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

Request for BSA Concept Approval
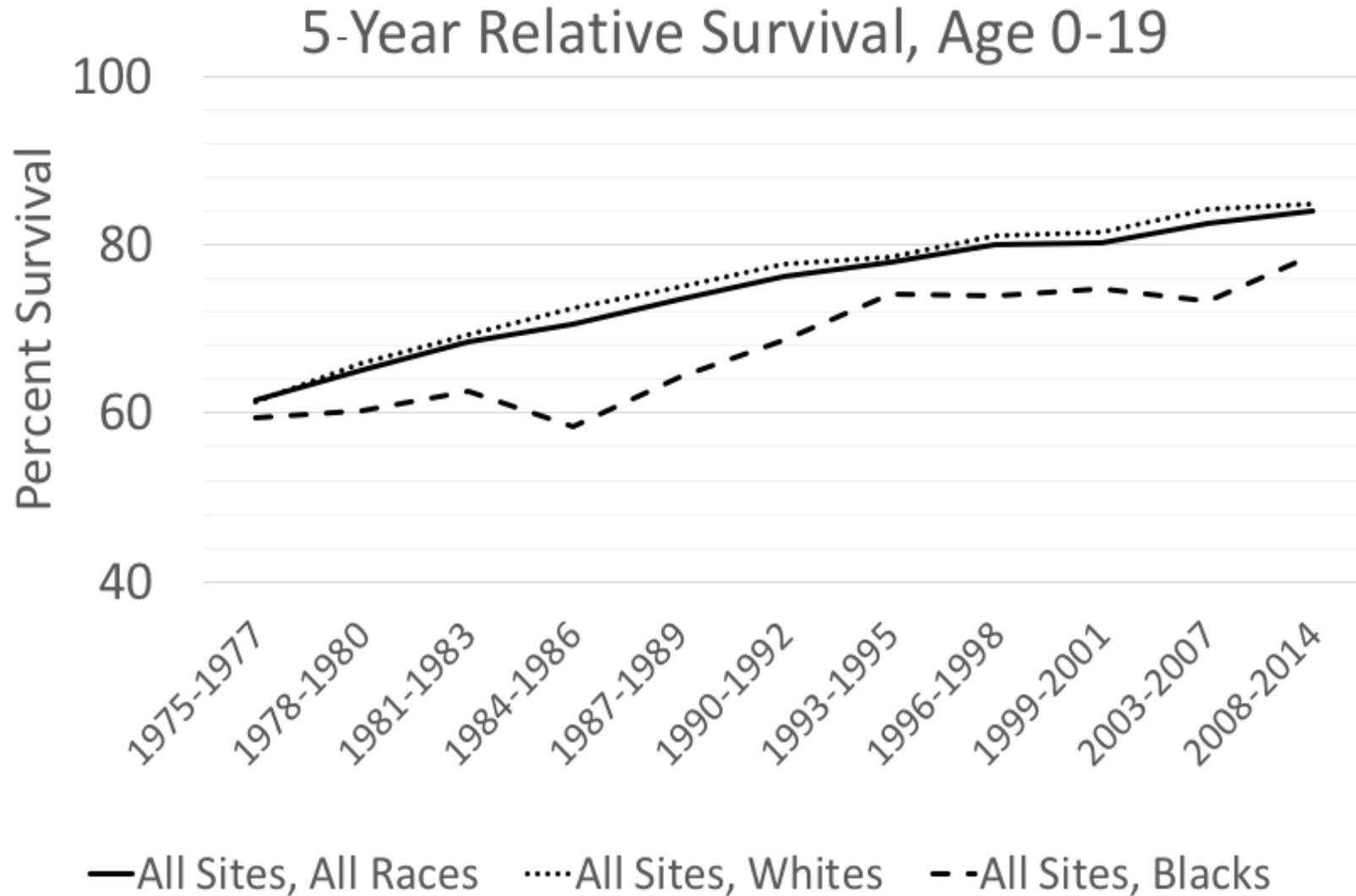*RFA in Response to the STAR Act*
December 2019

Danielle Daee, PhD
Kelly Filipski, PhD, MPH
Michelle Mollica, PhD, MPH, RN
Wendy Nelson, PhD, MPH
Nonniekaye Shelburne, CRNP, MS

NIH > **NATIONAL CANCER INSTITUTE**
Division of Cancer Control & Population Sciences

Background – Growing Population of Survivors

5-Year Relative Survival, Age 0-19

- Growing population of survivors

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

Legend: —All Sites, All Races ····· All Sites, Whites - - All Sites, Blacks

Background - Data from Observational Studies

Adverse Effects		Healthcare Delivery

Physical

- Symptoms (fatigue, sleep disturbances, peripheral neuropathy)
- Impaired physical function
- Neurocognitive impairments
- Late treatment effects (endocrine, cardiopulmonary, 2° 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

NCI's Initial Effort Addressing the STAR ACT

RFA-CA-19-033: *Improving Outcomes in Pediatric, Adolescent and Young Adult Cancer Survivors*

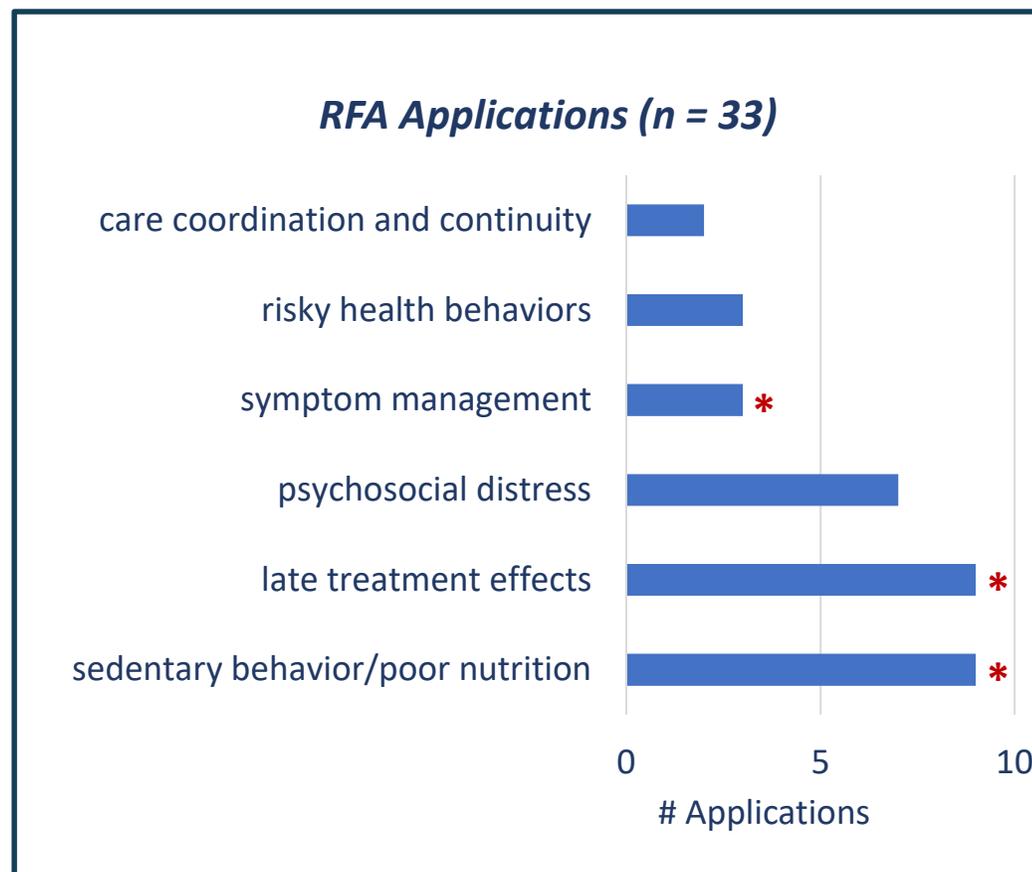*Interventions to improve healthcare delivery or prevent/mitigate adverse effects*

Receipt Dates:
March 2019, January 2020

2 Receipt Set Aside: $4.8M
(Cancer Moonshot funding)

Awards: ~6 total

Applications: 33 (1st receipt)

RFA Applications (n = 33) — bar chart of # Applications by category:
- care coordination and continuity: ~2
- risky health behaviors: ~3
- symptom management: ~3 *
- psychosocial distress: ~7
- late treatment effects: ~9 *
- sedentary behavior/poor nutrition: ~9 *

The STAR Act – Six Priority Areas

Proposed New RFA

1. Survivor outcomes
2. Familial, socioeconomic, and environmental factors
3. Risk factors, predictors and molecular basis identification
4. Barriers to follow-up care ← **Initial RFA**
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

Proposed New RFA: Research to Reduce Morbidity and Improve Care for Pediatric and AYA Cancer Survivors

- ✓ Purpose: solicit mechanistic, observational and interventional proposals, to address the full spectrum of STAR Act priorities for pediatric/AYA cancer survivors

- ✓ Mechanisms: R01 and R21

- ✓ Non-responsive topics: cancer-directed treatments/interventions

- ✓ Encourage and prioritize research relevant to disparities and underserved populations

- ✓ Requesting $5M total annual costs for each of 2 receipt dates

- ✓ Unsuccessful applications from the initial RFA can apply
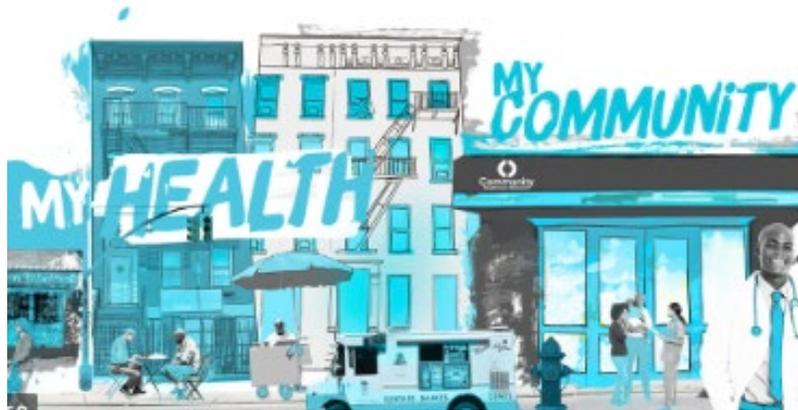
Example Research Questions:

✓ What is the **incidence, severity, and trajectory over time** of emerging chronic, progressive and late and long-term effects associated with new cancer-directed therapies, long-term cancer, or emerging health behaviors?

✓ What population-specific interventions can **effectively prevent or mitigate** these effects or promote healthy behaviors?

Example Research Questions:

✓ Which **behavioral and/or psychosocial interventions** effectively address adverse health outcomes in pediatric/AYA survivors?

✓ What strategies can **identify survivor subgroups who are at higher risk** for these adverse outcomes and may receive the greatest benefit from an intervention?

Example Research Questions:

✓ What are the **major barriers** to survivorship care, especially for pediatric and AYA survivors living in medically underserved areas?

✓ What are the components, features, costs, and values of **models of care that address these barriers** and strengthen self-management capacity, improve adherence to evidence-based care, and improve clinical outcomes?

Timeline

RFA: Research to Reduce Morbidity and Improve Care for Pediatric and AYA Cancer Survivors

2018   2019   2020   2021   2022

STAR Act

Initial RFA CA-19-033 FY19 Receipt

Initial RFA CA-19-033 FY20 Receipt

New Proposed RFA FY21 Receipt

New Proposed RFA FY22 Receipt

~6 new projects

~12-14 new projects

BSA Subcommittee Recommendations

Clarify what is meant by health disparities and the strategy for prioritizing this research.

- ✓ Health disparities are broadly defined to encompass geographic disparities, socioeconomic disparities, racial/ethnic disparities and other underserved populations.

- ✓ The inclusion of a health disparities component will be strongly encouraged (but not required), and will be a consideration when prioritizing awards for funding.

Clarify how this RFA will complement the current NCI portfolio.

- ✓ This RFA solicits studies across all STAR priority areas. After analyzing the NCI portfolio in the context of the STAR priorities and the literature we recognized the need for additional research to address persistent problems (e.g. developing indicators for long-term follow-up) and emerging problems (e.g. identifying and addressing late effects associated with new cancer-directed therapies or exposures from emerging health behaviors).

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

Extra Slides

NCI Pediatric/AYA Survivor Portfolio* by STAR Priority:

*active projects in 2017

Literature: Persistent and Emerging Issues across the STAR Priorities

STAR Priority Areas (not mutually exclusive)

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

71 NCI Projects

# of Projects

STAR Priorities

Mechanistic/Observational

Interventional

NIH NATIONAL CANCER INSTITUTE