinary efforts in aging research across the centers through five complementary strategies: conferences, pilot programs, early career faculty education, web-based resource identification tools, and fundraising/proposal development.





RCCN Research Compass:

The Research Compass points you to WHAT topics are being studied WHERE among the NIA Supported Research Centers

This tool cross-references centers publications and Medline (MeSH) search terms for publications reported to PubMed from February 2018 through February 2023.

'he Center Programs are

Alzheimer's Disease Research Centers

Centers on the Demography and Economics of Aging

Claude D. Pepper Older Americans Independence Centers (OAICs)

Nathan Shock Centers of Excellence in the Basic Biology of Agin

Resource Centers for Minority Aging Research (RCMAR

Roybal Centers for Translational Research on Aging

Artificial Intelligence and Technology Collaboratories (AITC) for Aging Research

RESET FORM

Setting Stated:

Setting Stated:

Search for Negwords you want to target

Search for Negwords you want to target

Search for Negwords to target

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Some other NIA-supported networks



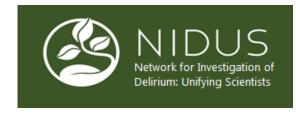








https://www.mycarg.org/



https://deliriumnetwork.org/



https://deprescribingresearch.org/

NIA Health Disparities Research Framework



| | • | | | | |
|--|------------------------------|--|-------------------------------------|--|--|
| Environmental | Sociocultural | Behavioral | Biological | | |
| Geographical and Political Factors | <u>Cultural Factors</u> | <u>Coping Factors</u> | Physiological Indicators | | |
| <u>Socioeconomic</u> <u>Factors</u> | <u>Social Factors</u> | <u>Psychological</u> <u>Risk/Resilience</u> | <u>Genetic Stability</u> | | |
| <u>Health Care</u> | <u>Psychological Factors</u> | <u>Health Behaviors</u> | Cellular Function and Communication | | |
| LIFECOURSE PERSPECTIVE + | | | | | |

The Butler-Williams Scholars Program

For junior faculty and researchers new to the field of aging



Dates: August 23-25, 2023

Location: To be held virtually

Eligibility: Doctoral degree (e.g., PhD, DrPH,

MD, etc.)

To apply for the 2023 cohort (by April 21, 2023):

https://www.nia.nih.gov/form/bw-scholars-23

For more details:

https://www.nia.nih.gov/research/blog/2023/01/butler-williamsscholars-program-one-kind-opportunity-grow-your-career



Save the Date: 2023 Geroscience Summit



https://www.nia.nih.gov/2023-fourth-geroscience-summit



Research Infrastructure Development

PAR-23-053: "Research Infrastructure Development for Interdisciplinary Aging Studies" (R61/R33)

PAR-23-054: "Advanced-Stage Development and Utilization of Research Infrastructure for Interdisciplinary Aging Studies" (R33)

- To support research infrastructure to advance the science of aging in areas requiring interdisciplinary partnerships or collaborations
- Intended to support a research platform rather than direct hypothesisdriven research
- Expectation to develop new knowledge, tools, or other scientific resources and results

Example platform activities



NOT-AG-22-048: Advancing the Science of Geriatric Palliative Care

- Foci include
 - relief of symptoms and suffering
 - communication of prognosis and treatment options in the context of patients' goals
 - coordination of care within and across healthcare settings
- Participating IC's: NIA, NCI, NINR, NHLBI, NIMHD, ORWH

We're Hiring!

We're looking for talented scientists with a health-related doctoral degree (e.g., MD, PhD, DSc) to serve as program officers in our Geriatrics Branch and Clinical Gerontology Branch.

If interested, please contact:

Basil Eldadah, MD, PhD Chief, Geriatrics Branch DGCG

Basil.Eldadah@nih.gov

Chhanda Dutta, PhD
Chief, Clinical Gerontology Branch
DGCG

Chhanda.Dutta@nih.gov



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

NCI Community Oncology Research Network: Opportunities for Engagement

Diane St. Germain
Nurse Consultant/Program Director
Division of Cancer Prevention
NCI



CARG February 15, 2023

Objectives

- 1. Provide an overview of NCORP Program
- 2. Describe efforts to increase accrual of older adults to NCI clinical trials
- 3. Describe broadening trial eligibility initiative

The NCI Community Oncology Research Program (NCORP)

- The NCI Community Oncology Research Program (NCORP) is a national network that brings cancer clinical trials and care delivery studies to people in their own communities.
- Is the primary source of accrual to NCI cancer control, symptom management trials, and to health-related quality of life trials that are embedded into NCTN treatment trials.
- Goal is to generate a broadly applicable evidence base that contributes to improved patient outcomes and reduction in cancer disparities.

NCORP Structure

Research Bases

Alliance
COG
ECOG-ACRIN
NRG
SWOG
URCC
Wake Forest



NCORP Community & Minority/Underserved Sites

- Develop protocols
- Data Management
- Analysis
- Quality Assurance

- Accrual to protocols
- Data Management
- Quality Control

NCORP Network Attributes

People:

- 4,739 Physician Investigators
- 1,036 Non-Physician Investigators
- 5,444 Research Staff (Associate/Associate Plus)
- 11 Health Care Systems
 - Advocate/Aurora, Baptist, CommonSpirit Health System (formerly Catholic Health Initiatives), Essentia, Geisinger, Kaiser Permanente, MaineHealth, Nemours, Northwell Health, Prisma, Sanford





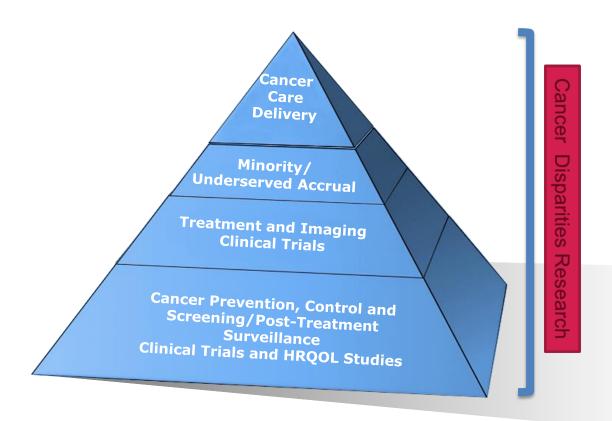
930 Affiliates and Sub-Affiliates

- Non-Academic Hospitals 336
- Academic Hospitals 68
- Community Physician Practice 271
- Academic Physician Practice 19
- Free Standing Oncology Clinic 130
- VA Hospital 7
- Government Facility 3
- Military 3
- NCI Cancer Center 3
- Administrative Clinical 5
- Undesignated 85

July 15, 2022



NCORP Research Priorities



Using NCORP's Network to Conduct Research

- Research must be conducted via Research Base (RB) sponsorship
- Contact NCORP staff at ncorp@mail.nih.gov
 - Determine if within scope of program
 - Decide which RB best suited to support proposed research
 - Researcher contact RB to secure sponsorship
 - RB to notify NCI if plan to submit for federal (R01, etc.) or non-federal funding support
 - Study chair, RB and NCI PD discuss aims, population, rationale/feasibility, possible overlap, confirm scope is appropriate, timeline/budget considerations, NCORP site interest

Older Adult Trials Supported in the NCORP Network

| Dates | Protocol Number | Title | Status | Sample Size |
|----------------------|-----------------|---|----------------------|-------------|
| 5/15/14 – 3/15/19 | URCC-13059 | A Geriatric Assessment Intervention for Patients Aged 70 and Over Receiving Chemotherapy or Similar Agents for Advanced Cancer: Reducing Toxicity in Older Adults | Closed to Accrual | 733 |
| 6/26/14- 8/15/17 | URCC-13070 | Improving Communication for Cancer Treatment: Addressing Concerns of Older Cancer Patients and Caregivers | Closed to Accrual | 546 |
| 8/15/18- 3/3/20 | A171601 | A Phase II Trial Assessing the Tolerability of Palbociclib in Combination with Letrozole or Fulvestrant in Patients Aged 70 and Older with Estrogen Receptor-Positive, HER2-Negative Metastatic Breast Cancer | Closed to Accrual | 93 |
| 8/16/19- | WF-1806 | Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer: the M&M Study | Active | 300 |
| 10/1/20- | A171901 | Older Non-Small Cell Lung Cancer Patients (>/= 70 Years of Age) Treated with First-Line MK-3475 (Pembrolizumab)+/- Chemotherapy (Oncologist's/Patient's Choice) | Active | 100 |
| 10/8/21- | URCC-19178 | Optimizing Functional Outcomes of Older Cancer Survivors After Chemotherapy | Active | 1560 |

Engaging Older Adults in the NCI Clinical Trials Network: Challenges and Opportunities

Virtual Event • April 26-27, 2021



Supriya Mohile (Wilmot Cancer Institute;

CARG)



NCI Meeting Objectives/Goals

- Identify modifiable barriers to participation of older adult patients in cancer clinical trials, with an emphasis on clinician bias, and develop actionable interventions to address them.
- Engage patients to enhance our understanding of the barriers to enrollment of older adults to clinical trials and discuss
 ways to overcome these barriers.
- Identify patient needs and concerns and develop and implement interventions to address those concerns.
- Build consensus around the best approaches and measures to define "fitness"/frailty in clinical research.
- Develop a broader research plan to guide the implementation of geriatric assessments in future NCI-supported clinical trials to address gaps in research.

Working Groups

| Study Design | Infrastructure | Stakeholders |
|--|---|--|
| Consider trial designs that promote enrollment of older adults (e.g. cohort designs, extended cohorts, parallel cohorts, less fit older adults), stratification by vulnerability | Development of a roadmap from conceptualization of research question to dissemination of results Necessary resources Consideration of the older adult throughout the process | Identify modifiable accrual barriers from each stakeholder perspective |
| Use of geriatric assessment in clinical trials: identify research gaps | Infrastructure needs to perform comprehensive geriatric assessment | Identify interventions that can address the identified barriers to enhance accrual of older adults to NCI sponsored clinical trials |
| Identify best approach and measures to define fitness/frailty to enroll in a clinical trial | Use of technology/telehealth to engage older adults in clinical research | Address clinician biases toward enrolling older adults to clinical trials |
| | | Identify patient needs and concerns and develop interventions to address |

Study Design Recommendations

- Prioritize trial designs that have been shown to be effective at increasing accrual of older adults with cancer across heterogeneity of fitness levels (i.e. older adult specific trials)
- Emphasize under-utilized trial designs that have potential for augmenting accrual of older adults (i.e. parallel cohort)
- Incorporate pragmatic design elements (see PRECIS, e.g., relaxing eligibility requirements) for any trial
- Consider the role of geriatric assessment measures for capturing important information for any trial that is intended to enroll older adults

Example of Trial designs for Older Adults

- Definitive evaluation of novel therapeutics in CLL
 - Does treatment with ibrutinib improve PFS compared to standard cytotoxic chemotherapy?
 - Need for separate trials for older and younger patients—why?
 - The standard control treatment may be different for older patients
 - Accrual rates differ by age group
 - Ibrutinib toxicity may be different by age group

The NEW ENGLAND IOURNAL of MEDICINE The NEW ENGLAND IOURNAL of MEDICINE ORIGINAL ARTICLE ORIGINAL ARTICLE Ibrutinib Regimens versus Chemoimmunotherapy Ibrutinib-Rituximab or Chemoimmunotherapy in Older Patients with Untreated CLL for Chronic Lymphocytic Leukemia J.A. Woyach, A.S. Ruppert, N.A. Heerema, W. Zhao, A.M. Booth, W. Ding T.D. Shanafelt, X.V. Wang, N.E. Kay, C.A. Hanson, S. O'Brien, J. Barrientos, N.L. Bartlett, D.M. Brander, P.M. Barr, K.A. Rogers, S.A. Parikh, S. Coutre, D.F. Jelinek, E. Braggio, J.F. Leis, C.C. Zhang, S.E. Coutre, P.M. Barr, A.F. Cashen, A. Hurria, * J.R. Brown, G. Lozanski, J.S. Blachly, H.G. Ozer, B. Major-Elechi, A.R. Mato, A.K. Singh, M.P. Mullane, R.F. Little, H. Erba, R.M. Stone, M. Litzow, B. Fruth, S. Nattam, R.A. Larson, H. Erba, M. Litzow, C. Owen, C. Kuzma, and M. Tallman J.S. Abramson, R.F. Little, S.E. Smith, R.M. Stone, S.J. Mandrekar, and J.C. Byrd

Geriatric Assessment

Path of an Treatment/ Pre-Enrollment Outcomes individual in a enrollment Intervention clinical trial: GA to inform GA as outcome treatment GA as Inclusion criteria Understand the allocation characteristics, Identify group that is including agingeligible for associated Role for Change in GA investigational therapies vulnerabilities, of over course of geriatric **GA-directed** the enrolled study assessment supportive care patients interventions (GA) at different GA as Exclusion criteria time points: Identify individuals who GA-directed care Predictor of may be at excessive risk delivery outcomes for study therapy

Magnuson et al. J Natl Cancer Inst Monogr (2022); 2022, 60

4 key Recommendations to Strengthen Infrastructure



01

CENTRALIZE

Resources and Expertise



02

TRAIN

Clinical Research Staff



03

DEVELOP

Common Data Elements



04

EVALUATE

What works and what doesn't



Background: ASCO-Friends Eligibility Criteria Initiative

2017: ASCO-Friends publish broadened eligibility criteria to include patients with:

- Brain metastases
- Prior and concurrent malignancies
- HIV infection
- Organ dysfunction, and
- Patients younger than age 18 years

2018: NCI's Cancer Therapy Evaluation Program (CTEP) incorporates recommendations into protocol template for use in CTEP-supported trials



Kim, ES, et al. J Clin Oncol 2017

ASCO-Friends Recommendations 2021

- ASCO-Friends leadership group appointed multi-stakeholder working groups to propose recommendations for more inclusive eligibility criteria in these areas:
 - Washout periods
 - Concomitant medications
 - Prior therapies, including type and number
 - Laboratory reference ranges and test intervals
 - Performance status
- Kim, ES, et al, Continuing to Broaden Eligibility Criteria to Make Clinical Trials More Representative and Inclusive: ASCO–Friends of Cancer Research Joint Research Statement, Clin Cancer Res, Feb. 2021. PMID: 33563632

CTEP Pilot to Prospectively Broaden Eligibility Criteria in Clinical Trials

Goal: CTEP Protocol Review Committee to conduct focused reviews of eligibility criteria (EC) and compare to ASCO/Friends EC and NCI protocol template language in NCTN and ETCTN protocols to further expand EC.

Pilot Implementation:

- Study teams will need to provide scientific and/or clinical rationale for protocols that have EC restricted and NCI will review.
- CTEP Project Managers will review and track EC in protocols prospectively.
- Pilot began January 2022, ASCO/Friends further expanded EC



https://ctep.cancer.gov/protocolDevelopment/templates_applications.htm





