

## NOT-CA-22-045

### Notice of Special Interest (NOSI): Addressing Cancer-Related Financial Hardship to Improve Patient Outcomes

#### General

#### **What is a Notice of Special Interest (NOSI)?**

NOSIs highlight a specific topic of interest; NOSIs direct applicants to one or more active funding opportunity announcements (FOA) for submission of applications for the initiative described.

#### **How do I indicate on my application that I am responding to this NOSI?**

On the first page of the SF 424, in the field titled 'Agency Routing' indicate NOSI NOT-CA-22-045

#### **What is the due date for applications submitted in response to this NOSI?**

Check the "Key Dates" listed in Part 1 of the funding opportunity announcement (FOA) that you choose to submit to. Some of the FOAs that you can use to respond to this NOSI use standard NIH due dates, but some do not. Be sure to check the due dates carefully.

#### **How many years can applications be funded for?**

Check the "Award Project Period" listed in **Section II. Award Information** in the funding opportunity announcement (FOA) that you choose to submit to. Generally, the scope of the proposed project should determine the project period. In general, the maximum project period for R01s is 5 years. Be sure to check your targeted FOA however.

#### **Will NCI accept applications with multiple Principal Investigators (MPI applications)?**

Yes, we encourage MPI applications when such a leadership arrangement aligns with the research aims and goals. MPI applications should include clear, detailed plans for project leadership and management. Before deciding to pursue an MPI application, please carefully review the MPI policy on the [Multiple Principal Investigators Web site](#). Also, it is important to note that if only one of the PIs is an Early Stage Investigator (ESI), the application will NOT be designed as an ESI application. For an MPI application to be designated as an ESI application, all PIs must meet the NIH ESI definition.

#### **If my application was not funded may I resubmit it?**

In general, yes, resubmission applications are allowed. But, check the funding opportunity announcement (FOA) that you are actually applying for to be sure.

**Does Early Stage Investigator (ESI) or New Investigator (NI) status apply to applications submitted in response to the NOSI?**

Yes, ESI/NI statuses apply. For grant applications that involve more than one PI (e.g. multi-PI), all PD/Pis must meet the definition of NI or ESI for the application to be designated as such. NCI is committed to supporting Early Stage Investigators (ESIs) and will place special emphasis on supporting ESI-designated applications.

**What mechanisms are allowed through NOT-CA-22-045?**

R01s, R21s, R03s, and P01s are responsive to this NOSI. Please see the list of related announcements for the funding opportunity announcements (FOAs) that support these mechanisms.

**Are applications from foreign institutions accepted in response to this NOSI?**

Check the “Eligible Applicants” listed in Section II of the FOA to which you choose to submit.

**If I plan to request that my application be assigned to an Institute other than NCI, can I submit my application through this NOSI?**

Since NCI is the only Institute participating on the NOSI, if you submit an application through this NOSI, it will likely be assigned to NCI.

**Is an Awaiting Receipt of Application (ARA) required for budgets that exceed \$500K direct costs in any of the grant years?**

Yes, for budgets of \$500K or more in direct costs in any of the grant years, an ARA is required. In the Division of Cancer Control and Population Sciences, the ARA must be submitted at least 8 weeks prior to the submission date.

**What study section will be reviewing applications to this NOSI?**

Applications to this NOSI will be reviewed by standing study sections within the Center for Scientific Review (CSR) that are deemed the best fit for each application.

**Are applications submitted to this NOSI required to include a clinical trial component?**

Yes, this NOSI is focused on interventional research. A NIH defined clinical trial is required and the FOA you are responding to should be a clinical trial optional or clinical trial required FOA.

**Research sites: NCI Research Networks**

**I would like to use the NCI Community Oncology Research Program (NCORP) network to conduct my study. Is there anything special I need to do if I am going to use the NCORP network?**

Yes, there are additional steps that need to occur if you are proposing to use the NCORP network to conduct your study and this process takes additional time. You must speak with NCI NCORP staff (6 weeks) before submitting an application proposing a study in NCORP. Please send an email to Kathleen Castro at [kathleen.castro@mail.nih.gov](mailto:kathleen.castro@mail.nih.gov) as soon as possible to let her know that you are planning to conduct your proposed study in NCORP. She will work with NCI NCORP staff to set up a call and outline the process.

**Research Design & Population**

**Are there particular research designs that will or will not be funded by this announcement?**

No. However mixed-method study designs and multilevel interventions are encouraged.

**Are there specific cancer sites, cancer types, and diseases that NCI is interested in seeing in applications responding to the NOSI?**

Applications can focus on any cancer type, but the investigator should consider how appropriate the cancer type chosen is to addressing cancer-related financial hardship to improve patient outcomes.

**Is it better to focus on multiple cancer types or a single cancer type?**

An application can focus on a single cancer type or multiple cancer types. The investigator must justify the choice of the cancer or cancers to be studied. If an application focuses on a single cancer type, the investigator is encouraged to describe the relevance and potential future application to other cancer types.

## **Scope & Outcomes**

### **Is an application proposing work in a non-U.S. population responsive to this NOSI?**

Please check the FOA to which you choose to submit. If an investigator proposes a study in a non-U.S. population or populations, the investigator must describe how the findings apply, or can be generalized, to the U.S. population.

### **Are childhood cancers within the scope of this NOSI?**

Yes. Applications that are submitted in response to this NOSI may focus on childhood cancer patients, survivors, or their caregivers.

### **Are staff/clinician outcomes a potential area of interest, understanding that improving patient outcomes is the primary motivation for this NOSI?**

Yes. A multi-level study that examines staff/clinician outcomes in addition to quality or patient outcomes could be of interest. Applications could also examine staff/clinician outcomes as secondary outcomes of interest.

### **Would studies that look at how social workers, financial counselors, legal advocates and oncologists work together to address cancer-related financial hardship to improve patient outcomes qualify as interprofessional?**

Yes, studies focused on addressing cancer-related financial hardship to improve patient outcomes among non-clinical members of the care team and clinical members of the care team could be responsive to this NOSI. If you have specific questions about your project please be sure to reach out to the program contact for this NOSI: Kathleen Castro ([kathleen.castro@mail.nih.gov](mailto:kathleen.castro@mail.nih.gov)).

### **As Sickle Cell disease is often treated in cancer treatment facilities and is representative of a minority and disadvantaged population disease, would cancer-related financial hardship to improve patient outcomes related to Sickle Cell treatment be considered eligible for this funding opportunity?**

To be responsive to this NOSI applications should focus on cancer-related financial hardship. If you have specific questions about your project please be sure to reach out to the program contact for this NOSI: Kathleen Castro ([kathleen.castro@mail.nih.gov](mailto:kathleen.castro@mail.nih.gov)).

**When talking about addressing cancer-related financial hardship to improve patient outcomes, is there interest in interventions that involve engaging with primary care?**

Yes, studies focused on coordination and communication among primary care and specialists involved in comprehensive care during diagnosis and active treatment may be responsive to this Notice. Applications addressing cancer-related financial hardship between care settings (e.g., between primary and specialty care) following the cancer diagnosis and during active treatment are encouraged.

**How much pilot or preliminary data is needed for the R01 application?**

Reviewers will evaluate the application for scientific merit, which includes an assessment of the rigor of the prior research (developed either by the applicant or cited from the literature) that supports the scientific premise for the proposed project. Additional preliminary data (developed by applicants as needed) should be sufficient to support any gaps in the premise of the proposed project and/or to demonstrate that your proposed research approach is potentially promising, sufficiently rigorous, and that the applicant and their team have the skills, experience, and environmental resources to address the study aims. You may also email the program contact for this NOSI: Kathleen Castro ([kathleen.castro@mail.nih.gov](mailto:kathleen.castro@mail.nih.gov)) to discuss your proposal in more detail.

**Do applications need to include a data sharing plan?**

Per the NIH policy notice, NOT-OD-03-032 applicants seeking \$500,000 or more in direct costs in any year of the proposed project must address a Data Sharing Plan.

**Are there any special IRB considerations for this FOA?**

This NOSI follows standard NIH requirements for IRB review and approval.