# Frequently Asked Questions: NOT-CA-21-019

Notice of Special Interest (NOSI): Tailoring Follow-up Care for Survivors Using Risk-Stratified Pathways

#### General

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

NOSIs succinctly 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.

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

Check the "Key Dates" listed in Part 1 of the 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 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. However, be sure to check your targeted FOA.

#### 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 Multiple Principal Investigators website. Also, it is important to note that if only one of the PIs is an Early Stage Investigator (ESI), the application will NOT be designated 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 FOA that you are 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 <u>Early Stage Investigators (ESIs)</u> and will place special emphasis on supporting ESI-designated applications.

#### Can I submit a R21 or R03 application in response to this NOSI?

No. The FOAs listed in this NOSI only allow R01 grant applications.

## 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.

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

No, clinical trials are not required for submission to this NOSI. However, if an application is focused on the development and evaluation of a risk-stratified care pathway for cancer survivors based on an existing framework/algorithm and on improvement of meaningful outcomes, it must include an intervention component and NIH clinical trials guidelines should be followed.

## **Scope and Outcomes**

Is an application proposing work in a non-U.S. population responsive to this NOSI? Please check the targeted 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.

#### What is the definition of the term cancer survivorship as used in this NOSI?

This NOSI utilizes the NCI Office of Cancer Survivorship definition of the term <u>cancer</u> <u>survivorship</u>. An individual is considered a cancer survivor from the time of diagnosis, through the balance of his or her life. Cancer survivorship research seeks to improve the health and well-being of cancer survivors and caregivers providing care to survivors.

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

No. Applications that are submitted in response to this NOSI must focus on survivors of adultonset cancers. For the purpose of this NOSI, an adult is defined as an individual 18 years of age or older.

#### For what types of cancers should the work be conducted?

Applications can focus on any cancer type, but the investigator should consider how amenable the cancer type chosen is to risk stratification and risk stratified survivorship care. If a cancer type includes only individuals at high risk for an adverse outcome, this cancer type may not be optimal, as care is not likely to change with the development of an algorithm or intervention.

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 include relevance and potential future application to other cancers types.

# For the algorithm/framework development, what variables should be included in the algorithm/model?

The investigator should determine the variables to be included in the algorithm/framework. Important variables <u>may</u> include, but are not limited to, patient characteristics such as sex, race and physical functioning/mobility; clinical characteristics of the cancer; and treatments that the patient received.

#### Can biomarker data be included in the algorithm/framework?

Yes. Inclusion of biomarker variables, as with other types of variables, in the algorithm/framework should be justified in the application.

What is the preferred endpoint for the algorithm and/or intervention? There is no preferred outcome; however, applications that are submitted in response to this NOSI must focus on more than one domain of follow-up care for survivors: 1) surveillance for recurrence and subsequent cancers; 2) surveillance and management of physical and psychological effects of cancer and its treatment; and/or 3) health promotion/prevention. The outcome proposed in the study must be justified. Outcomes could include mortality, recurrence, subsequent malignancies, or longer-term adverse events.

# The IOM/NAS report emphasized the need for communication in delivery of survivorship care. Is this also a focus of attention in this NOSI?

Communication is a key component of survivorship care delivery and should be considered in the design of risk-stratified survivorship care interventions for this NOSI. It is not a requirement, however, to explicitly focus on communication in the intervention or as an outcome or endpoint.