RFA (UG3/UH3- Clinical Trials Not Allowed)

Addressing Gaps in Knowledge Utilizing Cancer Survivor Cohort Studies

Joanne Elena – Presentation to BSA, Dec 3, 2019

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Background

- Prospective cohort studies provide important information about key factors and cancer outcomes among survivors.
  - Results inform interventions, clinical guidelines, and/or patient management to mitigate adverse health outcomes
- Gap areas identified in the DCCPS portfolio of cancer survivors cohort studies:
  - Less common cancer sites
  - Racial/ethnic/otherwise diverse cancer survivors
  - Late-effects from newer treatments
- Priority for clinically-significant and actionable research

NCAB Cohort Subcommittee Report (June 2019)

Key Recommendations

- Understudied populations
- Opportunities for new adult cohort studies
- Leveraging existing infrastructure tools
  - (e.g., SEER, VPR, state cancer registries)

“Where Opportunity Meets Research Gap”

Purpose

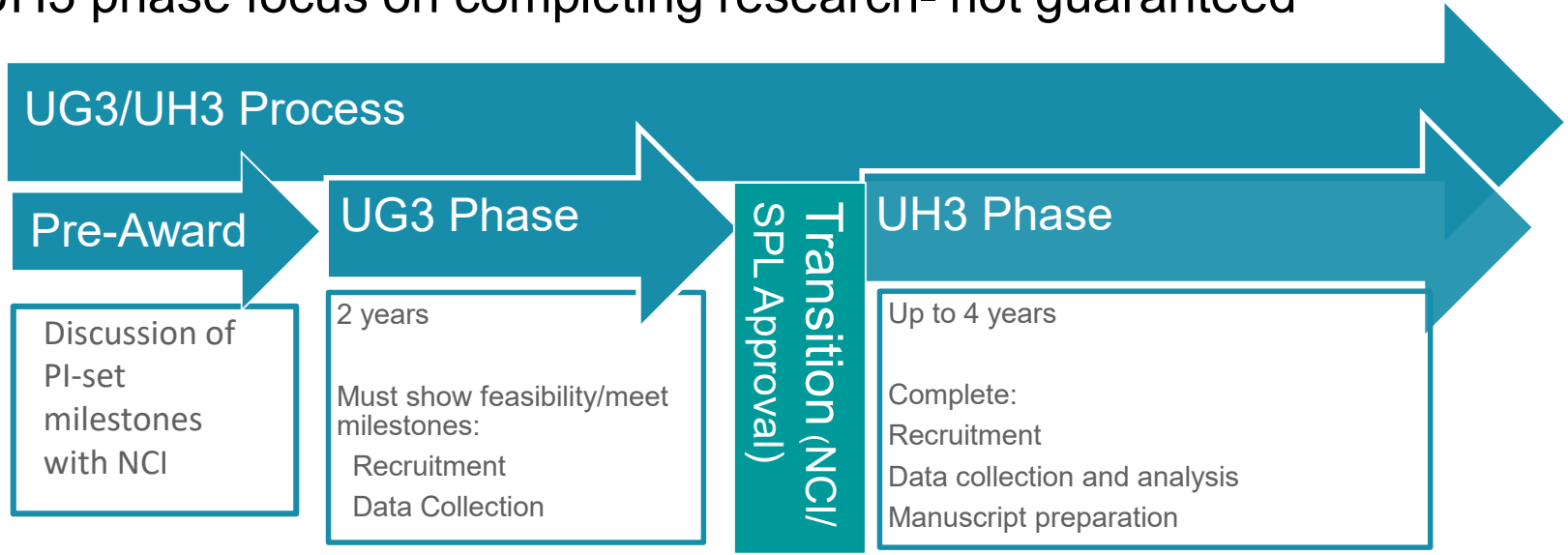
- RFA will support research to identify key factors that impact outcomes for cancer survivors in new prospective cohorts
  - Sample size, data collection, and all methodologic approaches must be driven by the proposed research questions.
  - Address important racial, ethnic, and geographic cancer health disparities.
  - Use of registries strongly encouraged for recruitment and as a comparison to understand how the proposed cohort reflects the relevant US cancer survivor population.
  - Survivors may be recruited at a variety of timepoints following diagnosis

Possible Research Questions

- Do long-term outcomes for emerging, novel, and combination cancer therapies differ among populations (e.g., age, race, comorbidities)?
- How are obesity, physical activity, and inflammation-related pathways related to cancer outcomes (progression, recurrence, subsequent cancers, and mortality) among understudied adult cancer survivors?
- How does cancer and its treatment alter aging trajectories among adult cancer survivors?
- What clinical, genomic, and lifestyle factors influence long-term outcomes for survivors with metastatic disease?

UG3/UH3 Mechanism

- PI sets milestones for recruitment and data collection in UG3 (requires approval from NCI program and NCI leadership)
  - Cap for UG3 phase: $750K direct costs for years 1&2
- UH3 phase focus on completing research- not guaranteed



NCI Portfolio Analysis

- NCI currently supports 18 cohort studies of cancer survivors
  - Common adult cancers, childhood cancers, bone marrow transplant patients, and NHL are represented.

- Gaps:
  - Less common cancers
  - Emerging treatment regimens
  - Diverse/understudied groups (e.g., racial, ethnic, geographic, age)

Evaluation Criteria

- Must address a pressing gap in NCI portfolio, focus on research questions that will affect the health of cancer survivors, and include robust data sharing plan.
- Data from 5 domains required to capture survivor experience:
  - Disease characteristics
  - Individual survivor characteristics
  - Treatment, treatment-related effects, and follow-up care
  - Lifestyle and/or behavioral factors
  - Quality of life outcomes
- Novelty may arise from the study population.

RFA Justification

- Set aside funds
  - Fund robust cohorts that address identified gap areas
  - Required demonstrated feasibility: 1) to recruit and retain cancer survivors and 2) collect and use data appropriately

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	All Years
Total Costs (3 applications)	3.9 M	3.9 M	7.5 M	7.5 M	7.5 M	7.5 M	37.8 M

U Mechanism Justification

- Facilitate NCI additional involvement
  - Additional oversight of awarded grants
  - Promote collaborative work among awardees
    - Establish minimal set of data to be collected
    - Serve as research resource for extramural community

- Specialized review
  - Clinical and epidemiological expertise

Initial Reviewer Comments (Ferrans, Bondy, Robison)

- **Clarification of health outcome, use of 5 domains, treatment**
  - "…health outcomes (e.g., morbidity, mortality, quality of life, physical, social, and psychological outcomes) for cancer survivors"
  - "…domains may represent exposures and/or outcomes, depending on the research questions, and should be measured at multiple timepoints"
  - "Treatment data should be collected directly from records… and must include information about specific therapies received and cumulative doses."
- **Genetics and biospecimens were not featured in concept**
  - "Additional data collection (e.g., biospecimen collection, family history), as dictated by the proposed research, is acceptable"
- **Added requirement for multidisciplinary team**
- **Will include an online link to funded NCI portfolio in RFA**

www.cancer.gov

www.cancer.gov/espanol