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)

Danielle Daee, PhD, Epidemiology and Genomics Research Program
Michelle Mollica, PhD, MPH, RN, OCN Healthcare Delivery Research Program
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

Michelle Mollica, Ph.D., M.P.H., R.N., O.C.N.
Program Director
Outcomes Research Branch
Healthcare Delivery Research Program
mollicama@mail.nih.gov

Danielle Daee, Ph.D.
Program Director
Genomic Epidemiology Branch
Epidemiology and Genomics Research Program
Danielle.Daee@nih.gov
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

5-Year Relative Survival, Age 0-19

Percent Survival


- All Sites, All Races  ---- All Sites, Whites  --- All Sites, Blacks

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

<table>
<thead>
<tr>
<th>Physical</th>
<th>Psychosocial</th>
<th>Behavioral</th>
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<tbody>
<tr>
<td>- Symptoms (fatigue, sleep disturbances, peripheral neuropathy)</td>
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<td>- Impaired physical function</td>
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<td>- Neurocognitive impairments</td>
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<td>- Late treatment effects (endocrine, cardiopulmonary, 2° malignancies)</td>
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<tr>
<td>- Accelerated aging and comorbidity</td>
<td></td>
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<tr>
<td>- Fertility concerns</td>
<td></td>
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<td>- Adverse body composition</td>
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<tr>
<td>- Psychological distress</td>
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<tr>
<td>- Disrupted social development</td>
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<tr>
<td>- Financial hardship, insurance coverage, school/employment difficulties</td>
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<tr>
<td>- Reduced physical activity</td>
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<td>- Potential for risky behaviors (alcohol, tobacco, non-adherence)</td>
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<tr>
<td>- Obesity</td>
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### 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*

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
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

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

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

<table>
<thead>
<tr>
<th></th>
<th>* 1st Receipt *</th>
<th>2nd Receipt</th>
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<tbody>
<tr>
<td>Application Due Date</td>
<td>October 1, 2020</td>
<td>July 30, 2021</td>
</tr>
<tr>
<td>Letter of Intent Due Date</td>
<td>30 days prior to application due date</td>
<td>30 days prior to application due date</td>
</tr>
<tr>
<td>Scientific Merit Review</td>
<td>January 2021</td>
<td>Oct./Nov. 2021</td>
</tr>
<tr>
<td>Advisory Council</td>
<td>May 2021</td>
<td>January 2022</td>
</tr>
<tr>
<td>Earliest Start Date</td>
<td>July 2021</td>
<td>April 2022</td>
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* 1st receipt dates have been modified; [https://grants.nih.gov/grants/guide/notice-files/NOT-CA-20-057.html](https://grants.nih.gov/grants/guide/notice-files/NOT-CA-20-057.html)
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

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<tr>
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<th>R21</th>
<th>R01</th>
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<tbody>
<tr>
<td>Budget</td>
<td>$\leq$ 275,000 in direct costs over two years</td>
<td>Not Limited</td>
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<tr>
<td></td>
<td>$\leq$ 200,000 for any year</td>
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</tr>
<tr>
<td>Project Period</td>
<td>Up to 2 years</td>
<td>up to 5 years</td>
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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!

- 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

Stay connected with us!
https://cancercontrol.cancer.gov/

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