

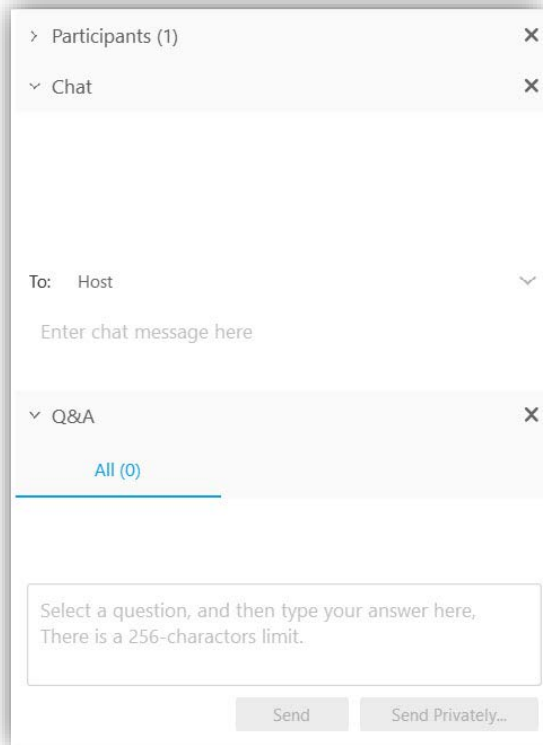
RFA-CA-20-030

Utilizing Cohort Studies to Address Health Outcomes in Cancer Survivors (UG3/UH3 Clinical Trial Not Allowed)

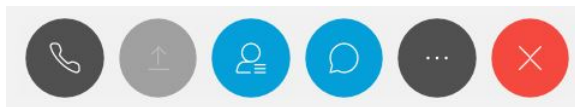
Pre-Application Webinar May 8, 2020

Joanne Elena PhD, MPH

Using WebEx and Webinar Logistics



- All lines will be in listen-only mode
- Submit questions at any time using the Q&A or Chat Panel and select *All Panelists*
- You may need to activate the appropriate box using the floating navigation panel. Found on the center of your screen



- This webinar is being recorded

Webinar presenter



Joanne Elena, Ph.D., M.P.H.

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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

Purpose

- RFA CA 20-030 will support ~3 new prospective cohorts that address health outcomes for cancer survivors
 - 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

Study Requirements

- New prospective cohort of cancer survivors;
- Must address a pressing gap in the [NCI portfolio](#); and
- Include a robust data sharing plan.
- Data collection must include:
 - Appropriate measures of relevant exposures, outcomes, and treatment information that can inform the health of cancer survivors;
 - Information about specific therapies and cumulative doses. Treatment data should be collected directly from records, where possible;
 - Recurrence as a disease endpoint (unless strong justification); and
 - Data from all 5 specified data domains.

Required 5 Data Domains

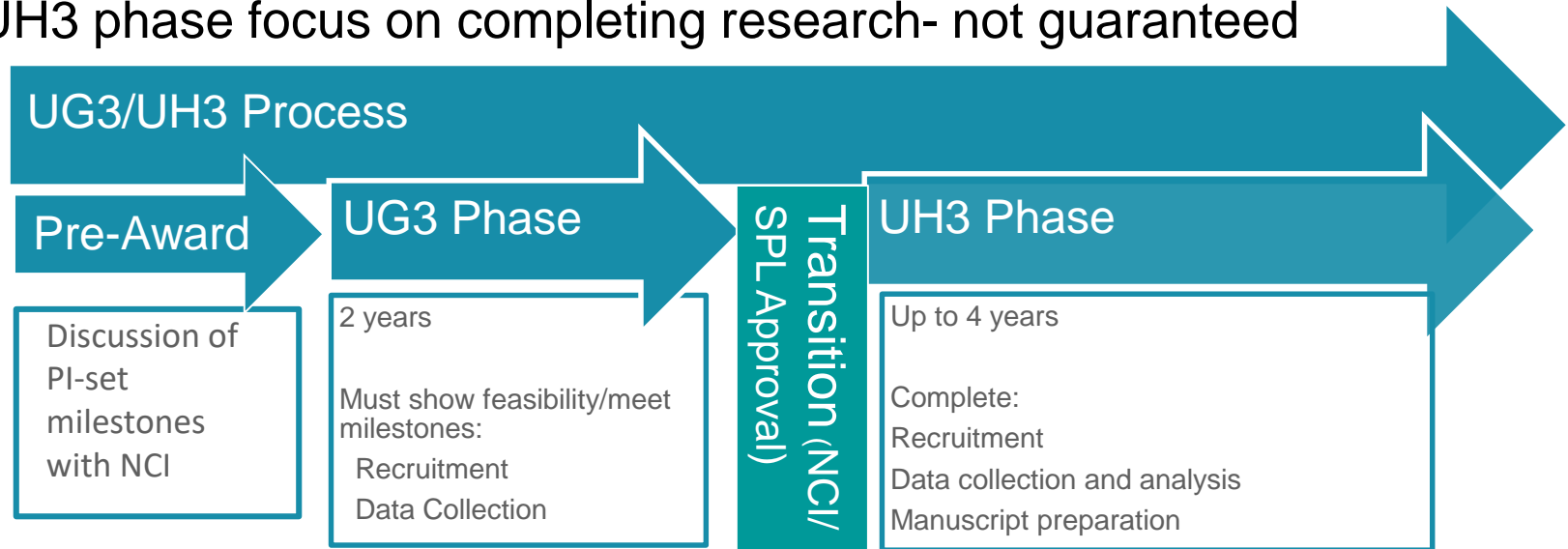
- Data from 5 domains required to capture survivor experience (the depth of each domain may vary from minimal to extensive):
 - Disease characteristics (e.g., type, stage, tumor biomarkers)
 - Individual survivor characteristics (e.g., comorbidities, socioeconomic status, social connections, information seeking, access to care measures)
 - Treatment, treatment-related effects, and follow-up care (e.g. dose, adverse events, palliative care)
 - Lifestyle and/or behavioral factors (e.g., diet, physical activity, adherence)
 - Quality of life outcomes (e.g., HRQOL, patient symptom reports)

Example of 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/use in UG3
 - Requires approval from NCI (after selected for funding, before NOA)
 - Cap for UG3 phase: \$750K direct costs for each year in years 1&2
- UH3 phase focus on completing research- not guaranteed



UG3/UH3 is a cooperative mechanism

- 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
 - Plan for in-person meetings for Years 1 and 5
- RFA allows for specialized review to ensure appropriate cancer survivor content expertise

Next steps

- After this webinar, we will post these slides, a recording of the webinar, and FAQs to: <https://epi.grants.cancer.gov/cohorts/>
- If you have specific questions, please contact Joanne Elena joanne.elena@nih.gov (preferred) or (240) 276-6818
- Submission deadline: July 7, 2020; Letter of Intent due 30 days prior
- Good luck!



Joanne Elena



Kelly Filipski



Lisa Gallicchio



Nonniekaye Shelburne



Andrew Freedman

Pre-submitted Questions

Are 2 sets of specific aims needed for the UG3 and UH3 phases?

No, one set of scientific specific aims will guide the entire application. Milestones are required for transition from the UG3 to UH3 phase.

How many milestones are required?

Enough to demonstrate feasibility for recruitment and data collection/use. Must be robust enough to show feasibility, but attainable.

Is it expected that at least one aim has clinical recurrence as a main endpoint? Are biomarkers or intermediate prognostic indicators of high recurrence risk acceptable, given the time frame?

Recurrence certainly may be an endpoint, but is not required. Recurrence data must be collected, unless there's strong justification.

Pre-submitted Questions (cont'd)

Is this RFA going to be re-issued with additional dates?

This RFA currently has one submission- July 7, 2020

Are international institutions allowed to apply? What about international partners and/or subcontracts?

Yes, Studies that are based in foreign countries are eligible for this FOA; however, priority will be given to studies with direct relevance to the U.S. cancer survivor population.

Are registries required for recruitment?

No. Use of population-based cancer registries for recruitment is strongly encouraged for broad representation. Use of registries is required as a comparison to assess the representativeness of the proposed study population compared to the relevant cancer survivor population.

Pre-submitted Questions (cont'd)

Are all 5 data domains required for all grants?

Yes. The breadth and depth of the domains will differ based on research questions.

Is the letter of intent required?

Yes, and it's very helpful for determining the review panel.

Do you have specific projects in mind?

No. Priority will be given to novel projects that address identified gaps- (i.e., rarer cancers, understudied populations, understudied treatments).

How do I know what is in the NCI portfolio?

A list of currently funded cohorts is available at:

<https://maps.cancer.gov/overview/DCCPSGrants/grantlist.jsp?method=portfolio&owner=rogerssc&portfolio=Cancer%20Epidemiology%20Cohorts>).

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