

Frequently Asked Questions RFA-CA-19-035

What should be included in the Letter of intent?

A letter of intent (LOI) is strongly recommended for RFA-CA-19-035. LOIs assist NCI in identifying expert reviewers without conflicts of interest. LOIs are due by May 28, 2019 for the June 28 due date.

LOIs should include the following:

- Descriptive title of proposed activity
- Draft 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-19-035" to michelle.mollica@nih.gov

Will there be another receipt date or solicitation issued?

RFA-CA-19-035 has one receipt date planned at this time: June 28, 2019.

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

As application budgets for this RFA may not exceed \$500,000 (direct costs) per year, the ARA policy does not apply.

How many projects does the NCI intend to fund?

Contingent on receiving funds and meritorious applications, NCI intends to fund up to 6 awards, corresponding to a total of \$5 million, for fiscal year 2020.

How many years can this R01 be funded for?

The scope of the proposed project should determine the project period. The maximum project period is 5 years.

Populations of survivors

Are Adolescent and Young Adult (AYA) cancer survivors included in this RFA?

This RFA includes survivors of adult-onset cancers. This could include young adults, but should be focused on those with adult-onset cancers. Please refer to [RFA-CA-19-033](#) for an RFA focused on pediatric populations.

Are adult survivors of pediatric cancers included in this RFA?

This RFA does not include adult survivors of pediatric cancers. This could include young adults. Please refer to [RFA-CA-19-033](#) for an RFA focused on pediatric populations.

Are we required to include specific outcomes, measures, or levels (patient, provider, system)?

There is no requirement for common data elements or specific endpoints. We encourage investigators to consider meaningful endpoints for their study. The RFA suggests endpoint areas including (but not limited to) patient-centered outcomes (e.g., patient experiences of their care, symptom burden, health-related quality of life), health care utilization (e.g., visits with providers other than oncology specialists, avoidance of unplanned hospitalizations and emergency department visits); indicators of care quality (e.g., receipt of recommended follow-up care, receipt of appropriate preventive care); and/or cost of care.

What is the priority in the RFA for health disparities research, including studies addressing the outcomes for ethnic minority and low SES cancer survivors?

Interventions that focus on the needs of racial/ethnic minority or medically underserved adult survivors are strongly encouraged, but not required.

The RFA indicates that applications addressing multiple cancer sites are desired but not required. Would a study focusing on one cancer site be considered responsive?

Applicants are strongly encouraged to include samples of survivors that include more than one cancer type. A study focusing on one cancer site would be considered responsive.

How many cancer sites are optimal?

The number of cancer sites should depend on the application. You may also contact the NCI Scientific Program Contact to discuss your proposal in more detail.

How much pilot or preliminary data is needed for this RFA?

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 contact the NCI Scientific Program Contact to discuss your proposal in more detail.

The RFA requires applications address sustainability and scalability. Do we have to submit an implementation science application?

The RFA requires applicants to address the potential for an intervention to be scaled and sustained. We are not requiring applicants to submit an implementation science-based application, although applications should address the potential for scalability and sustainability in the development, design, and testing of proposed interventions.

Is it acceptable for a trial intervention to be delivered within one health care system that includes different hospitals?

An intervention delivered within a single health care system would be considered acceptable. You may also contact the NCI Scientific Program Contact to discuss your proposal in more detail.

Should applications include multiple sites, or will single institution applications be considered competitive?

Both single institution and multi- site applications are allowed.

Are multiple PI submissions possible and/or encouraged?

Multiple PI submissions are acceptable, but not required. There is a requirement to include both oncology and non-oncology providers on the co-investigator team, but this does not need to be as a multiple PI submission.

I would like to use the NCI Community Oncology Research Program (NCORP) network to conduct my clinical trial in response to this funding announcement. 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 before submitting an application proposing a study in NCORP. Please send an email to Michelle Mollica at michelle.mollica@nih.gov as soon as possible to let us know you are planning to conduct your proposed study in NCORP. We will work with NCI NCORP staff to set up a call and outline the process.

Does my application need to include a data sharing plan?

Yes, all applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan. Please see the [Access and Data Sharing Requirements](#) for projects funded as part of the Cancer Moonshot Initiative.

How can I be sure if my study meets the definition of a clinical trial?

Please visit the [NIH Clinical Trials website](#) for tools and resources that will help you determine if your study meets NIH's definition of a clinical trial.