Cancer Moonshot℠ Funding Opportunities Related to Inherited Cancer Syndromes
RFA-CA-19-017 & RFA-CA-19-001
Frequently Asked Questions
Webinar - October 11, 2018

Administrative

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

   No. The ARA policy does not apply to applications responding to Requests For Applications (RFAs).

2. Is the letter of intent required? What should be included?

   The letter of intent is not required, but highly encouraged. It should include the descriptive title, contact information for PIs, names of key personnel, participating institutions, and the RFA it is responding to. Study abstract and/or aims are also accepted, but not required. This information assists NCI in identifying expert reviewers without conflicts of interest.

3. Have the grantees from the previous cycle of funding been announced? Could you please briefly discuss what types of research projects were funded last year for this mechanism?

   One application was selected for FY18 funding for RFA-CA-17-041 and it is listed on NCI's Cancer Moonshot Implementation webpage for Prevention and Early Detection of Hereditary Cancers. The limiting factor for funding more grants was that some studies lacked follow-up to inform care delivery of evidence-based healthcare.

4. Are there future submission dates for these RFAs beyond January 9, 2019?

   No. Both RFAs were issued with a single submission date, and there are no current plans for re-issuance of either RFA.

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5. Have the priorities that were included last year in RFA-CA-17-041 changed since the RFA was reissued as RFA-CA-19-017?

   The priorities and focus of this RFA remain the same.

6. How will grants be handled that previously submitted to RFA-CA-17-041 and want to resubmit to RFA-CA-19-017?

   RFA-CA-19-017 will accept resubmissions from RFA-CA-17-041. Per the NIH resubmission policy, resubmitted applications must include a one-page introduction summarizing substantial additions, deletions, and changes to the applications. The review panel will have access to the previous review comments and applicants must respond to the summary statement criticisms in their resubmission. A PI may also elect to submit as a new application, in which case the review panel will not have access to the previous review comments and responses to prior review will not be accepted.

Research Team

1. How would an application from a nonprofit coupled with industry be viewed? Do we need an academic partnership to respond to RFA-CA-19-017?

   An academic partner is not required. An application between a nonprofit and industry organizations is eligible to respond and would be responsive if it proposed to test strategies within the target audiences and had access to the healthcare system for risk evaluation, genetic counseling, genetic testing, and follow-up care.

2. Can the same team submit proposals to both RFA-CA-19-017 and RFA-CA-19-001? If so, can the same or very similar tools be used in both proposals?

   Yes, the same team can submit proposals to both RFAs.

   The use of similar tools in applications responding to both RFAs must consider potential overlap, substantial differences, competing for the same study population, and study outcomes. Per the guidance on overlapping applications from NIH's Center for Scientific Review, it is not allowable to have overlapping applications under review at the same time. Scientific overlap occurs when essentially the same research is proposed in more than one application, or a specific research objective and study design are closely

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related in 2 or more applications. You may use a similar methodological approach for a substantially different question,OR use a very different methodological approach to address a similar issue. The grants cannot be dependent on both being funded. In addition, the applications would need to address feasibility of enrollment of both studies within the population and how one would not affect the outcomes in the other.

3. Can different teams with overlapping investigators submit proposals to both RFAs?

   Yes, different teams with overlapping investigators may submit proposals to both RFAs.

4. For applications submitted in response to RFA-CA-19-001, does the study team need to include experts in both communication and decision making, and do they need to all be seasoned investigators?

   The study team needs to be representative of the proposed science and have the expertise to support study implementation and analysis. The investigators' biosketches need to effectively communicate their individual expertise to the peer reviewers. Please see Question 5 below regarding early stage investigators.

5. Does Early Stage Investigator (ESI) or New Investigator (NI) status apply to these RFAs?

   In 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.

Approach

1. Which RFA should be used for projects studying communication methods in pre-genetic testing or when reaching out to family members and implementing screening for genetic testing? Is there overlap between RFA-CA-19-017 and RFA-CA-19-001?

   The difference is in the outcomes of measure. Is the study measuring increased ascertainment and follow-up care, or is it measuring risk communication and decision making?

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A project using communication as a strategy to increase case ascertainment (both in probands and in at-risk family members) and increase follow-up care would respond to RFA-CA-19-017. This includes pre-testing and post-testing counseling. The study design for this RFA must address the continuum of care from ascertainment through follow-up care management.

A project developing, testing, evaluating, or implementing a communication/decision making intervention that improves understanding and decision making would respond to RFA-CA-19-001. This could address one or multiple aspects in the continuum of care.

2. Does genetic testing have to be done in a clinical lab or lab setting?

   All genetic testing must be done in a CLIA-approved lab.

Study Section

1. Will submissions to both RFAs be reviewed by the same study section?

   This has yet to be determined by NCI's Division of Extramural Activities. Given that they both address aspects of care for those at risk for inherited cancer syndromes, combining the reviews is a possibility.

Budget

1. Please clarify what you are looking for in the budget for RFA-CA-19-017. Is $1M total cost justified for a possible five-year project?

   There are no budget restrictions with RFA-CA-19-017. The budget must be reflective of and justified by the proposed science. In Fiscal Year 2019, NCI intends to commit approximately $4M total costs to this RFA per year, contingent upon receiving scientifically meritorious applications. NCI will fund the more meritorious awards based on peer review and responsiveness to the RFA, and the number depends on those application budgets. Please note that while RFA-CA-19-017 does not have a budget cap, RFA-CA-19-001 does cap at $600K direct costs per year.

2. Can genetic testing costs be included in the grant budget?

   Yes, genetic testing can be included in the budget. A statement justifying why the services cannot be covered otherwise and how the services will be sustained after the grant funding has ended must be included, as all applications will be scored on their programmatic sustainability.

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	RFA-CA-19-017	RFA-CA-19-001
Mechanism	U01 Cooperative Agreement	U01 Cooperative Agreement
Clinical trial requirement	Clinical trial **required**	Clinical trial **optional**
Leadership	**Multiple** PI/PD required	**Single or multiple** PI/PDs allowed
Aims	Strategies to increase case ascertainment and follow-up	Interventions and approaches to improve communication and decision making
Populations of interest	➢ General population ➢ Patients with cancer ➢ At-risk family members	➢ Patients with cancer ➢ At-risk family members
Study requirements	➢ Test strategies across **at least 2** health care settings ➢ Address **at least 2** inherited cancer syndromes ➢ Represent underserved and diverse populations	➢ Test strategies in **at least 1** health care setting ➢ **All** inherited cancer syndromes are of interest ➢ Represent underserved and diverse populations
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