RFA-CA-22-027: Research to Understanding and Address the Survivorship Needs of Individuals Living with Advanced Cancer Frequently Asked Questions (FAQs)

A. Research FAQs

1. Is there a definition for likely 'incurable cancer'?

Response: Per White et al. (2021), incurable refers to the "expectation that the cancer is highly unlikely to be eradicated and there is a high chance that, in the absence of other more imminent causes of death, this cancer will lead to death."

2. Is there a definition of 'living with'?

Response: For this RFA, we are interested in the survivorship experience of individuals who have an incurable cancer. 'Living with' presumes the survivor has been treated with some first line treatment, does not currently have a poor prognosis, and has survivorship needs. It is up to the applicant to justify in the grant application that the population or populations under study are 'living with' incurable cancer and, therefore, have survivorship needs. Applications focused specifically on end-of-life care are not responsive to this RFA.

3. Is there a specific cancer type or cancer type(s) that are of higher priority?

There is no specific cancer type or types that are of higher priority than others. However, the applicant must justify the inclusion of the specific population or populations under study as a population 'living with likely incurable cancer'.

4. Is there a template for the survivor stakeholder engagement plan that is required?

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.

5. Are studies utilizing pediatric or childhood cancer populations appropriate for this RFA?

Applications focusing on pediatric or childhood cancer populations are responsive to this RFA, with justification that the population is one that is living with likely incurable cancer. There is no exclusion criterion based on the age of the population.

B. Application FAQs

6. Is a letter of intent required and by what deadline? What should be included?

Yes. A letter of intent (LOI) is strongly encouraged. LOIs assist NCI in preparing and planning for review. With this information, NCI can assess workload (e.g. how many applications will be reviewed) and allow us to begin identifying expert reviewers without conflicts of interest. Letters of intent are due 30 days prior to the receipt date.

Letters of intent should include the following:

- Descriptive title of proposed activity
- Specific Aims for the proposed project
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)

- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The LOI should be sent by email, with the subject "Letter of Intent for RFA-CA-22-027" to michelle.mollica@nih.gov.

7. What are the current NIH clinical trials policies?

Please note that this FOA is clinical trials optional. Key policy notices are available <u>here</u>. Clinical trial requirements for grants are available <u>here</u>.

8. Can you say more about what should be included in the data sharing plan?

All applications, regardless of the amount of direct costs requested for any one year, should include a Data Sharing Plan that is compliant with the current NIH Data Management and Sharing Policy and, if applicable, the Genomic Data Sharing Policy. Please see the <u>NIH Scientific Data Sharing</u> <u>webpage</u> for additional information. Please note that there is a new NIH Data Management and Sharing Policy for applications submitted on or after January 25, 2023.

9. How many submission dates are there?

There are two submission dates – September 30, 2022, and September 29, 2023. Please see the RFA announcement in the NIH Guide for more information.

10. Are resubmissions allowed?

Applications that are submitted for the first submission due date (September 30, 2022) but are not funded can resubmit to the second submission due date (September 29, 2023).

Applications (both new applications and resubmissions) that are submitted but not funded for the second submission due date (September 29, 2023) are encouraged to resubmit their applications as <u>new</u> applications to other FOAs (e.g., NIH Parent R01 FOA, PA-20-185, PA-20-183).

11. Will the grants be reviewed in a special study section?

Yes, the RFA applications will be reviewed in a special study section for those applications submitted to this FOA.

12. Are foreign institutions eligible to apply?

Foreign institutions are not eligible to apply for grants under this FOA. However, foreign components to domestic institution applicants are allowed, with justification.

13. How will funding decisions be made?

After the peer review, Program will propose a funding plan based on scientific and technical merit of the proposed project and the relevance of the project to program priorities. The funding plan will then be reviewed by NCI senior leaders and the National Cancer Advisory Board.

14. 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.

15. How will ESI status play into funding decisions?

We will consider ESI status as one factor in our funding decisions.

16. What is the payline for this RFA?

RFAs do not have established paylines. After the peer review, Program will propose a funding plan based on scientific and technical merit of the proposed project and the relevance of the project to program priorities. The funding plan will then be reviewed by NCI senior leaders and the National Cancer Advisory Board.

17. How much preliminary data is needed for this RFA?

The R01 mechanism is meant for well-developed projects supported by preliminary data. Reviewers will evaluate the application for scientific merit, which includes an assessment of the rigor of the prior research that serves as the scientific premise for the proposed project. Preliminary data should be sufficient to support gaps in the premise of the proposed project and/or demonstrate that your proposed research is promising and that your ability to carry it out is credible (e.g., demonstrating a proof of concept or expertise for a technique).