


## Pre-Application Funding Opportunity Announcements (FOAs) Webinar Questions

	Question	Answer
1	Does program have clear expectations about the organizational structure of the submissions and whether PIs need to have roles on all components of the proposed center? (e.g. Can the PI that is leading the Admin Core have a smaller role on the methods unit?)	<p>Center PIs have flexibility in determining the organizational structure for their center. A P50 could have multiple PI/PDs, and therefore the Admin Core and the Research Program could have different PI/PDs. Note, a contact PD would have to be identified. Please work closely with your grants office regarding the PD/PI designations on your application.</p> <p><b>Eligible Individuals (Program Director/Principal Investigator)</b></p> <p>Any individual with the skills, knowledge, and resources necessary to carry out the proposed research as a Program Director/Principal Investigator is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support. Institutions/organizations proposing multiple PDs/Pis should visit the Multiple Program Director/Principal Investigator Policy and submission details outlined in the Senior/Key Person Profile (Expanded) Component of the <a href="#">SF424 (R&amp;R) Application Guide</a>.</p> <p>An individual designated as a PD/PI on an application for a Developing Center (under RFA-CA-19-005) is not eligible to serve as a PD/PI on an application for an Advanced Center submitted in response to this FOA.</p> <p><b>Additional information on Multiple PD/PI Models can be found below and at <a href="https://grants.nih.gov/grants/multi_pi/overview.htm#decision">https://grants.nih.gov/grants/multi_pi/overview.htm#decision</a></b></p> <p><b>Principal Investigators</b></p> <ul style="list-style-type: none"> <li>○ All PD/Pis are designated by the applicant institution</li> <li>○ All PD/Pis share the responsibility and authority for leading and directing the project</li> <li>○ All listed PD/Pis must be registered in eRA Commons with a PD/PI role type</li> <li>○ All listed PD/Pis will have access to Status on the eRA Commons at <a href="https://commons.era.nih.gov/commons/">https://commons.era.nih.gov/commons/</a></li> <li>○ The first PD/PI listed must be affiliated with the institution submitting the application and will serve as the contact PD/PI</li> <li>○ The contact PD/PI will be responsible for communication between the NIH and the rest of the leadership team</li> <li>○ Being named contact PD/PI does not imply any particular role within the leadership team</li> </ul>

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		<ul style="list-style-type: none"> <li>○ When requested by the grantee institution at the time of a non-competing application, another member of the leadership team may assume the role of contact PD/PI</li> <li>○ All PD/PIs will be listed on summary statements</li> <li>○ All PD/PIs will be listed on the Notice of Award (NoA)</li> <li>○ All PD/PIs will be listed in project descriptions available in <a href="#">RePORTER</a> </li> <li>○ The role type, “co-PI” is not used by the NIH</li> <li>○ A change from a multiple PD/PI model to a single-PD/PI model, or from a single-PD/PI model to a multiple PD/PI model, requires the prior approval of the IC Grants Management Officer and must be based on the scientific needs of the project (<a href="#">NOT-OD-11-118</a>).</li> </ul> <p><b>New and Early Stage Investigator Policies</b></p> <ul style="list-style-type: none"> <li>○ 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 (see <a href="http://grants.nih.gov/grants/new_investigators/index.htm">http://grants.nih.gov/grants/new_investigators/index.htm</a>).</li> <li>○ For the purpose of classification as a New Investigator, successfully competing as a multiple PD/PI on a substantial NIH independent research award is equivalent to serving as a PD/PI on a single PD/PI grant in that it will discontinue status as a <a href="#">New Investigator</a>. An individual who meets the definition of New Investigator and is added as a PD/PI on an active substantial NIH independent research award after peer review will not lose their new investigator status.</li> </ul> <p>Please also note the instructions specified in the RFA:</p> <ul style="list-style-type: none"> <li>• <b>Research &amp; Related Senior/Key Person Profile (Administrative Core)</b> <i>In the Project Director/Principal Investigator section of the form, use Project Role of ‘Other’ with Category of ‘Project Lead’ and provide a valid eRA Commons ID in the Credential field. In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component. Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component. If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used. Research Program is expected to be led by an individual(s) designated as PD(s)/PI(s) on the application.</i></li> </ul>

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2	May key personnel (co-investigators) be involved in the pilots as well as in other aspects of the proposal (e.g., methods unit?)	Yes (please see question 1 above)
3	Can there be co-directors on cores and/or multiple PIs on pilots?	Yes, (please see question 1 above)
4	Should biosketches for faculty who will receive D/I research mentorship as part of the Center's activities be included in the application?	<p>The RFA does not specify that faculty who would receive mentoring need to be listed. However, if the individuals in question are seen as having a specific role on the research program, admin core, and/or laboratory, then yes, their biosketches should be included in the application. Please note that this P50 is not specifically a training mechanism and PIs are encouraged to seek and apply to other training mechanisms, if that is the focus.</p> <p>As listed in RFA Subsection B:</p> <ul style="list-style-type: none"> <li>Investigator Team. Without repeating information in individual biosketches, explain how the collective expertise and experience of the investigators will include the necessary expertise and experience to support the team science environment needed to complete the proposed multidisciplinary work. The application should also describe how the Advanced Center will expand opportunities for junior investigators, particularly for underrepresented racial and ethnic groups, individuals with disabilities and individuals from disadvantaged backgrounds. Established investigators, including clinicians, data scientists, economists, other social scientists, and organizational researchers, willing to refocus their efforts on implementation science in cancer can also be included in these opportunities. The direct support of training efforts (e.g., stipends); however, should be sought through other NIH training and career development grant mechanisms.</li> </ul>
5	If an early stage investigator is the implementation pilot leader, would the policy regarding "ESI applications with meritorious scores [being] prioritized for	No, ESI policies do not apply to being the lead on an implementation pilot study. The ESI policy applies if an individual is the contact PI on an NIH application, but P50s are not covered by the ESI policy (please refer to <a href="https://grants.nih.gov/grants/glossary.htm#R01EquivalentGrant">https://grants.nih.gov/grants/glossary.htm#R01EquivalentGrant</a> ).

	Question	Answer
	funding” count towards the pilot study?	
6	How is program defining cancer control? Can implementation studies be proposed to span the cancer continuum from prevention to control or is Program’s emphasis on studies of cancer patients (either survivors or those in current treatment)?	<p>NCI defines Cancer Control as follows: <i>Cancer control science is the conduct of basic and applied research in the behavioral, social, and population sciences to create or enhance interventions that, independently or in combination with biomedical approaches, reduce cancer risk, incidence, morbidity and mortality, and improve quality of life</i> (Cancer Control Program Review Group, 1998—modified). For more information, visit <a href="https://cancercontrol.cancer.gov/od/about.html">https://cancercontrol.cancer.gov/od/about.html</a>.</p> <p>These “cancer control” research activities can occur across the <a href="#">cancer continuum</a>.</p> <p>Applicants should consider the central Implementation Science question that the center will be examining in selecting a Center theme. The theme should be implementation science focused and should serve to frame the activities of each required center component as well as the research agenda that the center will pursue. This theme should build and expand implementation science in cancer control. For more information on past implementation science grants that NIH has funded, please visit <a href="https://projectreporter.nih.gov/reporter.cfm">https://projectreporter.nih.gov/reporter.cfm</a>.</p>
7	How narrowly should themes be defined?	<p>The scope of the theme will depend on the type of center (developing or advanced) and should unify the proposed activities for each component. Note that the potential themes listed in the RFAs (and reproduced below) can include an emphasis on implementation science topics related to a particular cancer control area, or may be implementation science topics across multiple cancer control areas.</p> <p>Please refer to the following language from the RFAs:</p> <p style="padding-left: 40px;">Theme will frame the activities of each required center component and the research agenda that the center will complete. Centers will identify an overall scientific theme which will include specific goals, including:</p> <p style="padding-left: 40px;"><b>Potential theme areas for a Developing Center to focus on include but are not limited to:</b></p> <ul style="list-style-type: none"> <li>○ Developing and testing strategies to facilitate evidence-based de-implementation of ineffective, sub-optimal or harmful cancer control or cancer care interventions;</li> <li>○ Advancing implementation of precision medicine across the cancer control continuum;</li> <li>○ Optimizing scale-up of cancer control policies and interventions;</li> </ul>

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		<ul style="list-style-type: none"> <li>○ Examination of the role of policies or changing policies (organizational, regulatory) on implementation processes, outcomes and adaptations;</li> <li>○ Improving the implementation of evidence-based survivorship care, secondary prevention and quality of life;</li> <li>○ Use of technologies to support rapid cycle and real time deployment and testing of implementation processes and adaptations within cancer control service systems.</li> </ul> <p><b>Potential theme areas for an Advanced Center to focus on include but are not limited to:</b></p> <ul style="list-style-type: none"> <li>○ Developing and testing implementation strategies for evidence-based cancer control interventions in areas such as tobacco control, HPV vaccination, and cancer screening, and other health behaviors across the cancer control continuum;</li> <li>○ Advancing the knowledge base around sustainment of evidence-based cancer control interventions;</li> <li>○ Advancing the implementation of evidence-based symptom management across the cancer continuum;</li> <li>○ Improving health equity among traditionally underserved populations through implementation science;</li> <li>○ Building the evidence base for integration of research-tested interventions across the cancer continuum (from prevention through survivorship) in cancer care delivery systems;</li> <li>○ Scaling up evidence-based cancer control interventions across systems and communities; and</li> <li>○ Advancing the science of intervention adaptation in the context of clinical and community settings.</li> </ul>
8	How does Program envision the interaction between the Implementation Lab and the Implementation Studies/Methods Units, apart from funded pilot studies?	How each applicant responds to this issue is part of the innovation of the Center being proposed. However, there are some key pieces that would be expected in the application. In the RFA, it states: <i>“Applicants should describe how the Methods Unit and Implementation Studies Unit are integrated in the service of this Research Program and how the Research Program will relate to the Implementation Laboratory.”</i> How the pilot studies will synergize with the rest of the Center to achieve more than what could be achieved through an independent research study is seen as a component of a proposal’s innovation.

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		<p>As stated in the RFA: <i>Subsection C. Center Organization and Integration. Include a concise description of the structure of the Center including the organizing framework. Explain how the components of the Center (administrative core, research program, and implementation laboratory) will interact to form a multidisciplinary effort and why each component is essential for addressing the organizing framework of the Center. Applicants should demonstrate that use of the research Center mechanism is essential to accomplishing studies and capacity building activities that would not occur without the climate, facilities, and research resources that a research Center can uniquely provide. Briefly describe the initial set of proposed pilot studies, including those located in the research program, including their scientific integration, staffing plan and a rationale for how each study will help, within the funded period, to generate sufficient results to drive the development of new knowledge on implementation science in cancer control.</i></p> <p>Please review the evaluation criteria for the Implementation Laboratory in the FOA.</p>
10	If an organization is planning to submit a P50 proposal for an advanced center and has also been invited to participate in another organization's advanced center application as a laboratory, is this permissible under the P50 announcement - assuming the two applications have different focus areas?	<p>Collaborating with another institution regarding the laboratory is allowable. Please note the following section of the RFA:</p> <ul style="list-style-type: none"> <li>• <b>Facilities and Other Resources:</b> <i>Document the environment, characteristics and/or commitments of participating institutions. As applicable, explain how multi-institutional collaborations will broaden the range of expertise required for a comprehensive, transdisciplinary approach to the implementation science theme proposed by the center.</i></li> </ul> <p><i>The Advanced Center may consist of several collaborating sites that are not all located in a single institution or geographic region. The collaboration of multiple institutions and settings to create a virtual center must be specified and explained in this section so the feasibility of such arrangements can be evaluated.</i></p> <p>Institutions that are considering collaboration are encouraged to carefully review the requirements outlined for the laboratory (especially the evaluation criteria). It is also important that applications are clear about the selected theme and do not to overlap with the collaborating Centers' applications.</p>

	Question	Answer
11	<p>The RFA notes that applicants must describe at least two implementation studies intended to be conducted in the first two years of the study period. Does each of these studies need to be funded as a two-year pilot, or is there flexibility for the pilots to be awarded as one year or 18-month pilot projects?</p> <p>Is there a minimum time period required for future pilot implementation studies? Is there an anticipated minimum number of pilots to be supported in Years 3-5?</p>	<p>Centers have the flexibility to determine the timeline for the initial pilot studies as well as future pilot studies. Initial and future pilots should be noted in the Center timeline. However, it is generally anticipated that pilots not exceed 2 years. <b>At minimum</b>, the following are required:</p> <ul style="list-style-type: none"> <li>• Implementation Studies Unit: <ul style="list-style-type: none"> <li>○ Developing Center: 1 study and 2 additional innovative study concepts related to the center theme that will be smaller scope</li> <li>○ Advanced center: 2 studies and 2 additional innovative studies</li> </ul> </li> <li>• Methods Unit: <ul style="list-style-type: none"> <li>○ Developing: 1 methodologic study</li> <li>○ Advanced: 2 methodologic studies</li> </ul> </li> </ul>
12	For future implementation pilots and methods pilots, is it expected that there should be a call for applications and a peer review process for selecting proposals, or could they be developed through an internal collaborative process that is not competitive?	Yes, either approach could work. Each Center will determine and describe the process selecting future pilot studies. Keep in mind that the pilots should relate to the Center's overarching theme.
13	Is it your expectation that pilot studies would be open to all implementation scientists or could we limit the pools to researchers within our institutions?	That is up to the center. If this is a multi-site application with multiple institutions, then opening the pilot studies to other researchers could be a possibility. If you do decide to open it to researchers in other institutions, be clear about this process for selection and why doing so enhances the science the Center can accomplish related to the research theme.

	Question	Answer
14	How many methodological research studies are expected to be conducted over the five-year period and is there flexibility in terms of the time period for these pilots? Is it anticipated that these pilots could potentially build on either the implementation studies pilots and/or other existing cancer control programs?	<p>Centers have the flexibility to determine the timeline for the methodological research studies. Initial and future studies should be noted in your Center timeline. However, in general, the pilot studies should not exceed 2 years. <b>At minimum</b>, the following is required:</p> <ul style="list-style-type: none"> <li>• Methods Unit: <ul style="list-style-type: none"> <li>○ Developing: 1 methodologic study</li> <li>○ Advanced: 2 methodologic studies</li> </ul> </li> </ul> <p>The application should specify how the Methods Unit will facilitate the development and design of additional ISCCC measurement and methods studies over the study period, and how these will address additional gaps in implementation science methods and measurement. The application should also describe how these studies will lead to further research and how they contribute to the overall focus of the ISCCC. The applications should be clear in summarizing the initial research pilot studies (each of which should offer potential for future R01 applications), and how these studies will relate to and support one another as well as studies in other units. Applicants should describe how the Methods Unit and Implementation Studies Unit are integrated in service of this Research Program and how the Research Program will relate to the Implementation Laboratory.</p>
15	Although implementation science outcomes are to be prioritized, is there an expectation that we also measure health and behavioral outcomes?	This depends on the Center theme and the research questions and aims that are a part of the application.
16	For the pilot project awards, do applicants need to provide a sum total of resources allocated for each pilot with a separate pilot project budget? Do centers have the flexibility to provide pilot awards through vouchers for discrete services (e.g., biostatistics support, machine learning, engineering	<p>The RFA provides the following instructions regarding budget: <i>Budget forms appropriate for the specific component will be included in the application package. <b>Outline requested budget for research studies and pilots planned over the course of the ISCCC.</b> This budget request may include funding for equipment, software, and computing resources. It is expected that the Research Program should be the largest proportion of the budget for the Center. Funds for research supplies and equipment should not be duplicated in other parts of the budget.</i></p> <p>It is not clear, what is meant by “voucher” in this question, but the Center application has flexibility to budget as is appropriate for the nature and structure of your Center.</p>



	Question	Answer
	resources, research coordinator)?	
17	Could you provide more detail on the budget expectations for the annual network meeting? Should travel be budgeted for teams to attend each year and also costs associated with hosting once or multiple times. Should those hosting costs be put in one particular year?	PI/PDs can determine how to allocate the budget for the application. Funded centers will meet annually in person and the hosting responsibilities will rotate over the course of the five years of the funding, so each funded center will have the opportunity to host at least once. PI/PDs and core personnel should plan on participating in these meetings in person.
18	Can grantees who receive an award under this funding announcement use the NCI Cancer Control IRB as the single IRB of record?	The Center that is holding the award should submit to its institution's IRB. Here are the FAQ's regarding single IRB and multisite research: <a href="https://grants.nih.gov/grants/policy/faq_single_IRB_policy_research.htm">https://grants.nih.gov/grants/policy/faq_single_IRB_policy_research.htm</a>
19	Would a pilot study that includes randomization at the clinic level qualify as a "clinical trial" per the NIH definition?	<p>Yes, presuming that the outcomes would be health-related, that pilot appears to be consistent with the NIH Clinical Trial definition. Center PIs are responsible for determining if proposed research would qualify as a clinical trial.</p> <p><b>NIH clinical trial definition:</b> <i>A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.</i></p> <p>Please note that experimental and quasi-experimental designs (usually) qualify as trials if other criteria are met under the NIH definition. Clinical trials are <b>not</b> limited to RCT (experimental) designs and are also <b>not</b> limited to patients as the unit of manipulation.</p>

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		<p>More information and guidance for determining if a study qualifies as a clinical trial can be found here: <a href="https://grants.nih.gov/policy/clinical-trials.htm">https://grants.nih.gov/policy/clinical-trials.htm</a>.</p> <ul style="list-style-type: none"> <li>It is suggested that applicants review the case studies on this site as there are several that are focused on health care delivery interventions (e.g., changing provider behavior to increase referral to care) and that NIH defines as clinical trials.</li> </ul>
20	<p>If the first two years of a Center's research would not be considered a clinical trial, but the Center may want to support pilot projects that qualify as clinical trials in future years, should the application note "clinical trials" via delayed onset studies or can the initial application note "not clinical trials" and be adjusted when annual progress reports are submitted?</p>	<p>"Delayed Onset" generally means that human subjects research is anticipated within the period of award but definite plans for this involvement cannot be described in the application. It does not apply to a study that can be described but will not start immediately.</p> <p>If future pilot projects are anticipated to meet the NIH definition of a clinical trial, then applicants should submit as a delayed onset study.  <a href="https://grants.nih.gov/policy/clinical-trials/definition.htm">https://grants.nih.gov/policy/clinical-trials/definition.htm</a></p> <p>Because these P50s are award mechanisms that include funds for small projects that will be selected and funded by the awardee, the P50 pilots would fall into the three categories of delayed onset.  <a href="https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-129.html">https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-129.html</a></p>
21	<p>How does NCI intend to engage with Centers under the P50 mechanism? Will partnership/engagement be more limited than under the 'U' mechanisms often used for consortia?</p>	<p>In addition to administering the grants, NCI's Implementation Science team can foster trans-center coordination (in terms of data sharing, dissemination, meeting support, etc.). NCI staff will also actively participate in consortia related activities, capacity building for the field, and network activities under the Administrative Core (Network Unit).</p>
22	<p>Are program staff available for calls with PIs to discuss their specific proposals?</p>	<p>Yes, Program staff are available to talk to PIs about their proposals. A 20-minute appointment can be arranged via e-mail, but the PI should plan to send a brief 1-page description of their Center aims ahead of the call to ensure a productive discussion.</p>
23	<p>Would a P50 Center that has its population in a Low or Middle-Income Country (LMIC) be eligible for this funding announcement?</p>	<p>Because funding for this initiative comes from the Cancer Moonshot, a domestically focused center with some global activities that contribute to understanding and advancement of Implementation Science in the US could be within the scope and goals of the RFA. However, an exclusive global focus would be beyond this RFA. Applicants that would like to propose a globally focused research project can contact</p>

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		program staff to be referred to other Program Contacts at NCI who may be able to advise on other funding opportunities that may be available.