Pre-Application Webinar on Approaches to Identify and Care for Individuals with Inherited Cancer Syndromes (RFA-17-041)
Frequently Asked Questions

Budget

Does $4 million in FY 2018 mean $1 million direct cost per year for each project and will this continue over 5 years?
NCI intends to commit $4.0 million (total costs) in FY 2018 contingent on receiving meritorious application and anticipates funding up to 4 awards. Each application is limited to no more than 5 years of funding. Project length and budget are project specific and should reflect the proposed science.

Does the NIH policy requiring prior approval for applications with direct costs of $500,000 and above (Awaiting receipt of applications [ARA]) apply to RFA-CA-17-041?
The ARA policy for large budget grant applications >$500,000 does NOT apply to applications submitted in response to a RFA where budget limits are included. There is a letter of intent request in the RFA that will be used to inform the grant review process.

Can the grant budget include new workforce (e.g. genetic counselors) to absorb the increase in demand, with the thought that these positions would be paid for within a system if the program is successful?
The budget for new workforce may be included in the grant application along with justification of how the proposed workforce needs will be sustained after grant funding has ended.

Can the grant budget include genomic testing?
The funding announcement goal is to identify sustainable models of case ascertainment, testing, and care; thus, testing methods should include those that are obtainable via insurance or national, state, local or private programs. The budget for genetic testing may be included in the grant application along with justification of why testing cannot be covered otherwise and how testing will be sustained after grant funding has ended.

Population

Regarding the need for "two different healthcare settings or two different populations," what exactly does this mean? Some integrated health systems have significant socioeconomic and racial/ethnic diversity as well as various types of healthcare settings (integrated vs academic).
The goal is to demonstrate what method(s) work(s) across different population groups and health care settings. A one-size fits all approach across all populations and settings may not obtain the desired case ascertainment and follow-up. Utilizing an integrated healthcare setting that services multiple populations (e.g. gender, race/ethnicity, socioeconomic status, age, etc.) would be responsive to the RFA, as this approach would be utilizing multiple care settings within a single system (e.g. academic center with affiliated community sites).

Would a health system that has both primary care clinics and hospitals count as two systems, or would one be required to have to be two unique health systems?
The goal of the RFA is to examine multiple care settings in which genetic counseling, testing and follow-up care are provided. Typically, these services are provided in an outpatient setting. A hospital-based

care setting (e.g. a cancer center based at the hospital) and affiliated primary care clinics would be considered as two health care settings.

What populations should applications focus on – cancer patients or those at-risk populations?
Both populations would be responsive to the RFA. All applications must address the totality of care from methods to ascertain individuals with an inherited susceptibility to cancer, whether diagnosed with cancer or at-risk of developing cancer, to delivery of appropriate follow-up care of the patient and family.

Multiple PIs

This FOA solicits multiple principal investigator (PI) applications with academic expertise to interpret and validate the success of ascertainment strategies. Does one of the PI's need to have expertise in quality improvement?
Investigator expertise needs to represent the scientific components of the proposal. For example, an application could include an expert in epidemiology, implementation science, or clinical scientists (genetics, oncology, health care delivery) with experience in implementing programs/quality improvement.

Are you looking for multiple principal investigators (PI) from different institutions or can the PIs be from the same institution?
The investigators may be from the same institution. PI's need to represent the leadership and scientific expertise needed to support the scientific components of the proposal, thus the answer depends on the scope of the proposed project.

Is it correct that the new investigator status is only applicable if all investigators are new investigators?
Correct, NIH policies related to applications from New Investigators and or Early Stage Investigators (ESIs) will be applied to multi-PD/PI applications only when all PD/PIs involved are classified as New Investigators and/or ESIs. View the NIH definition of Early Stage Investigator.

Given the focus on multiple investigator (PI) projects that address diverse populations or health care settings, can you share any thoughts on what entity would be the most appropriate prime agency?
The prime agency would depend on where the majority of the work is being carried out, the population, and leadership capabilities of the investigators. This is a decision to be made by the investigative team.

Applicants

Are foreign institutions allowed to respond?
Foreign (non-U.S.) institutions are not eligible for Cancer Moonshot funding, including RFA-CA-17-041. The funding announcement goal is to test U.S. models of care delivery. Refer to RFA-CA-17-041 Section III for details on eligibility.

What type of applicants are you most interested in (e.g. academics, private business, advocates)?
The most scientifically meritorious applications will be selected. The healthcare settings and population groups represented by the applications will be taken into consideration.

Are scientific consortia allowed/encouraged to apply as consortia?
Yes, consortia can apply to RFA-CA-17-041.

Scope

Can an application include the development of a risk prediction tool or validation of a tool?
No. RFA-CA-17-041 is focused on health care delivery and elicits projects to identify best practices for case ascertainment and follow-up care in inherited cancer syndromes. Study findings should lead to sustainable implementation of care delivery models at the end of funding. Applications focused on the development and validation of new risk predication models should apply to a relevant NIH Parent Announcement.

Will a project focusing on discovering new risk variants/genes without an implementation plan in clinical practice be considered responsive to this RFA?
No. RFA-CA-17-041 is focused on implementation of known risk variants/genes. Study findings should lead to sustainable implementation of care delivery models at the end of funding. Applications focused on new risk variants/genes should apply to a relevant NIH Parent Announcement.

Is it allowable to use telemedicine (like genetic counseling) for areas where there are no professional genetic counselors available?
Yes. This funding announcement aims to increase ascertainment, testing and follow-up care, including those without current access to resources.

Is it required that the implementation is sustainable beyond the time of the grant?
Yes, applications must consider how the interventions can be implemented and sustained. This is in accordance with the Cancer Moonshot Initiative goal of making a decade's worth of progress in cancer prevention, diagnosis, and treatment in 5 years.

Is it acceptable to evaluate cost-effectiveness of panned approaches if it is appropriately integrated into the science and approach?
Yes.

Does the application need to cover both case ascertainment and follow-up care? How much balance between the two are you looking for? Is an application focusing on identifying individuals without addressing how to change their care responsive?
All applications must address case ascertainment and improvement in delivery of evidence-based healthcare for individuals with an inherited susceptibility to cancer. Case ascertainment and follow-up care are equally important to meet the Cancer Moonshot Recommendation G: Expand use of proven cancer prevention and early detection strategies.

Metrics

What sorts of care delivery metrics do you have in mind?
The metrics should be tailored to the study design and population served, measuring the success of program implementation and sustainability once the grant funding period has ended.

Applications are expected to "consider how the intervention can be implemented and sustained". What might some metrics of sustainability be?
For reference, we are providing links to two papers that address metrics and value for dissemination and implementation science:

> Neta G, Glasgow RE, Carpenter CR, Grimshaw JM, Rabin BA, Fernandez ME, Brownson RC. A Framework for Enhancing the Value of Research for Dissemination and Implementation. *Am J Public Health*. 2015 Jan; 105 (1): 49-57.
>
> Rabin BA, Lewis CC, Norton WE, Neta G, Chambers D, Tobin JN, Brownson RC, Glasgow RE. Measurement Resources for Dissemination and Implementation Research in Health. *Implement Sci*. 2016 Mar 22; 11: 42.

Miscellaneous

Per the announcement, Advisory Council Review is August 2018, but "earliest start date" is July 2018. What is the correct start date?
This is an error in the announcement. The earliest start date should read October 2018.