RFA-CA-21-029: Centers on Telehealth Research for Cancer-Related Care (P50 Clinical Trial Required)

Frequently Asked Questions following April 29, 2021 Pre-application Webinar

https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-21-029.html

---

RFA Focus

While the focus is on patient/provider telehealth visits, can applications also include asynchronous data (e.g., remote monitoring, patient portal use)?
Per the requirements in the RFA, the Center must have synchronous patient/provider telehealth visits as the key focus. Applications are encouraged to include various asynchronous telehealth elements as appropriate to accomplish research goals.

Regarding synchronous patient-provider telehealth, is the RFA primarily focused on clinical video visits, or are there other synchronous communication examples of interest?
All synchronous patient/provider telehealth communication formats (e.g., video, phone, hybrid) are encouraged.

Does each center component need to cover the entire spectrum of cancer care delivery from diagnosis to survivorship? Do all cancers have to be included?
Applications can address cancer care at any point(s) of the cancer control continuum from cancer prevention to end of life; applications are not required to focus on multiple points on the continuum. All cancers do not have to be included in the research. The point(s) on the cancer control continuum and cancer sites covered in the application should fit the scope and focus of the proposed research.

Much work is needed in engaging families in cancer care and supporting family caregivers of cancer patients. Would family caregiver to provider synchronous telehealth be responsive?
The focus of the P50 mechanism is on the delivery of cancer-related care via synchronous telehealth communication between patients and providers. Caregivers are an important part of the patient's care team and applications that include caregivers in its research would be deemed responsive, assuming that interactions between patients and providers are the primary focus.

Would the definition of "provider" also include health educators from the clinic?
The focus of the P50 mechanism is on the delivery of cancer-related care via synchronous telehealth communication between patients and providers. Per the RFA, "Healthcare Providers: Healthcare professionals who deliver cancer-related care. Examples include, but are not limited to, physicians, physician assistants, nursing practitioners, nurses, psychologists, social workers, and patient navigators." In this case, health educators could be another example of a healthcare provider. Investigators are encouraged to contact NCI Program staff with specific questions.

For the synchronous telehealth visit, are the tools provided to manage COVID 19 as waived by OCR going to be considered?
Applicants are responsible for compliance with relevant federal, state, and local regulations, waivers, and other policies related to the practice of telehealth in the design and conduct of the P50 application and collaboration with the Clinical Practice Network. In addition, the proposed research must be in compliance with relevant human subjects protections.

Required Components

Do each of these components have a specific aims page in addition to the page limit on main narrative or is specific aims page part of the page limits noted?
As stated in the RFA, there are five required components to the P50 Center: Overall Center, Administrative Core, Research and Methods Core, Clinical Practice Network, and Pragmatic Trial. Each component will have a specific aims page, plus a 12-page research strategy.

Regarding a Data Core Requirement, for a multi-site Center, where should the Data Core Component be found? For example, the Admin Core or Research and Methods Core?
The RFA does not require a standalone Data Core; placement of related project activities in the Administrative Core or the Research and Methods Core is at the discretion of the investigative team. Applicants are encouraged to review the characteristics and attributes of each component as well as the associated review criteria as outlined in the RFA.

Budget, Effort Allocation, and Study Teams

What is the maximum project period and award budget?
The maximum project period is 5 years. The budget is limited to $800,000 in direct costs per year.

Do Principal Investigators (PI) 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 a different component?)
Please review the RFA for specific guidance on effort requirements related to the overall Center and across components. We encourage investigators to balance programmatic expertise with required responsibilities and leadership of the Center as a whole and of each component. Applicants are encouraged to contact NCI Program staff with specific questions about effort allocation.

Given the PI effort requirements across components, how should MPIs allocate their effort?
Please review the RFA for specific guidance on effort requirements related to the overall Center and across components. We encourage investigators to balance programmatic expertise with required responsibilities and leadership of the Center as a whole and of each component. Applicants proposing MPI applications are encouraged to contact NCI Program staff with specific questions.

May key personnel (co-investigators) be involved in the pilot studies and/or pragmatic trial as well as in other aspects of the proposal (e.g., Clinical Practice Network)?
Yes, co-investigators and other key personnel may be involved in multiple aspects of the Center including pilot studies and pragmatic trials.

Where in the application should we highlight clinical expertise (e.g., medical oncology, palliative care, primary care, social work)?
Clinical expertise is a foundational element to cancer care delivery. This type of expertise and focus should be reflected in the Center investigative team and could be highlighted in the Clinical Practice Network section of the application, for example.

If proposing an MPI project, do all PIs have to be cancer researchers. If the PI is a cancer researcher, but a co-PI has telehealth expertise, but not in cancer research, would that be reviewed well?
Applicants are encouraged to put together investigative teams with collective expertise and experience needed to support the research goals of the Center. Applicants are encouraged to reflect on the review criteria for Investigators, for example, which includes questions such as:

- If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise?
- How well does the proposed PD/PI(s) record of leadership in the area of science and their record of scientific achievements support their ability to lead the Center?
- How well does the range of experience and disciplines of the investigative team correspond with the ability to facilitate research on the integration of telehealth into models of cancer care delivery?

The RFA states that individuals can only serve as PI of one P50. Does this mean only one P50 in this mechanism, or that you are ineligible if you serve as PI on a P50 funded through a different mechanism?
Per the RFA, investigators can only serve as a PI/MPI on one [telehealth research] Center. However, investigators may have other roles (i.e., co-leader, Core director, consultant) on other P50 [telehealth research] Centers. Investigators may serve as PI on P50 centers funded through other NIH funding opportunity announcements (FOA).

Note: It is unacceptable for investigators to concurrently submit the same or overlapping research proposal as a P50 Center Project and an independent R01, R21, etc., application to the NIH. Potential overlap will be evaluated by NCI staff prior to award; submitted applications will not be reviewed if they do not conform to NIH policies or if they fail to meet the minimum requirements specified in this FOA.

Can a single institution submit multiple P50 applications?
Yes, applicant organizations may submit more than one application, provided that each application is scientifically distinct.

Center Research Theme

Can the Center research theme focus on cancer screening?
As stated in the RFA, the research theme is designed to reflect research disciplines and fields, with a focus on developing methods and approaches for examining telehealth care delivery models. In this case, cancer screening cannot be a research theme. However, it could be a phase of the cancer control continuum being explored in the application; the specialty area of the Clinical Practice Network; and/or the cancer-related care being assessed in either the pragmatic trial and/or pilot studies.

Can the research theme focus on specific cancers, e.g., uterine and cervical cancer, rather than methods?
As stated in the RFA, the research theme is designed to reflect research disciplines and fields, with a focus on developing methods and approaches for examining telehealth cancer care delivery models. Specific cancer types cannot be a research theme, though there may be telehealth-related care delivery topics relevant to specific cancers that could be addressed in a research theme. The Clinical Practice Network could focus on specific cancers if reflected in the scope and focus of the proposed research.

Pilot Studies

How long and detailed of a pilot study do we need to include in the Research and Methods Core section?
Per the RFA, Centers must conduct two rapid-cycle pilot studies focusing on cutting-edge scientific questions within the Center's broader proposed research theme. Within the Research and Methods Core, investigators should describe one pilot intended to be conducted within the first two years of the study period. The initial pilot study should be described in the following sections: Significance, Innovation, Approach, Investigator, and Environment. The application should describe a detailed, systematic process by which the Research and Methods Core will develop, review, select, and launch one additional pilot related to the overall Center research theme later in the project period (but no later than year 4).

Given the number of topics to be described in the Research and Methods Core, investigators are encouraged to be concise and succinct with the pilot studies narrative yet provide enough detail so that all required sections can be adequately reviewed. Investigators are also encouraged to consider cross-referencing other sections of the Research and Methods Core as appropriate (e.g., Environment) in the pilot studies description.

Must the pilots directly relate to the Aims/Activities of the pragmatic trial, or may they test/explore related issues but not directly part of the pragmatic trial?
Centers must conduct two rapid-cycle pilot studies focusing on cutting-edge scientific questions within the Center's broader research theme. It is expected that these pilot projects will generate preliminary findings on high-impact topics that are distinct from the pragmatic trial or

signal important intervention adaptations within the pragmatic trial that will accelerate the further evaluation of telehealth-focused models of cancer-related care delivery.

Pragmatic Randomized Controlled Trial

Must the pragmatic trial be randomized or would novel trial design be considered?
See RFA, including definitions section. The proposed large-scale pragmatic randomized controlled trial must use a randomized design. Note that it can be one of several types of randomized designs, including (but not limited to) an individual randomized controlled trial, cluster randomized controlled trial, and stepped-wedge cluster randomized controlled trials. The type of pragmatic randomized controlled trial should be selected based on its ability to best answer research question(s), balanced against other considerations, where applicable.

Would effectiveness-implementation hybrid trials qualify as pragmatic clinical trials under this NCI call?
See RFA for the definition of a pragmatic randomized controlled trial. If an effectiveness-implementation hybrid design (type 1, 2, or 3) is proposed, and conceptualized and designed to be consistent with the RFA definition of the pragmatic trial, it may be considered as a pragmatic trial. Note, however, that effectiveness-implementation hybrid designs are not inherently pragmatic randomized controlled trials.

Clinical Practice Network

May some sites serve in the Practice Network but not participate in the trial (i.e., they participate in the pilots but not the trial)?
The intention is that the Clinical Practice Network will support the pragmatic trial and the pilot studies. At the discretion of the investigative team, clearly justified other uses/services of the Clinical Practice Network are allowed. If investigators plan to use sites of the Clinical Practice Network for reasons other than the pragmatic trial and pilot studies, please reach out to NCI Program staff to ensure application responsiveness.

How large should the Clinical Practice Network be ideally?
The Clinical Practice Network should be large enough to appropriately power one large pragmatic RCT trial and two pilot studies. Appropriate size will vary based on the Center's research theme, methods, and scientific questions.

Should the Clinical Practice Network be places where oncology services are provided? Or could they be places of primary care?
The clinical composition of the Clinical Practice Network will depend on the research question and aims of the proposed research studies. The network should cover the clinical expertise, point(s) on the cancer control continuum, and clinical care delivery setting reflected in the proposed research.

Does the Clinical Practice Network need to be already existing?
Per the RFA, if the network is not already active, applicants must clearly demonstrate plans to activate the clinical practice network by the end of the year 1 project period.

Cross Center Collaboration and NCI Involvement

What expectations does NCI have for cross center collaboration?
Per the RFA, the funded Centers will be expected to form a Steering Committee, which will identify and promote collaborative projects, common data elements, measures and metrics, and dissemination activities across all of the telehealth research Centers funded by NCI. Investigators from the funded Centers initiative will be expected to participate in annual grantee meetings as a means to promote trans-initiative interaction to present results, initiate cross-center collaborations, provide opportunities for career development for early career investigators, and to communicate with other funded Centers' investigators.

Collectively, the P50 Centers on Telehealth Research for Cancer-Related Care are expected to represent national efforts at the forefront of cancer-related telehealth research. In combination, the goal is to improve access to care, care quality, patient-provider communication, and health outcomes across the cancer control continuum. Collaboration is viewed by NCI as key to accomplishing these goals.

How does NCI intend to engage with Centers under the P50 mechanism?
In addition to administering the grants, NCI Program staff will support coordination between Centers (e.g., annual meeting support, dissemination, capacity building) and the overall Centers initiative.

Is NCI Central IRB allowed or required?
Applicants are encouraged to contact NCI Program staff with specific questions, particularly if they are considering working with a NCI-sponsored program or network such as the NCI Community Oncology Research Program (NCORP), which requires the use of the Central Institutional Review Board of the NCI.

How many Centers will be funded?
NCI intends to commit $3.36M in FY 2022 to fund three awards.

Will applications to this RFA be reviewed by standing study sections?
Applications will be evaluated for scientific and technical merit by a special emphasis panel convened by the NCI Division of Extramural Activities.

Who should we contact at NCI with questions about the Telehealth P50 RFA?

Scientific/Research Contact(s):
Roxanne E. Jensen, Ph.D.
National Cancer Institute (NCI)
Telephone: 240-276-7588
Email: roxanne.jensen@nih.gov

Robin C. Vanderpool, DrPH
National Cancer Institute (NCI)
Telephone: 240-276-6558
Email: robin.vanderpool@nih.gov

Peer Review Contact(s):
Referral Officer
National Cancer Institute (NCI)
Telephone: 240-276-6390
Email: ncirefof@dea.nci.nih.gov

Financial/Grants Management Contact(s):
Dawn Mitchum
National Cancer Institute (NCI)
Telephone: 240-276-5699
Email: dm437a@nih.gov