Pre-Application Webinar for RFA-CA-027/028

Research to Reduce Morbidity and Improve Care for Pediatric, and Adolescent and Young Adult (AYA) Cancer Survivors (R01/R21 Clinical Trial Optional)

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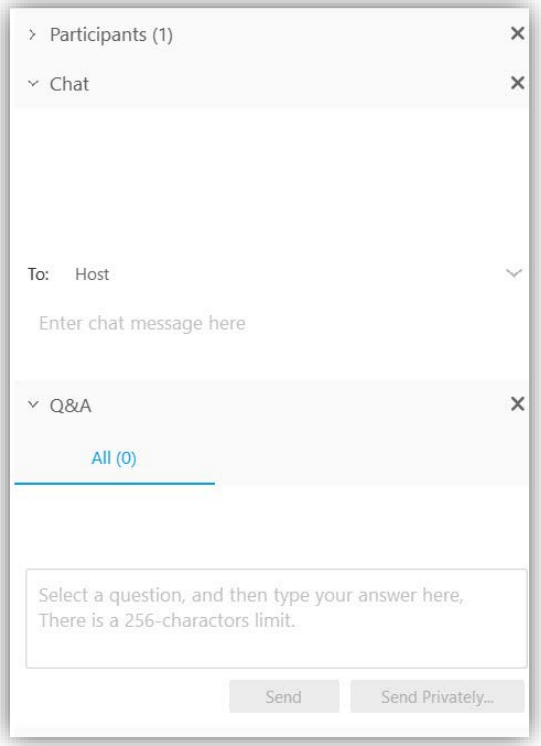
NIH NATIONAL CANCER INSTITUTE
Division of Cancer Control & Population Sciences

Using WebEx and Webinar Training Logistics



- All lines will be in listen-only mode
- Submit questions at any time during the presentation. Type into the Q&A Panel and select Host
- A moderator will ask the question on your behalf during the Q&A portions of the training
- This training webinar is being recorded and will be posted at a later date

Webinar Presenters

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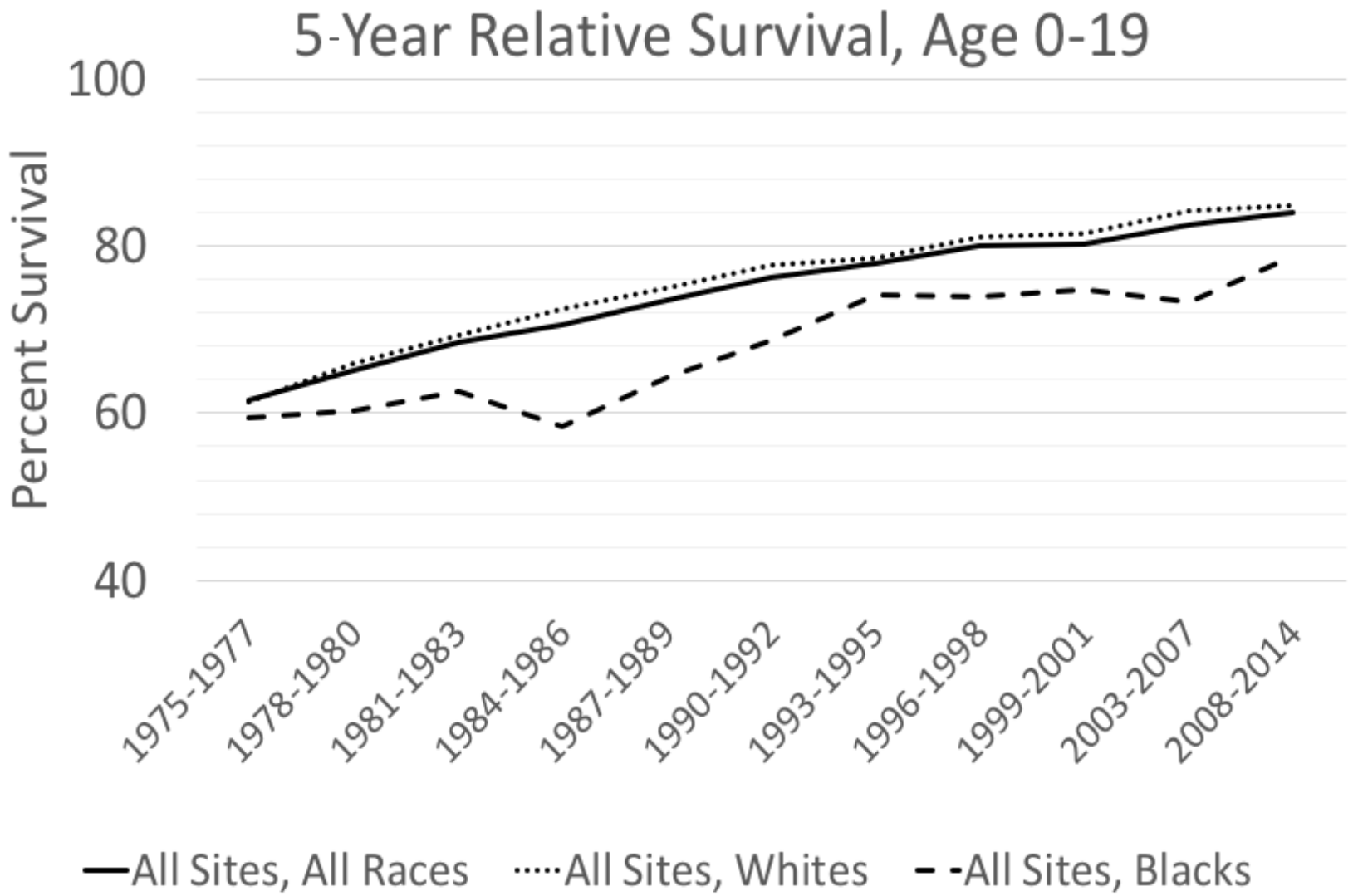
Webinar Outline

I. Background and Scope of the Problem
II. Goals of the Request for Applications (RFA)
III. Application Requirements
IV. Questions

I. Background and Scope of the Problem

Growing Population of Survivors



- Growing population of survivors
- Estimated 630,000 cancer survivors age 0 – 39 in US

[1]SEER 9 areas. Based on follow-up of patients into 2015. Expected survival rates are derived from the U.S. Annual Life Tables.

Data from Observational Studies

Adverse Effects

Physical

- Symptoms (fatigue, sleep disturbances, peripheral neuropathy)
- Impaired physical function
- Neurocognitive impairments
- Late treatment effects (endocrine, cardiopulmonary, 2^{o} malignancies)
- Accelerated aging and comorbidity
- Fertility concerns
- Adverse body composition

Psychosocial

- Psychological distress
- Disrupted social development
- Financial hardship, insurance coverage, school/employment difficulties

Behavioral

- Reduced physical activity
- Potential for risky behaviors (alcohol, tobacco, non-adherence)
- Obesity

Healthcare Delivery

- Unmet needs for long-term follow-up
- Follow-up care often delivered by provider not familiar with late effects
- Continuity of care across multiple providers and settings

The Childhood Cancer Survivorship, Treatment, Access and Research (STAR) Act – June 2018

- **Congress strongly encourages efforts to advance pediatric, adolescent, and young adult (AYA) cancer survivor research**
- Authorizes improvements to:
  1. Biospecimen collections and infrastructure
  2. Cancer registry infrastructure
  3. **Research to improve the care of and quality of life for survivors**
  4. Additional survivorship care provisions

The STAR Act – Six Priority Areas

1. Survivor outcomes
2. Familial, socioeconomic, and environmental factors
3. Risk factors, predictors and molecular basis identification
4. Barriers to follow-up care
5. Indicators used for long-term follow-up
6. Targeted interventions to reduce the burden of morbidity

Consideration of health disparities, minorities or other medically underserved populations

The STAR Act – Six Priority Areas

RFA-CA-20-027/028 solicits Interventional and Observational Studies across all 6 areas

RFA-CA-20-027/028 Interventions and Observational Studies

1. Survivor outcomes
2. Familial, socioeconomic, and environmental factors
3. Risk factors, predictors and molecular basis identification
4. Barriers to follow-up care
5. Indicators used for long-term follow-up
6. Targeted interventions to reduce the burden of morbidity

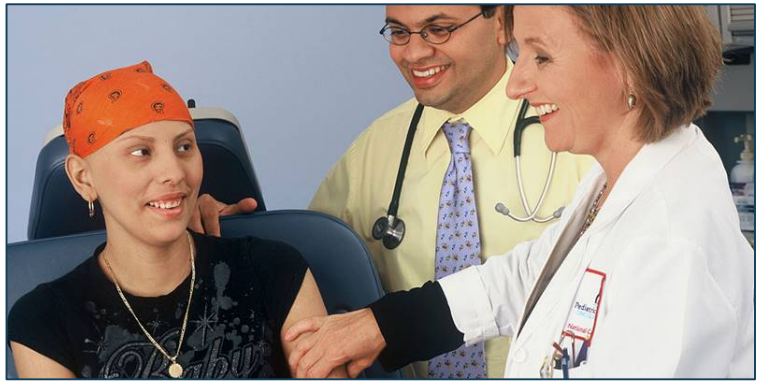
RFA-CA-19-033
Intervention focused

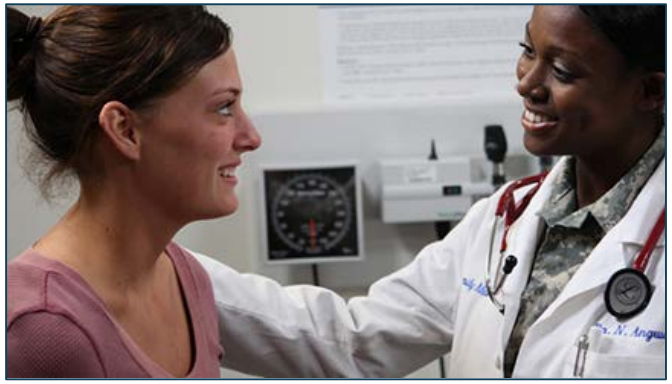
Consideration of health disparities, minorities or other medically underserved populations

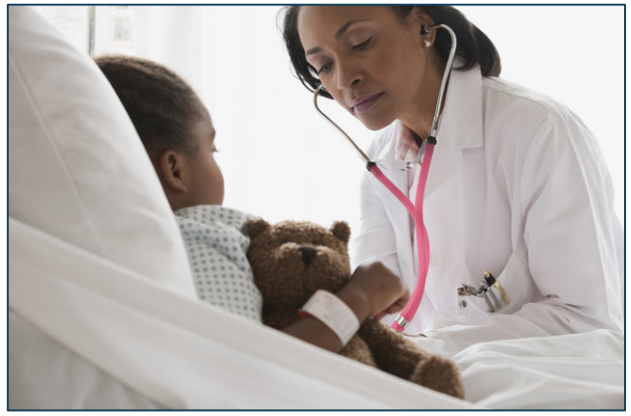
II. Goal of the RFA

Goals of RFA-CA-20-027/028

To support research projects that improve the care and/or quality of life for childhood and adolescent young adult (AYA) cancer survivors







Purpose

Solicit applications that propose mechanistic, observational and/or interventional studies that aim to understand and/or to address one or more of the following domains related to pediatric/AYA survivors:

1. disparities in survivor outcomes;
2. barriers to follow-up care (e.g. access, adherence);
3. impact of familial, socioeconomic, and other environmental factors on survivor outcomes;
4. indicators for long-term follow-up needs related to risk for late effects, recurrence, and subsequent cancers;
5. risk factors and predictors of late/long-term effects of cancer treatment; and
6. development of targeted interventions to reduce the burden of cancer

Grant Mechanisms- R01 and R21

NIH Exploratory/Developmental Grant (R21)	NIH Research Project Grant (R01)
▪ Supports new, exploratory, and developmental research projects ▪ May be used for pilot and feasibility studies ▪ Combined budget for direct costs for the two-year project period may not exceed $275,000 ▪ Up to 2 years of funding	▪ Supports a discrete, specified, and circumscribed research project ▪ Most commonly used grant program ▪ No specific budget limits ▪ 3-5 years of funding

For more information: grants.nih.gov/grants/funding/funding_program.htm#RSeries

Population Focus

- Survivors of pediatric and/or AYA cancers (diagnosed before age 39)
  - Study populations may be defined by a single diagnosis or multiple primary diagnoses, cancer treatment modalities, presence of co-morbidities, or other defining characteristics as appropriate and with justification
- Must focus on pediatric and/or AYA cancer survivors but may also focus on other relevant populations, including informal cancer caregivers and clinicians/healthcare providers

Applications Considered Responsive

Proposed projects must have all of the following attributes:

- Focus on a subset of the pediatric and/or AYA cancer survivor population (age at primary diagnosis 0-39)
- Focus on understanding and/or addressing physical, psychosocial, and/or behavioral adverse effects or improving healthcare delivery in survivors of pediatric and/or AYA cancers
- Address one or more of the six key domains within the STAR Act:

1. disparities in survivor outcomes
2. barriers to follow-up care (e.g. access, adherence)
3. impact of familial, socioeconomic, and other environmental factors on survivor outcomes
4. indicators for long-term follow-up needs related to risk for late effects, recurrence, and subsequent cancers
5. risk factors and predictors of late/long-term effects of cancer treatment
6. development of targeted interventions to reduce the burden of cancer

Applications Considered Non-Responsive

- Applications addressing short-term, transient adverse effects (e.g., nausea due to cancer treatment)
- Applications that propose development or testing of cancer-directed therapies

Additional Considerations

Applications with the following attributes are strongly encouraged:

- Applications that aim to understand and/or address health disparities (e.g., racial/ethnic, geographic, socioeconomic) and/or the needs/preferences of a minority or medically underserved population
- Applications that aim to understand and leverage advances in digital and mobile health solutions
- Applications that aim to accelerate simultaneous integration of research-tested interventions into clinical care delivery

III. Application Details and Requirements

Application Dates

	* 1st Receipt *	2nd Receipt
Application Due Date	October 1, 2020	July 30, 2021
Letter of Intent Due Date	30 days prior to application due date	30 days prior to application due date
Scientific Merit Review	January 2021	Oct./Nov. 2021
Advisory Council	May 2021	January 2022
Earliest Start Date	July 2021	April 2022

* 1st receipt dates have been modified; https://grants.nih.gov/grants/guide/notice-files/NOT-CA-20-057.html

Clinical Trial Requirements (if applicable, Clinical Trial Optional)

- NIH requirements for clinical trials research applications were updated in January 2018. Please be sure to learn about and understand the following policies:
  - Application form now consolidates all Human Subjects and Clinical Trial related information into one place and also expands the information required for applications that include a clinical trial (FORMS-E)
  - Investigators and staff must receive training in Good Clinical Practice
  - All sites participating in multi-site studies research will use a single IRB
  - All NIH-funded clinical trials are expected to register and submit results to Clinicaltrials.gov
- Information about the NIH Clinical Trial Requirements: https://grants.nih.gov/policy/clinical-trials.htm

Data Sharing Requirements

- The Data Sharing Plan is expected to include sharing relevant resources and data through appropriate NIH-supported repositories (as applicable)
- The Data Sharing Plan should address participants' Study Consents and include (whenever possible) the option to use data and/or biospecimens for future research studies
- You can learn more about the NIH policy for data sharing here: https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm

Budget Requirements

Proposed budgets should reflect the actual needs of the proposed project

	R21	R01
Budget	≤ $275,000 in direct costs over two years ≤ $200,000 for any year	Not Limited
Project Period	Up to 2 years	up to 5 years

Review

- Special Emphasis Panel convened by NCI
- **Review Criteria Specific to this FOA:**
  - *Significance*: How significant is the proposed research in terms of addressing a pressing need or an important knowledge gap for pediatric and/or AYA survivors?
  - *Environment*: How strong is the investigator team in terms of demonstrated expertise in cancer survivor research and/or pediatric and/or AYA cancer?
  - *Approach*: How appropriate is the selected population for the study proposed? If an intervention is proposed, how appropriate and meaningful are the proposed proximal endpoints?

Resources

- Read the FOA very carefully!
  - https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-20-027.html
  - https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-20-028.html
- Today's webinar and FAQ will be posted on our website:
  - https://healthcaredelivery.cancer.gov/media/webinars.html?Search=%27FOA%20Webinars
- Connect with us early!
  - Dr. Danielle Daee (Danielle.daee@nih.gov)
  - Dr. Michelle Mollica (mollicama@mail.nih.gov)

Questions?

Please type your questions in the Q & A section on WebEx

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