Childhood Cancer STAR Act Implementation

Childhood Cancer Awareness Month Community Webinar

September 12, 2022
NCI Speakers

Malcolm Smith, MD, PhD
Associate Branch Chief,
Pediatrics in the Clinical Investigations Branch,
Division of Cancer Treatment and Diagnosis (DCTD)

Nita Seibel, MD
Head,
Pediatric Solid Tumor Therapeutics in the Clinical Investigations Branch, Cancer Therapy and Evaluation Program, DCTD

Emily Tonorezos, MD, MPH
Director,
Office of Cancer Survivorship, Division of Cancer Control and Population Sciences (DCCPS)

Sandra Mitchell, PhD, CRNP
Senior Scientist and Program Director,
Outcomes Research Branch in the Healthcare Delivery Research Program, DCCPS

Danielle Dae, PhD
Program Director,
Genomic Epidemiology Branch, Epidemiology and Genomics Research Program, DCCPS

Paul Jacobsen, PhD
Associate Director,
Healthcare Delivery Research Program, DCCPS
The STAR Act is bipartisan legislation that was introduced in 2017 and signed into law in 2018. Several of the bill’s provisions are directed toward NCI:

- Sec. 101. Children's cancer **biorepositories and biospecimen research** (including collaboration with the Childhood Cancer Data Initiative (CCDI))
- Sec. 111. Inclusion of at least one **pediatric oncologist** on the National Cancer Advisory Board
- Sec. 112. Sense of Congress regarding **pediatric expertise** at NCI
- Sec. 121. **Reporting** on childhood cancer research projects
- Sec. 202. Grants to improve care for **pediatric cancer survivors**
- Sec. 203. **Best practices** in survivorship care (AHRQ Evidence Reports supported by NCI)
Biobanking Progress (Sec. 101)

- **FY 2019:** May 2019 Biobanking Meeting and immediate enhancements to NCI’s Children’s Oncology Group (COG) Biobank

- **FY 2020:** New Biobanking Projects (supplement awards to COG and Childhood Cancer Survivor Study (CCSS))
  - Childhood Cancer Survivor Study: Somatic & Germline Sequencing (CCSS)
  - Banking of Blood on Childhood Cancer Survivors with Chronic Health Conditions (CCSS)
  - NCI-COG Pediatric MATCH Diagnostic Tumor Specimens (COG)
  - Postmortem Tumor Tissue Collection at Autopsy (COG)*
  - Tumor Specimens from Patients at Relapse (COG)*
  - Rare and Under-Represented Cancer Tissue Banking (COG)*

- **FY 2021 and FY 2022:** new FY 2022 supplement awards to CCSS listed below; COG supplements noted with * continue, including partnership between the COG Rare and Underrepresented Tissue Bank and CCDI Molecular Characterization Initiative
  - Gene Expression analyses of biospecimens CCSS with grade 3 and 4 health conditions
  - Whole genome/whole exome sequencing for additional specimens from CCSS Cohort
# NCI Biobanking Supplements Contributing to 11 New Research Projects

## Projects that Requested and Used Biospecimens from STAR Act Funded Supplement Projects

### 2019 Supplement

<table>
<thead>
<tr>
<th>Investigator</th>
<th>Institution</th>
<th>Project Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Smita Bhatia</td>
<td>University of Alabama at Birmingham</td>
<td>Mitigating Long-Term Treatment-Related Morbidity in Childhood Cancer Survivors</td>
</tr>
<tr>
<td>Dr. Katherine Janeway</td>
<td>Dana-Farber Cancer Institute</td>
<td>Translocation Assessment of Ewing Sarcoma Cases Enrolled on Children's Oncology Group Clinical Trials</td>
</tr>
<tr>
<td>Dr. Elaine Mardis</td>
<td>Nationwide Children’s Hospital</td>
<td>A Phase 3 Study of 131I-Metaiodobenzylguanidine (131I-MIBG) or Crizotinib Added to Intensive Therapy for Children with Newly Diagnosed High-Risk Neuroblastoma (NBL)</td>
</tr>
<tr>
<td>Dr. Lisa Mirabello</td>
<td>NCI</td>
<td>Germline Genomic Variation of Pediatric Osteosarcoma Cases Enrolled in COG</td>
</tr>
<tr>
<td>Dr. Joshua Schiffman</td>
<td>University of Utah Huntsman Cancer Institute</td>
<td>Expanded Ewing Sarcoma Cohort for Tumor genomics and Association with DNA Repair Deficiencies, Clinical Presentation, and Outcome</td>
</tr>
<tr>
<td>Dr. Peter Schoettler</td>
<td>Western Michigan University</td>
<td>Clinical and Genomic Characterization of Renal Sarcomas</td>
</tr>
</tbody>
</table>

### Pediatric MATCH Diagnostic Specimen Banking

<table>
<thead>
<tr>
<th>Investigator</th>
<th>Institution</th>
<th>Project Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Donald Williams Parsons</td>
<td>Texas Children's Hospital</td>
<td>NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)</td>
</tr>
</tbody>
</table>

### Rare and Under-Represented Cancer Tissue Banking

<table>
<thead>
<tr>
<th>Investigator</th>
<th>Institution</th>
<th>Project Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Frederic Barr¹</td>
<td>NCI</td>
<td>Genetic Analysis of Tumor Progression in Rhabdomyosarcoma</td>
</tr>
<tr>
<td>Dr. Brian Crompton</td>
<td>Dana-Farber Cancer Institute</td>
<td>A Randomized Phase 3 Study of Vincristine, Dactinomycin, Cyclophosphamide (VAC) Alternating with Vincristine and Irinotecan (VI) Versus VAC/VI Plus Temsirolimus (TORI, Torisel, NSC# 683864) in Patients with Intermediate Risk (IR) Rhabdomyosarcoma (RMS)</td>
</tr>
<tr>
<td>Dr. Philip Lupo</td>
<td>Baylor College of Medicine</td>
<td>Germline and Somatic Genetic Landscape of Pediatric Rhabdomyosarcoma</td>
</tr>
<tr>
<td>Dr. Sarah Whittle</td>
<td>Texas Children's Hospital</td>
<td>Evaluation of MYC Amplification as a Prognostic Biomarker in Osteosarcoma</td>
</tr>
</tbody>
</table>

### Tumor Specimens from Patients at Relapse

<table>
<thead>
<tr>
<th>Investigator</th>
<th>Institution</th>
<th>Project Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Frederic Barr¹</td>
<td>NCI</td>
<td>Genetic Analysis of Tumor Progression in Rhabdomyosarcoma</td>
</tr>
</tbody>
</table>

¹This project included specimens from both supplements
STAR Act biobanking efforts include working in partnership with the CCDI Molecular Characterization Initiative (MCI) to support specimen collection for MCI.
The Molecular Characterization Initiative: A STAR Act partnership with NCI’s Childhood Cancer Data Initiative

- MCI provides access to comprehensive genomic characterization
- Results can contribute to diagnosis determinations and treatment plans
- Results may also be used for meeting eligibility requirements
- First available for children with newly diagnosed brain tumors in March 2022
- MCI became available for children with soft tissue sarcomas in June 2022
- Will be open to children with rare cancers in September 2022
Biospecimen Analysis

- DNA: WES or NGS targeted panel (CLIA)
- RNA-seq (CLIA; fusions)
- DNA Methylation array (CLIA)
- Return of results (2 – 3 weeks)

Eligible Patients (CNS tumors, Sarcomas, & Rare Cancers)

NCI Characterization Program

Potential examples include:
- WGS/deep molecular (DNA) profiling
- Single Cell RNA analysis

NCI-COG Partnership
CCDI/STAR Partnership
Protocol Enrollment/Sample Processing

Integration of data
- Data repository of molecular characterization and linkable phenomic/clinical, longitudinal data

Potential examples include:
- WGS/deep molecular (DNA) profiling
- Single Cell RNA analysis

• Data Repository
  - Demographic information
  - Epidemiological information
  - Disease-Specific Data

• Bio Repository
  - Tumor/Bone Marrow (snap frozen, fixed, fresh)
  - Whole blood (or saliva)
  - Serum
  - Parental DNA (if possible)
  - Disease-Specific Specimens

Clinical Services

Research Discovery

Clinical data submission

COG Therapeutic Trial or Treatment

- Disease-Specific Treatment
  - Systemic therapy
  - Local control
  - Key Toxicity Data

Outcomes

- Disease Outcomes
- Long-term Key Toxicity Data
- Second Malignancies

Disease-Specific Specimens
NCI-COG Pediatric MATCH Trial: Diagnostic Specimen Collection

- This biobanking project collects diagnostic samples for children and adolescent and young adults (AYA) who have already submitted samples at relapse through Pediatric MATCH.

- Enables molecular characterization to identify the changes in gene mutations and gene expression that occur between diagnosis and relapse.

- Aims to inform development of more relevant treatments through in-depth characterization.

- Additionally, through CCDI ~500 cases are being genomically characterized with sequencing to be completed by the end of the year.

- Collection of samples at both diagnosis and relapse is a priority for STAR Act biobanking efforts, including an additional project aiming to better understand tumor progression in rhabdomyosarcoma.
Specimen Collection of Subsequent Cancers

- The development of subsequent malignant neoplasms (SMN) is associated with significant morbidity and mortality for survivors of childhood cancer.
- This project prioritizes collection of specimens from survivors with confirmed cases of subsequent malignancies.
- Results aim to inform treatment protocols and interventions that will yield an increase in survival, while minimizing harmful late effects.
- Used to develop and expand programs for early detection and prevention of late effects in children and adolescent cancer survivors.
Specimen Collection to Study Chronic Health Conditions

- Over 62% of CCSS participants (mean age 26 years) have at least one chronic health condition
- Over 5,550 childhood cancer survivors in CCSS have a grade 3 (severe, disabling) or 4 (life-threatening) chronic health condition (stroke, heart failure, kidney failure, diabetes, etc.)
- Collection of a one-time blood sample from survivors that have a grade 3 or 4 chronic condition
- These specimens will enhance the CCSS as a resource for future molecular/genetic evaluations to better understand the causes of chronic health conditions in survivors of childhood cancer
New FY 2022 Supplement Awards to CCSS

- Additional collection of biospecimens for grade 3 and grade 4 health conditions
  - Because of COVID, in-home collection of a single blood specimen for grade 3 and grade 4 health conditions was slowed
  - Plan to recruit additional participants for a total of 2,400 blood specimens from survivors with grade 3 and 4 health conditions that will be made available to researchers to sequence and investigate for specific health conditions
  - Data will serve as a resource for investigators studying additional CCSS outcomes

- Whole Genome/Whole Exome Sequencing for additional germline specimen from CCSS Cohort
  - Since the time CCSS last performed sequencing there have been over 2,000 additional germline specimens collected
  - WGS/WES sequencing will be performed on germline DNA from these specimens
  - Results will be available through CCSS to scientists studying childhood cancer survivors to explore treatment-related complications, predicting individuals more likely to develop complications and prevention in future trials
Leveraging External Pediatric Oncology Expertise (Sec. 111 and Sec. 112)

- **National Cancer Advisory Board** *(NCAB: Dr. Andrea Hayes, UNC)*
- **Board of Scientific Advisors** *(BSA: Dr. Mary Beckerle, Huntsman; Drs. Les Robison and Martine Roussel, St. Jude’s; Dr. Kevin Shannon, UCSF)*
- **Clinical and Translational Research Advisory Committee** *(CTAC: Dr. Smita Bhatia, UAB; Dr. Anne-Marie Langevin, UT San Antonio)*
- **Board of Scientific Counselors** *(BSC: Dr. Paul Spearman, Cincinnati Children’s; Dr. Gail Tomlinson, UT San Antonio)*
- **National Council of Research Advocates** *(NCRA: Dr. Victoria Buenger, CAC 2, Texas A&M)*
- **Frederick National Laboratory Advisory Committee** *(FNLAC: Dr. Catherine Bollard, Children’s National; Dr. Nilsa Ramirez, Nationwide Children’s & CPG Biobank; Dr. Cheryl Willman, Mayo Clinic)*
- **National Clinical Trials Network (NCTN) Steering Committees**: More than 40 subject matter experts with pediatric expertise serve across three relevant steering committees (Pediatric and Adolescent Solid Tumors, Brain Malignancies, Pediatric Leukemia and Lymphoma), including a patient advocate serving on each committee
Childhood Cancer Reporting (Sec. 121)

- NIH Pediatric Research Initiative Report to Congress
- NIH Triennial Report
- NCI research and portfolio updates via cancer.gov, including:
  - NCI’s [childhood cancer research](#) landing page
  - Several online [resources for patients and families](#)
  - Regular features in NCI’s [Cancer Currents Blog](#)
NCI Continues to Conduct and Support Childhood and AYA Cancer Survivorship Research and Care (Sec. 202)

- Childhood and AYA cancer **survivorship research** continues to be supported through funding opportunity announcements and notices of special interest
  - NCI leads: Drs. Michelle Mollica, Sandra Mitchell, and Danielle Daee
- There have been new initiatives in survivorship through 2 funding announcements, with 31 awards issued from FY 2019 – 2022
  - Requests for Application (RFAs) issued: RFA CA-19-033 and RFAs CA-20-027/028
- Relevant **Notices of Special Interest (NOSI)**
  - NOT-HD-21-027: Navigating Pediatric to Adult Healthcare: Lost in Transition
  - NOT-CA-22-029: Disparities Affecting Healthcare Utilization and Health Outcomes among Childhood Cancer Survivors
Improving Outcomes for Pediatric, Adolescent and Young Adult (AYA) Cancer Survivors

RFA-CA-19-033 U01 Clinical Trial Required


Research to Reduce Morbidity and Improve Care for Pediatric, and Adolescent and Young Adult (AYA) Cancer Survivors

RFA-CA-20-027/028 R01/R21 Clinical Trial Optional

Six Key Research Areas to Improve the Care of and Quality of Life for Childhood and AYA Cancer Survivors

- Survivor outcomes
- Barriers to follow-up care
- Familial, socioeconomic and environmental contributors to outcomes
- Indicators to monitor late effects and patterns of follow-up care
- Risk factors, predictors & molecular basis of adverse outcomes
- Targeted interventions to reduce the burden of morbidity in survivors

Development of targeted interventions to reduce the burden of morbidity in survivors

Cross cutting priorities include health disparities, minorities or other medically underserved populations
RFA-CA-19-033: Overall Goal

Support the scientific development of interventions to *address adverse physical and psychosocial effects* in survivors of pediatric/AYA cancers

Interventions Leverage Insight from Observational Studies1-4

Symptoms (fatigue, disturbed sleep, neuropathic pain)
Impaired physical & neurocognitive function
Late effects of treatment (heart disease, osteoporosis, second cancers)
Infertility
Changes in body composition (obesity, muscle loss)

Accelerated aging and physiologic frailty
Disrupted social development
School and employment difficulties
Financial hardship
Insufficient insurance
Psychological distress

Survivors express unmet needs for organized long-term follow-up services
As survivors transition out of pediatric care settings, few are seen by a clinician familiar with late effects
Care coordination, continuity of care and communication suboptimal

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

4 Ness et al. (2013). J Clin Oncol. 31(36):4496-503
RFA-CA-19-033: Improving Outcomes for Pediatric, AYA Cancer Survivors

- Assemble a network of investigators focused on testing interventions to improve outcomes across the survivor’s lifespan
- Seven awards made to support randomized trials testing new interventions to:
  - Prevent, mitigate, or manage adverse outcomes in pediatric and AYA cancer survivors
  - Test care delivery models that strengthen coordination, continuity, quality, or reduce access barriers
- Prioritized applications that addressed health disparities, underrepresented and/or medically underserved populations and encouraged mobile health and digital solutions
Interventions Being Tested to Improve Outcomes for Pediatric and AYA Cancer Survivors
<table>
<thead>
<tr>
<th>Project Title</th>
<th>Tumor Type(s)</th>
<th>Late/Long Term Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Using Information Technology to Improve Outcomes for Children Living with Cancer</strong></td>
<td>All</td>
<td>Disease and treatment-related symptoms</td>
</tr>
<tr>
<td><strong>A Randomized Trial of a Mobile Health and Social Media Physical Activity Intervention Among AYA Childhood Cancer Survivors</strong></td>
<td>All</td>
<td>Sedentary behavior</td>
</tr>
<tr>
<td><strong>Utility Of Memantine In Preventing Cognitive Dysfunction In Children Receiving Cranial Radiotherapy</strong></td>
<td>Primary brain tumors</td>
<td>Cognitive dysfunction after cranial radiotherapy</td>
</tr>
<tr>
<td><strong>A web-based patient-reported symptom monitoring and self-management portal for AYA breast cancer survivors</strong></td>
<td>Breast cancer</td>
<td>Symptoms, unmet needs, concerns</td>
</tr>
<tr>
<td><strong>Telehealth based exercise intervention to improve functional capacity in survivors of childhood cancer with significantly limited exercise tolerance</strong></td>
<td>All</td>
<td>Reduced exercise capacity, impaired physical dysfunction</td>
</tr>
<tr>
<td><strong>An INteractive Survivorship Program to Improve Healthcare REsources [INSPIRE] for Adolescent and Young Adult (AYA) Cancer Survivors</strong></td>
<td>All</td>
<td>Emotional distress, adherence</td>
</tr>
<tr>
<td><strong>Implementation of a Provider-Focused Intervention for Maximizing HPV Vaccine Uptake in Young Cancer Survivors receiving Follow-Up Care in Pediatric Oncology Practices: A Cluster-Randomized Trial</strong></td>
<td>All</td>
<td>Elevated risk of HPV-related complications &amp; malignancies</td>
</tr>
<tr>
<td><strong>Sen-Survivors: An open-label intervention trial for frailty and senescence</strong></td>
<td>All</td>
<td>Frailty, chronic health conditions</td>
</tr>
</tbody>
</table>
## Developing Interventions: Two Examples from RFA-CA-19-033

<table>
<thead>
<tr>
<th>Utility Of Memantine In Preventing Cognitive Dysfunction In Children Receiving Cranial Radiotherapy</th>
<th>Telehealth Based Exercise Intervention to Improve Functional Capacity In Survivors Of Childhood Cancer With Significantly Limited Exercise Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PI:</strong> Nadia Laack (Mayo Clinic)</td>
<td><strong>PI:</strong> Kiri Ness (St. Jude)</td>
</tr>
<tr>
<td>Cognitive dysfunction is a persistent and often long-term effect of cranial irradiation that impairs a child’s performance at school/work and negatively affects relationships and overall quality of life.</td>
<td>Exercise intolerance is prevalent among childhood cancer survivors and is associated with all-cause mortality, impairments in function and well-being. Referral to trained specialists to learn to accommodate specific deficits when engaging in exercise.</td>
</tr>
<tr>
<td>Evaluate the neuroprotective effects of 6 months of oral memantine given during and following cranial radiation compared to placebo.</td>
<td>Test an individually tailored home-based aerobic exercise and strength training intervention to improve exercise capacity in childhood cancer survivors with exercise intolerance.</td>
</tr>
<tr>
<td>Time to cognitive decline, rate of decline in memory, executive function and processing speed; quantitative MRI.</td>
<td>Exercise capacity (VO2 Max); cardiac, pulmonary, musculoskeletal, cognitive and neurosensory function; quality of life.</td>
</tr>
<tr>
<td>Memantine is an inexpensive and well-tolerated oral agent that in adults has demonstrated favorable effects on radiation-related cognitive dysfunction in adults.</td>
<td>Sample enriched for underrepresented populations. Intervention delivered remotely using telehealth approaches that will enhance reach of the intervention and improve access to services.</td>
</tr>
</tbody>
</table>
RFA-CA-20-027/028: Overall Goal

Support projects proposing *mechanistic, observational, and/or interventional* studies to understand and/or address one or more of the STAR Act domains
<table>
<thead>
<tr>
<th>Study Title</th>
<th>Target Population</th>
<th>Topic Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Predicting and Preventing Chemotherapy-Induced Cardiotoxicity in African American Children</td>
<td>African American, doxorubicin-treated childhood cancer survivors</td>
<td>Cardiotoxicity</td>
</tr>
<tr>
<td>Bridging Information Divides and Gaps to Ensure Survivorship: The BRIDGES Randomized Controlled Trial of a Multilevel Intervention to Improve Adherence to Childhood Cancer Survivorship</td>
<td>Childhood cancer survivors and primary care providers</td>
<td>Follow-up care</td>
</tr>
<tr>
<td>Social Genomic Mechanisms of Health Disparities Among Adolescent and Young Adult (AYA) Cancer Survivors</td>
<td>Non-Hodgkin’s lymphoma and Hodgkin’s lymphoma survivors</td>
<td>Social determinants of health</td>
</tr>
<tr>
<td>SALSA – Study of Active Lifestyle Activation</td>
<td>Childhood cancer survivors</td>
<td>Cardiovascular disease</td>
</tr>
<tr>
<td>Individual, Cultural, and Area-Based Factors Associated with Survivorship Care Among Asian/Asian American Childhood Cancer Survivors</td>
<td>Asian and Asian American Childhood cancer survivors</td>
<td>Follow-up care</td>
</tr>
<tr>
<td>Optimization of a mHealth Physical Activity Promotion Intervention with Mindful Awareness for Adolescent and Young Adult Cancer Survivors</td>
<td>Childhood and AYA cancer survivor</td>
<td>Quality of life</td>
</tr>
<tr>
<td>Pilot Test of an mHealth Intervention for Reducing Alcohol Use Among Rural Adolescent and Young Adult Cancer Survivors</td>
<td>Rural AYA cancer survivors</td>
<td>Alcohol consumption</td>
</tr>
<tr>
<td>Treatment-Specific Genetic Risk Scores for Late Effects Prediction in Childhood, Adolescent, and Young Adult Cancer Survivors</td>
<td>Childhood cancer survivors</td>
<td>Risk for chronic conditions</td>
</tr>
<tr>
<td>Remote Monitoring of Cardiac Function in Childhood Cancer Survivors</td>
<td>Anthracycline-exposed, long-term childhood cancer survivors</td>
<td>Cardiac dysfunction</td>
</tr>
<tr>
<td>Caregiving For Young Adults with Cancer in Latino Families: Understanding Healthcare Engagement and Family Wellbeing</td>
<td>Latino AYA cancer survivors and their families and providers</td>
<td>Caregiving</td>
</tr>
<tr>
<td>Research Project</td>
<td>Target Population</td>
<td>Topic Area</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------</td>
<td>-------------------------------------------------</td>
</tr>
<tr>
<td><strong>Personalized Risk Prediction to Reduce Cardiovascular Disease in Childhood Cancer Survivors</strong>&lt;br&gt;PI: Drs. Rebecca Maureen Howell, Daniel A. Mulrooney, and Yutaka Mulrooney (University of Texas MD Anderson Cancer Center), R01</td>
<td>Radiotherapy-treated childhood Hodgkin lymphoma survivors</td>
<td>Cardiovascular disease risk</td>
</tr>
<tr>
<td><strong>Leveraging Digital Health Solutions to Reduce Learning and Functional Disparities in Children with Cancer</strong>&lt;br&gt;PI: Dr. Sunita K. Patel (Beckman Research Institute, City of Hope), R01</td>
<td>Parents of Latino childhood leukemia or lymphoma survivors</td>
<td>School success</td>
</tr>
<tr>
<td><strong>Enhancing Health Cost Literacy and Financial Capability among Young Adult Cancer Survivors</strong>&lt;br&gt;PI: Dr. Bridgette H. Thom (Sloan Kettering Institute for Cancer Research), R21</td>
<td>AYA cancer survivors</td>
<td>Health cost literacy and financial capability</td>
</tr>
<tr>
<td><strong>Early Identification of Childhood Cancer Survivors at High Risk for Late Onset Cardiomyopathy: An Artificial Intelligence Approach utilizing Electrocardiography</strong>&lt;br&gt;PI: Drs. Oguz Akbilgic and Melissa M. Hudson (Wake Forest University Health Science Center), R01</td>
<td>Childhood cancer survivors</td>
<td>Cardiomyopathy</td>
</tr>
<tr>
<td><strong>STEP-YA: An Online Self-Management Intervention for Young Adult Cancer Survivors with Insomnia</strong>&lt;br&gt;PI: Dr. Christopher John Recklitis (University of Southern California), R21</td>
<td>AYA cancer survivors</td>
<td>Insomnia</td>
</tr>
<tr>
<td><strong>FAACTS: Feasibility/Acceptability of Attentional-Control Training in Survivors</strong>&lt;br&gt;PI: Dr. Steven Hardy (Children’s National Hospital Research Institute), R21</td>
<td>Brain and leukemia childhood cancer survivors</td>
<td>Attention</td>
</tr>
<tr>
<td><strong>An Integrative Approach to Evaluate Neurocognitive Disparities in Latinos Undergoing Treatment for Childhood Leukemia</strong>&lt;br&gt;PI: Drs. Kimberly Pauline Raghubar and Philip Lupo (Baylor College of Medicine), R01</td>
<td>Latino childhood leukemia survivors</td>
<td>Neurocognitive performance</td>
</tr>
<tr>
<td>Outcomes in AYA Survivors of Pediatric Medulloblastoma</td>
<td>Rural childhood and AYA medulloblastoma survivors</td>
<td>Cognitive impairment</td>
</tr>
<tr>
<td>-----------------------------------------------------</td>
<td>-------------------------------------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>PI: Dr. Tricia Z. King (Georgia State University), R01</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chronic Health Conditions in Survivors of Down Syndrome-Associated Leukemia</th>
<th>Childhood leukemia survivors with Down syndrome</th>
<th>Assessing chronic health conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI: Drs. Maria Monica Gramatges, Philip Lupo, and Karen R. Rabin (Baylor College of Medicine), R01</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Assessing the effect of virtual navigation interventions to improve health insurance literacy and decrease financial burden: A CCSS randomized trial</th>
<th>Childhood cancer survivors</th>
<th>Financial hardship</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI: Drs. Elyse Park and Anne C. Kirchhoff (Massachusetts General Hospital), R01</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PreDM: An adaptive, open-label, pilot intervention trial for diabetes prevention</th>
<th>Prediabetic childhood cancer survivors</th>
<th>Diabetes prevention</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI: Drs. Stephanie Dixon and Kirsten Ness (St. Jude Children’s Research Hospital), R21</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>An mHealth Positive Psychology Intervention to Reduce Cancer Burden in Young Adult Cancer Survivors</th>
<th>AYA cancer survivors</th>
<th>Hope</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI: Drs. Carla Berg and Hannah Arem (George Washington University), R21</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Can risk-reducing medications improve breast cancer prevention in childhood and adolescent cancer survivors? Comparative modeling to inform care</th>
<th>Childhood and AYA cancer survivors</th>
<th>Modeling risk for subsequent breast cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI: Dr. Jennifer Yeh (Boston Children’s Hospital), R01</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Award Examples from RFA-CA-20-027/028

<table>
<thead>
<tr>
<th>Bridging Information Divides and Gaps to Ensure Survivorship</th>
<th>Treatment-specific genetic risk scores for late effects prediction</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI: Dr. Nina S. Kadan-Lottick (Georgetown University)</td>
<td>PI: Dr. Cindy Im (University of Alberta)</td>
</tr>
</tbody>
</table>

- **Survivorship Need**
  - Need for consistent and quality long term surveillance of late effects in primary care settings

- **Goal**
  - Improve follow-up care by primary care providers through structured communications with cancer centers and empower patients with tailored survivorship education
  - Leverage existing data from cancer survivors to develop a tool to better predict 10 chronic health conditions in survivors

- **Key Features**
  - Tested in diverse and vulnerable populations (rural, Latino, and African American); telehealth approaches
  - The tool will be developed for diverse populations; leverages the wealth of data currently available on survivors

- Genetic predictors for chronic health conditions are not tailored for cancer survivors
Transitions of Care From Pediatric to Adult Services for Children With Special Healthcare Needs

- **Goal:** to summarize the evidence base on care interventions, implementation strategies, and between-provider communication tools for children with special healthcare needs transitioning from pediatric to adult medical care
- Based on the findings, NCI joined a NOSI with fellow NIH Institutes and Centers focused on navigating transitions from pediatric to adult care (NOT-HD-21-027)

Models of Care That Include Primary Care for Adult Survivors of Childhood Cancer

- **Goal:** to better understand which models of care that include primary care improve outcomes for adult survivors of childhood cancer and under what circumstances
- NCI is using the findings to evaluate its current grant portfolio and to identify and assess potential gaps and opportunities for additional research on this topic

Disparities and Barriers for Pediatric Cancer Survivorship Care

- **Goal:** to summarize the evidence base on understanding and addressing barriers and disparities in survivorship care for childhood cancer survivors
- NCI held a public webinar to disseminate the findings, used them to justify and provide supplements to NCI-designated cancer centers, and used them to inform a recent NOSI on this topic (NOT-CA-22-029)
Progress Recap

- Several **new biospecimen research projects** are supported through supplements to COG and CCSS
- **Pediatric expertise** is leveraged across various groups at NCI
- NCI continues to conduct and support childhood and AYA cancer **survivorship research** through requests for applications
- NCI continues to **report** on childhood cancer research activities through various formal and informal reporting
- NCI supported AHRQ in developing a technical brief focused on **innovative models of care**, with an emphasis on adult survivors of childhood cancer
- **Opportunities to submit applications continue**, through NOSIs and other investigator-initiated research efforts
Please submit any questions to NCI’s Office of Advocacy Relations:

NCIadvocacy@nih.gov

Thank you!