Pre-Application Webinar

Research to Understand and Address the Survivorship Needs of Individuals Living with Advanced Cancer

RFA-CA-22-027

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Overview

- Background
- RFA details and requirements
- Questions
• “Likely Incurable Cancer”
  • People diagnosed with advanced or metastatic cancer, or who progress to metastatic cancer, make up a population of survivors with what is likely incurable cancer

• Characteristics:
  • May cycle on and off treatment
  • May have periods with and without active disease
  • Includes individuals with advanced/metastatic cancer receiving targeted therapies or immunotherapies
Survivors Living with Advanced or Metastatic Cancer

Cancer Control Continuum

Individual Living with Advanced or Metastatic Cancer

Metastatic diagnosis → Treatment to control or cure disease → Positive clinical response → End-of-life care

Survivorship Care
What is Survivorship Care?

- Prevention/surveillance of recurrence and new cancers
- Surveillance/management of effects of cancer and its treatment
- Health promotion/preventive care

Care Coordination

Goals for RFA-CA-22-027
Purpose of RFA-CA-22-027

To support R01 applications to better understand and/or address survivorship needs for individuals living with likely incurable cancers

**NIH Research Project Grant (R01)**

- Supports a discrete, specified, and circumscribed research project
- Most commonly used grant program
- 3-5 years of funding
- PIs strongly encouraged to present preliminary data to support proposed aims
Example Research Topics

- Examination of factors associated with physical and psychological symptoms, adverse effects, and other survivorship outcomes
- Determining components of survivorship care to optimize outcomes
- Understanding the impact of living longer with likely incurable cancer on employment and financial concerns
Example Research Topics (continued)

- Development and testing of models of survivorship care tailored based on the needs of the survivor and health system resources
- Development of interventions to address shared decision-making in the context of prognostic uncertainty among individuals with likely incurable cancers
Key Considerations

- Population: Any group of individuals living with likely incurable cancer
  - Diagnosed at any age
  - Single or multiple primary cancer types
  - Treatments received

- Studies must focus on survivors and measure outcomes at the survivor level, but can also include caregiver, provider, and health system-level targets
Additional Considerations

- Applications strongly encouraged (but not required) to:
  - collect clinical data including biomarker and radiologic data to characterize treatment response, toxicities, and disease status as appropriate
  - focus on individuals treated with newer therapies
  - include diverse populations: race/ethnicity, geography, socioeconomic factors
Applications not considered responsive

- Focus on populations other than individuals living with likely incurable cancers
- Development and/or testing of cancer-directed therapies
- Focused exclusively on end-of-life care
- Focus on caregivers only (without a focus on survivors)
- Applications proposing a non-randomized program evaluation of an existing model of survivorship care
RFA Details
## Application Dates

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<th>1&lt;sup&gt;st&lt;/sup&gt; Receipt</th>
<th>2&lt;sup&gt;nd&lt;/sup&gt; Receipt</th>
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<tbody>
<tr>
<td>Application Due Date</td>
<td>September 30, 2022</td>
<td>September 29, 2023</td>
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<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>
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<td>Scientific Merit Review</td>
<td>~March 2023</td>
<td>~March 2024</td>
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<td>Advisory Council</td>
<td>~May 2023</td>
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<tr>
<td>Earliest Start Date</td>
<td>July 2023</td>
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Application Details: Letter of Intent

- Due 30 days prior to the application due date
- Send by email to michelle.mollica@nih.gov
- Should include:
  - Title of proposed study
  - Contact information for the Principal Investigators
  - Names of other key personnel
  - Participating institutions
  - Number and title of this RFA
Application Details

- Applications proposing clinical trials should follow NIH Clinical Trials guidelines: [https://grants.nih.gov/policy/clinical-trials.htm](https://grants.nih.gov/policy/clinical-trials.htm)
- Application budgets should reflect the needs of the proposed project but must not exceed $500K in direct costs per year
Specific Application Requirements: Significance

- Justification of proposed study population
- Justification explaining how proposed research addresses pressing need or evidence gap
- Explanation of how study findings will inform future strategies to improve outcomes
Specific Application Requirements: Approach

- Plan for survivor stakeholder engagement during the development, planning, and conduct of proposed project
  - Proposed list of stakeholders and justification
  - Goals for working with stakeholders
  - Description of plan for collaboration
- Justification of the approach to include information, where appropriate, on disease characteristics and cancer treatment, individual characteristics, and socioenvironmental context
- Justification of the collection of biomarker and/or radiologic data where appropriate
Requirements: Resource Sharing Plan

• Detailed data/resource sharing plan that is consistent with NIH policy and follow Findable, Accessible, Interoperable, Reusable (FAIR) principles for Resource Sharing Plans

• Plan must describe:
  • Type of data to be shared
  • Data repository to which the data will be submitted for sharing
  • Timeline for the data to be shared
Application Review

- Applications reviewed by NCI Special Emphasis Panel
- Please note and address special review criteria included in the RFA
Resources

- Read the RFA carefully: https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-22-027.html
- Webinar and FAQ will be posted on our website: https://healthcaredelivery.cancer.gov/funding/opportunities.html
- Contact us early with questions
Expected Impact

- Address gap areas identified by stakeholders
- Enhance understanding of symptoms, care patterns, and unmet needs
- Increase effective strategies to improve care delivery
- Improve outcomes for this growing population
Pre-submitted and other FAQs

• How will ESI status be incorporated into the review process and funding decision, if at all?
  • ESI-submitted applications will not be reviewed separately from the EI applications in the SEP. We will consider ESI status as a factor in our funding decisions.

• Can you please provide additional guidance on expectations and examples for the stakeholder engagement plan?
  • NIH does not have a template for survivor stakeholder engagement. We encourage investigators to include a clear plan for how they will integrate survivor stakeholders as part of the design, conduct, and dissemination of the study and its findings.
Pre-submitted and other FAQs

• Are foreign institutions allowed to apply? What about foreign partners and/or subcontracts?
  • Foreign institutions are not eligible to apply for grants under this FOA. However, foreign components to domestic institution applicants are allowed, with justification.

• Will most grants be funded in the first round?
  • We plan to balance how many grants we fund between the first and second receipt dates.
Questions?

Contact Information:

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