January 26, 2022

Informational Webinar

Research Infrastructure Development for Interdisciplinary Aging Studies

(R21/R33 - Clinical Trial Optional)

PAR-20-070/NOT-CA-22-023

Speakers:

Jennifer Guida, PhD, MPH

Weiwei Chen, PhD

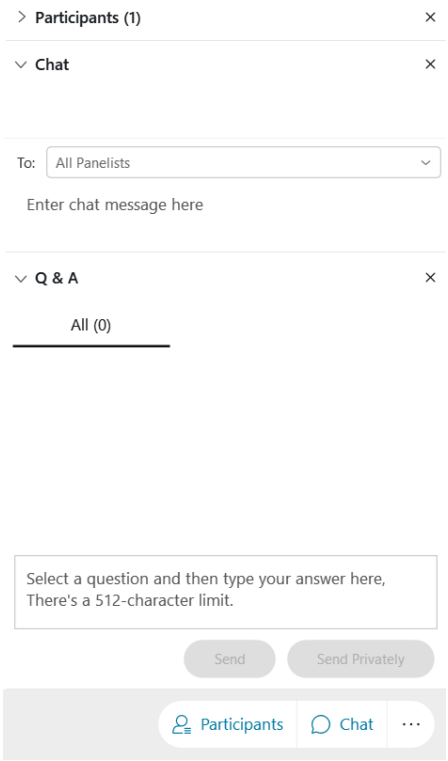
Konstantin Salnikow, PhD

Diane St. Germain, RN, MS, CRNP

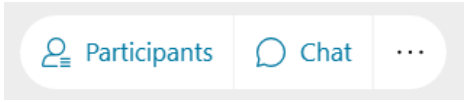
Anil Wali, PhD

NIH NATIONAL CANCER INSTITUTE

Using WebEx and Webinar Logistics



- All lines will be in listen-only mode
- Submit questions at any time using the Q&A or Chat Panel and select *All Panelists*
- You may need to activate the appropriate box using the floating navigation panel. Found on the bottom of your screen



- This webinar is being recorded

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Treatment & Diagnosis

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Center to Reduce Cancer
Health Disparities

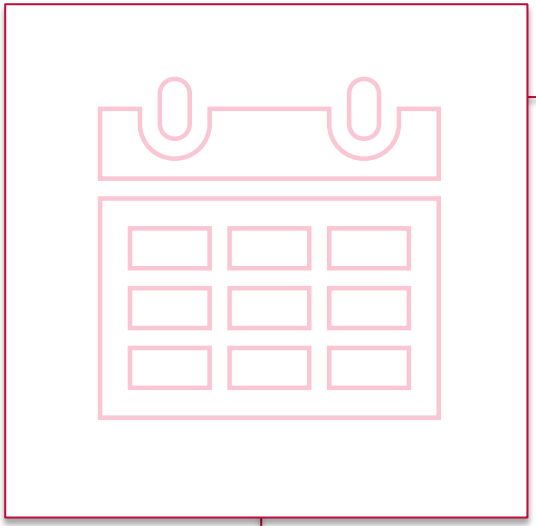
About the FOA

Purpose, Process and General Information

Purpose of the FOA

The NCI seeks applications that propose developing or scaling up a novel research infrastructure that will advance the science of cancer and aging in specific areas requiring interdisciplinary partnerships or collaborations

Application Due Dates

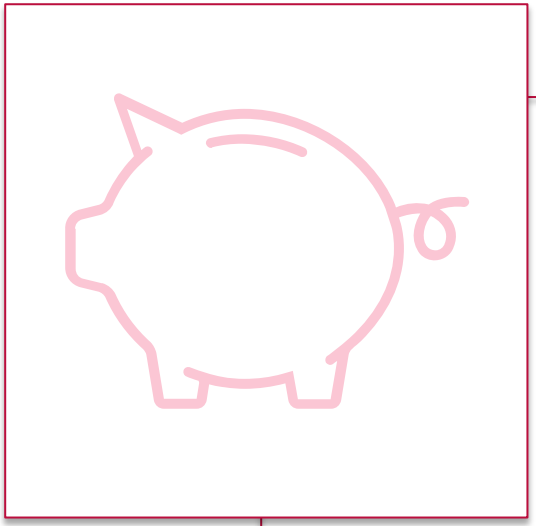


Standard Receipt Dates

- February 16, 2022
- June 16, 2022
- October 16, 2022

Note: PAR Expiration Date is Nov. 17, 2022

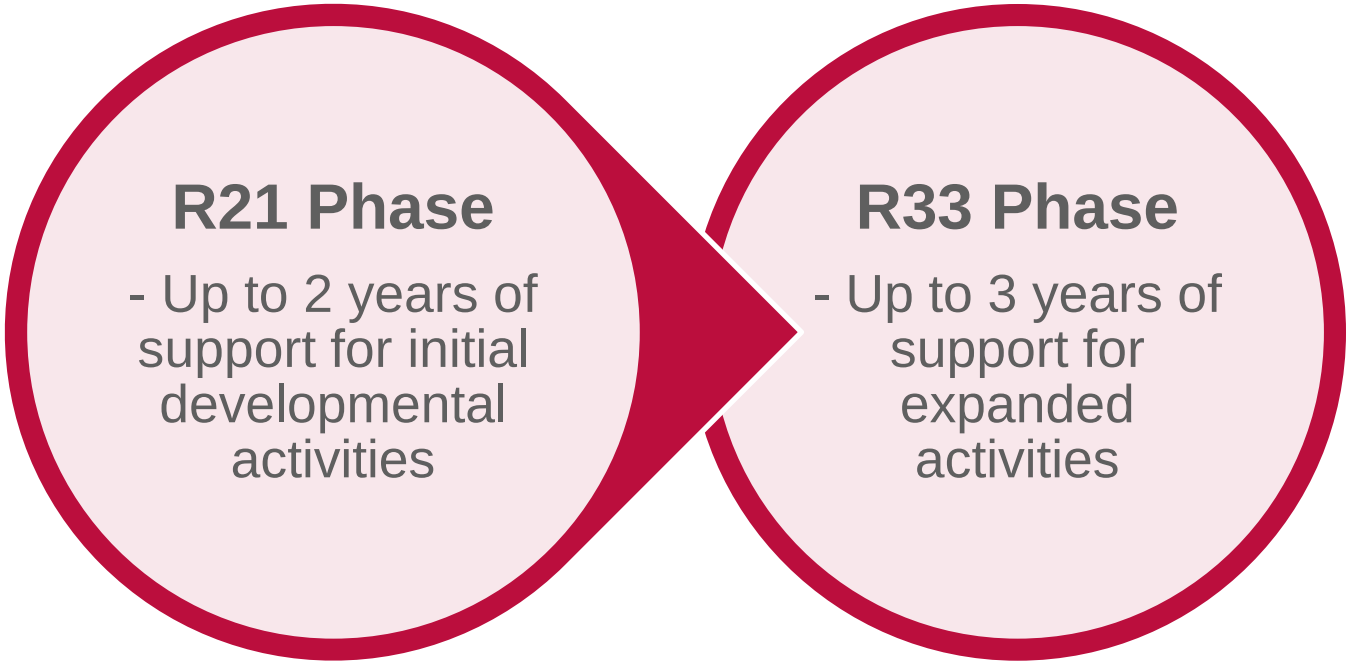
Application Budget



Budget

- R21 Phase:
  - Direct costs for a two-year project may not exceed $275,000
- R33 Phase:
  - Budgets must remain under $500,000 in annual direct costs

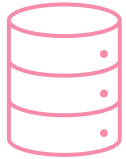
NIH Phased Innovation Award (R21/R33)



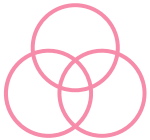
Activities Responsive to the FOA

Development or scaling up of research infrastructure

Replication studies

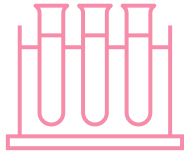


Merging and harmonization of data



Performing integrative analyses

Development of data-mining methods

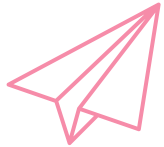


Development of accessible biospecimen repositories

Activities Responsive to the FOA

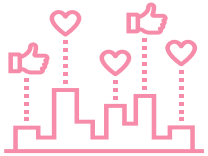
Development & validation of diagnostic tests/assays

Secondary analyses of existing data sets



Feasibility or pilot study interventions

Translation into practice or community settings



Data sharing and dissemination of methods, practice guidelines, etc.

Specific Aims

- Applications should include:
  - A unifying and testable hypothesis that transcends both the R21 and R33 phases
  - The specific aims for each phase
  - Clear milestones for the R21 and goals for the R33 phase
    - How those milestones accomplish the aims
    - The goals of the R33 phase should be based, in part, on findings collected during the R21 phase
  - Timelines for both the R21 and R33

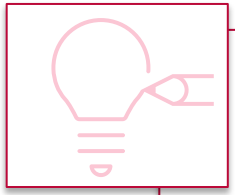
Research Strategy

- The specific goals to be achieved should be clearly stated in the application, including an explanation of:

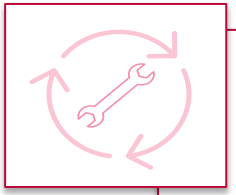
How the proposed infrastructure development activities will advance this emerging scientific area

Why these goals will serve to advance/accelerate cancer and aging research beyond what can be achieved through existing programs or structures

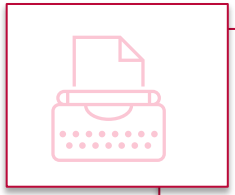
Research Strategy



Strong scientific rationale



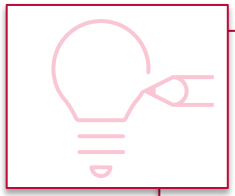
Clearly described plan for sustaining infrastructure



Description of both the R21 and R33 phases

Milestone section

Research Strategy



Strong scientific rationale

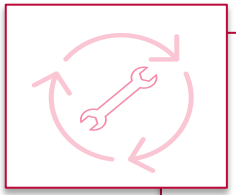
- Note: This mechanism **does not require preliminary data**, extensive background material or preliminary information
  - Appropriate justification for the proposed work can be provided through literature citations, data from other sources
  - Preliminary, investigator-generated data may be included, if available

Research Strategy

Description of both the R21 and R33 phases

- Clear description of what activities will be accomplished in the R21 and R33 phases:
  - R21 – initial development activities
  - R33 – expanded development activities

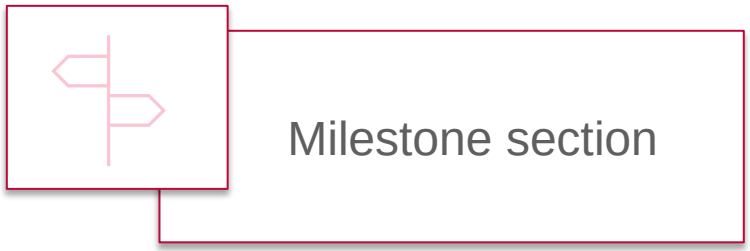
Research Strategy



Clearly described plan for sustaining infrastructure

- Applicants should clearly describe a plan for sustaining the infrastructure developed through this grant following the end of the R21/R33 award period
  - Examples of future support:
    - Research awards (R01s, P01s, U01s)
    - Center grants (P30s)
    - Other infrastructure support awards (R24)
    - Other NIH mechanisms
    - Non-NIH funding sources

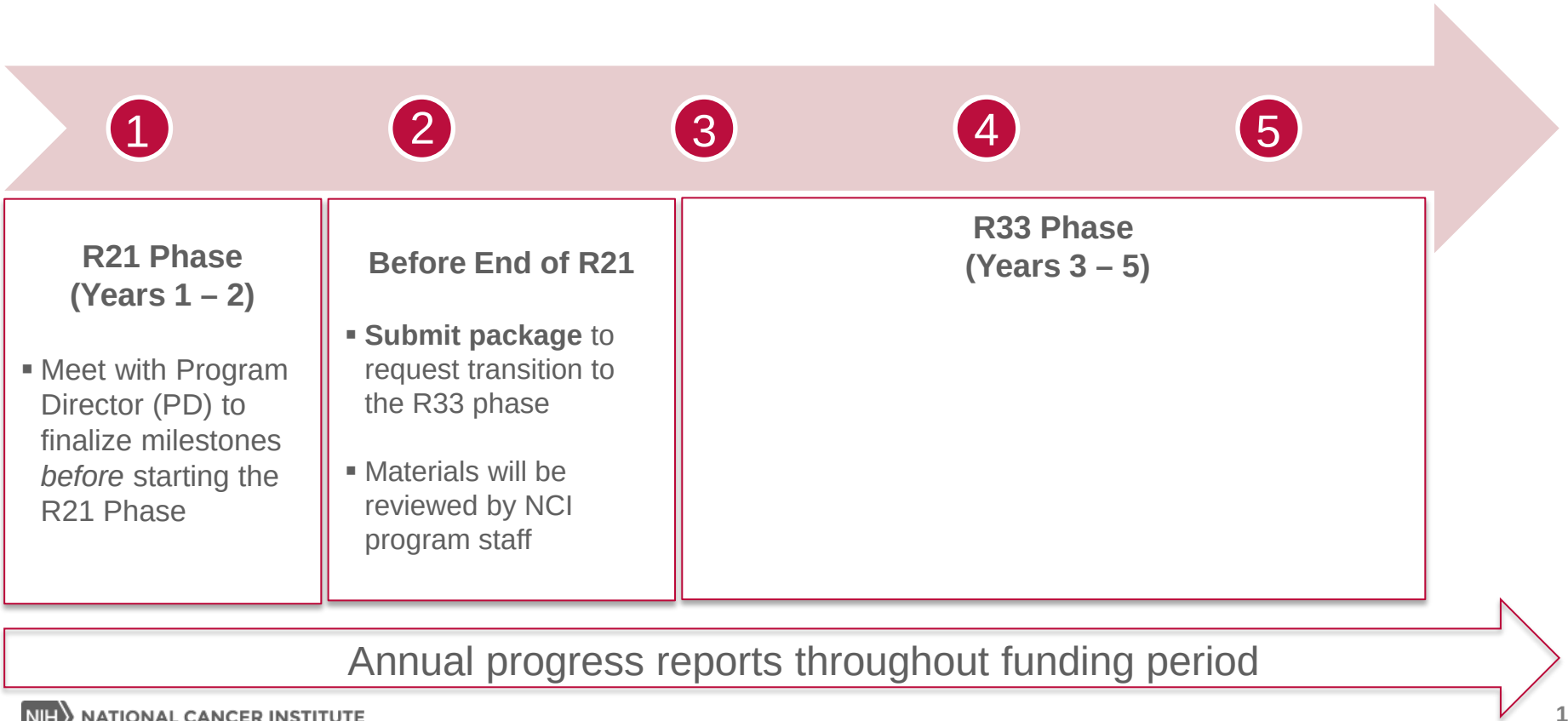
Research Strategy



- Milestones should be:
  - Clearly described
  - Feasible
  - Well developed
  - Quantifiable
  - Scientifically justified to transition to the R33 phase

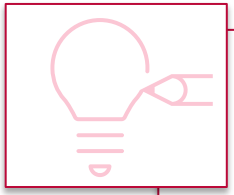
- A discussion of the milestones relative to the progress of the R21 phase and the implications of successful completion of the milestones for the R33 phase should be included

Timeline

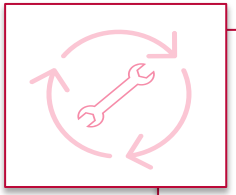

1
2
3
4
5
R21 Phase
(Years 1 – 2)
Meet with Program Director (PD) to finalize milestones *before* starting the R21 Phase
Before End of R21
Submit package to request transition to the R33 phase
Materials will be reviewed by NCI program staff
R33 Phase
(Years 3 – 5)
Annual progress reports throughout funding period

Research Strategy

To recap, the Research Strategy should include:



Strong scientific rationale



Clearly described plan for sustaining infrastructure

Description of both the R21 and R33 phases

Milestone section

Review

All applications sent to NIA for initial review

NIA determines which applications are to be assigned to NCI based on agreed upon criteria

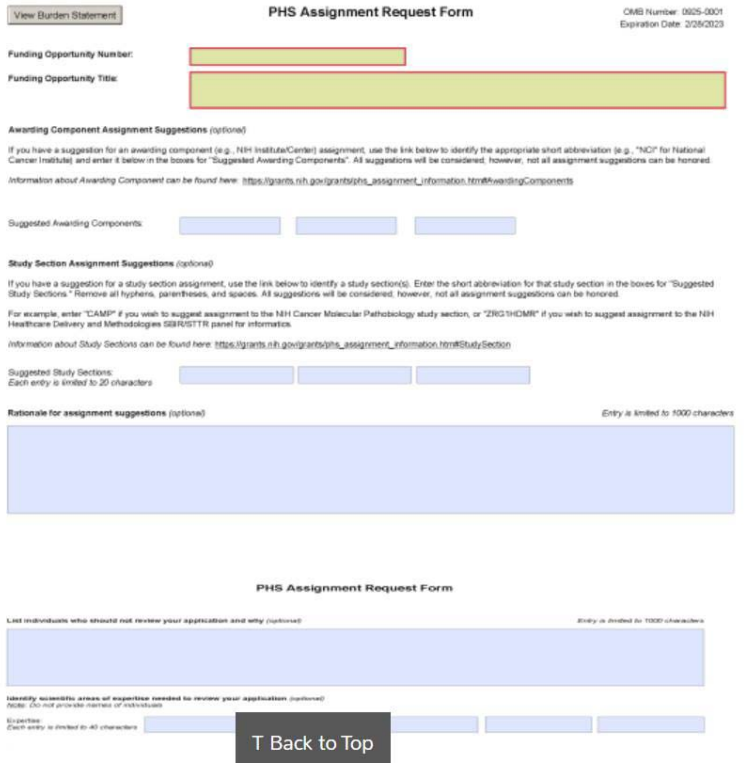
Applications referred to NCI will be reviewed by a CSR Study Review Group of “best fit”

Assignment to a Scientific Review Group will be shown in the eRA Commons

PHS Assignment Request Form

- O*ptional* form used to convey PI preferences to the Division of Receipt & Referral and Scientific Review Officers. Can be used to:
  - Improve the PI's chance that their application will be referred to NCI
  - Request up to three CSR-study section review groups
    - All review preferences submitted by the PI will be considered
  - Identify the types of expertise needed to appropriately review a grant application
    - Specific individuals should not be identified

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.600-phs-assignment-request-form.htm


View Burden Statement

PHS Assignment Request Form

OMB Number: 0925-0001
Expiration Date: 2/28/2023

Funding Opportunity Number:

Funding Opportunity Title:

Awarding Component Assignment Suggestions (optional)

If you have a suggestion for an awarding component (e.g., NIH Institute/Center) assignment, use the link below to identify the appropriate short abbreviation (e.g., "NCI" for National Cancer Institute) and enter it below in the boxes for "Suggested Awarding Components". All suggestions will be considered, however, not all assignment suggestions can be honored.

Information about Awarding Component can be found here: https://grants.nih.gov/grants/phs_assignment_information.htm#AwardingComponents

Suggested Awarding Components:

Study Section Assignment Suggestions (optional)

If you have a suggestion for a study section assignment, use the link below to identify a study section(s). Enter the short abbreviation for that study section in the boxes for "Suggested Study Sections." Remove all hyphens, parentheses, and spaces. All suggestions will be considered, however, not all assignment suggestions can be honored.

For example, enter "CAMP" if you wish to suggest assignment to the NIH Cancer Molecular Pathobiology study section, or "ZRG1HDMR" if you wish to suggest assignment to the NIH Healthcare Delivery and Methodologies SBIR/STTR panel for information.

Information about Study Sections can be found here: https://grants.nih.gov/grants/phs_assignment_information.htm#StudySection

Suggested Study Sections:
Each entry is limited to 20 characters

Rationale for assignment suggestions (optional)

Entry is limited to 1000 characters

PHS Assignment Request Form

List individuals who should not review your application and why (optional)

Entry is limited to 1000 characters

Identify scientific areas of expertise needed to review your application (optional)
Note: Do not provide names of individuals

Expertise:
Each entry is limited to 40 characters

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Helpful resources for finding a CSR study section

- Study section guidelines: https://public.csr.nih.gov/StudySections/StandingStudySections
- Assignment Request Tool: https://art.csr.nih.gov/ART/selection.jsp

NCI Division and Center Interests

Division of Cancer Biology (DCB)

Scientific/Research Contact:
Konstantin Salnikow, Ph.D.
Email: salnikok@mail.nih.gov

- DCB supports research in all areas of basic cancer biology, including the understanding of how the mechanisms responsible for fundamental cell processes are deregulated and result in cell malignant transformation and progression to metastasis

- DCB is interested in aging-associated molecular changes in the fundamental cellular processes that contribute to cancer susceptibility, progression, and metastasis

Division of Cancer Biology

Scientific/Research Contact:
Konstantin Salnikow, Ph.D.
Email: salnikok@mail.nih.gov

- Areas of interest:
  - Understanding the role of aging in genomic instability, epigenetic deregulation & cancer
  - The role of aging in deregulation of proteostasis, nutrient-sensing and mitochondrial dysfunction
  - Oxidative stress and intercellular communication in cancer development and progression
  - Understanding the mechanisms responsible for stem cell exhaustion and cellular senescence in cancer
  - Infrastructure for unveiling, visualizing, and analyzing age-associated molecular, cellular, and tissue-based differences and drivers in cancer development

Division of Cancer Biology

Scientific/Research Contact:
Konstantin Salnikow, Ph.D.
Email: salnikok@mail.nih.gov

- Areas of interest cont'd:
  - Infrastructure enabling integrated analyses of aging and cancer data
  - The use of aging-relevant model systems to understand basic mechanisms of cancer biology
  - The development of age-relevant models to study sex differences, and the role of gender in cancer and aging
  - The development of models comparing mechanisms of geriatric sarcopenia and cancer cachexia
  - The role of aging in response to cancer therapy and resistance
  - Mapping age-related changes as part of Human Tumor Atlas Network (HTAN) and the influences of the aging nervous system in cancer

Division of Cancer Prevention (DCP)

Scientific/Research Contact:
Diane St. Germain, R.N., M.S., C.R.N.P.
Email: dstgermain@mail.nih.gov

Cancer Prevention

- Intervention studies
  - Nutrition, cancer prevention interventions, vaccines, surgery and behavioral modifications
- Development of biomarkers
  - Early detection
  - New screening technologies
- Development of immune-based approaches for the prevention of cancer
- Development of animal models of cancer prevention

Division of Cancer Prevention

Scientific/Research Contact:
Diane St. Germain, R.N., M.S., C.R.N.P.
Email: dstgermain@mail.nih.gov

Symptom Science

- Testing of interventions to enhance treatment tolerability and reduce cancer and treatment related symptoms and toxicities in older adults including translational endpoints to enhance the mechanistic understanding of toxicities in this population
- Longitudinal studies to understand the trajectory and biological contributions of commonly occurring symptomatic toxicities
- Development of strategies tailored to older adults that address various modes of patient reporting of toxicities in clinical research

Division of Cancer Prevention

Scientific/Research Contact:
Diane St. Germain, R.N., M.S., C.R.N.P.
Email: dstgermain@mail.nih.gov

Clinical Trial Accrual of Older Adults

- Interventions that address clinician bias of older adult participation in clinical trials

- Use of the geriatric assessment and other determinants of fitness in clinical trials to understand patient factors that contribute to treatment tolerability, guide supportive care, and predict toxicity

Division of Cancer Treatment and Diagnosis (DCTD)

Scientific/Research Contact:
Weiwei Chen, Ph.D.
Email: weiwei.chen@nih.gov

- Areas of interest:
  - Identification of novel, age-related cancer targets that promote cancer progression and metastasis or modulate treatment response.
  - Development of novel drugs or drug combinations that improve therapeutic outcomes in age-specific subgroups.
  - Development of immunotherapy-based combinations for younger and older cancer patients.
  - Discovery and development of biomarkers to facilitate personalized cancer therapy.
  - Consideration of patient heterogeneity in treatment optimization for older adults with cancer.
  - Advancement of proteogenome science to elucidate the functional biology of tumors across the lifespan through large-scale multi-omic characterizations.

Center to Reduce Cancer Health Disparities (CRCHD)

Scientific/Research Contact:
Anil Wali, Ph.D.
Email: walia@mail.nih.gov

- NCI's CRCHD is committed to advance understanding of the multifactorial causes of cancer disparities, including biological and nonbiological bases of cancer incidence and progression in aging, and by facilitating new and ongoing linkages between research, training, and outreach in cancer and aging.

Areas of research infrastructure development include, but are not limited to:

- Basic, clinical, translational, and population-based research to address cancer health disparities and aging;
- Training students and investigators from diverse backgrounds to address cancer and aging research; and
- Building regional networks to foster collaboration, enhance disparities research, and dissemination of culturally appropriate, evidence-based information about cancer and aging to underserved communities.

Division of Cancer Control & Population Sciences (DCCPS)

Scientific/Research Contact:
Jennifer Guida, Ph.D., M.P.H.
Email: jennifer.guida@nih.gov

- Areas of interest:
  - Identification or development of aging measures and biomarkers to enable the investigation of aging trajectories among cancer survivors
  - Investigation of biological, behavioral, and psychosocial and other aging-relevant factors (e.g., age-related changes in body composition, energy balance, and health behaviors) associated with cancer risk and outcomes
  - Development and testing of interventions to prevent, lessen, or rehabilitate aging-related consequences of cancer treatment

Division of Cancer Control & Population Sciences (DCCPS)

Scientific/Research Contact:
Jennifer Guida, Ph.D., M.P.H.
Email: jennifer.guida@nih.gov

- Areas of interest cont'd:
  - Leveraging existing resources to address cancer survivorship and aging hypotheses; development and use of age/aging relevant and clinically-informative animal models of human cancers and treatment-related late effects
  - Examining use of patient-reported outcomes to stratify risk, support decision-making, and optimize cancer and aging outcomes in survivors
  - Inclusion of older adults in observational and intervention studies of cancer survivorship

FAQs

FAQs

- **Q: What scope of research is appropriate for the R21/R33 mechanism?**

  Many activities can be conducted under the scientific scope of the FOA, but the Aims should be focused on infrastructure building (i.e., building resources)

  For example:

  - Consensus building activities
  - Agenda setting for scientific research priorities
  - Harmonization of datasets

- NCI is particularly interested in applications that want to create a platform for which other research may be produced, rather than serving one independent research project

FAQs

- **Q: How do I know if my research question is appropriate for an R21/R33 versus an R01?**

R01:

- Aims are hypothesis driven
- Aims are independent
- Should be supported by preliminary data

R21/R33:

- Aims are focused on infrastructure building
- R33 aims are dependent on R21 aims
- Preliminary data is not required
- Must include aims/descriptions of both phases and clear milestones to transition from R21 to R33 phase

FAQs

- **Q: PAR-20-070 will expire in November 2022. Will the PAR be reissued?**

We cannot say at this time, but if it is reissued, it will be published in the NIH Guide

FAQs

- **Q: Can I apply for only R21 or only R33 funding through this mechanism?**

No, applications proposing R21 or R33 activities alone will be considered incomplete and will not be accepted

FAQs

- **Q: Can I apply for 1 year of R21 support (rather than 2 years), followed by 3 years of R33 support?**

Technically yes, but it is not advised

Individual circumstances may vary, so please talk with your program director ahead of time

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www.cancer.gov **www.cancer.gov/espanol**