

Centers on Telehealth Research for Cancer-Related Care

P50 Clinical Trial Required

RFA-CA-21-029



Pre-Application Webinar
April 29, 2021

Using WebEx and Webinar Logistics

The screenshot shows a WebEx interface with three main panels:

- Participants (1)**: Shows one participant.
- Chat**: A message input field with a red border containing the placeholder "Enter chat message here".
- Q&A**: Shows one question.

- All lines will be in listen-only mode
- Submit comments at any time using the **Chat** feature and select All Panelists
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- Closed captioning is available as a link in the Chat Box
- This webinar is being recorded

Speakers



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Webinar Outline

- 1. Background**
- 2. Funding Opportunity Announcement: RFA-CA-21-029**
- 3. Application Components: Key Elements and Highlights**
- 4. Question & Answer Session**

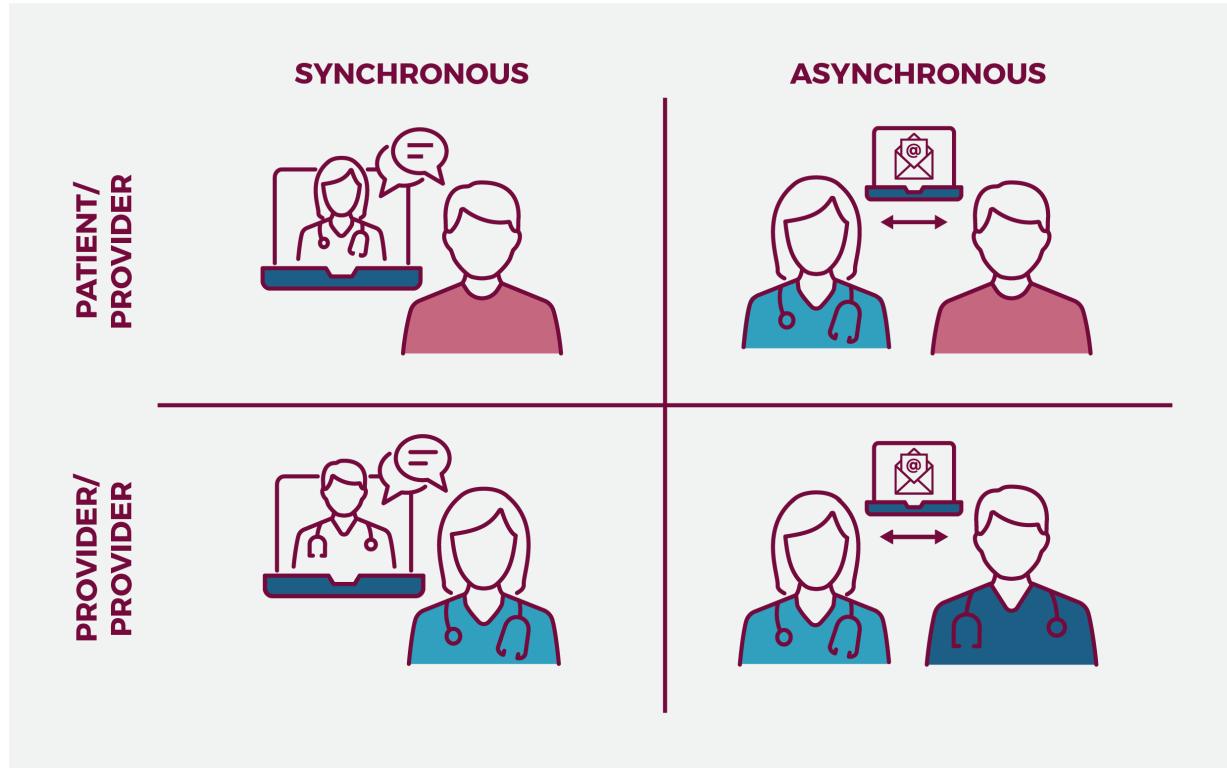
Background

Use of Telehealth in Cancer Care Delivery

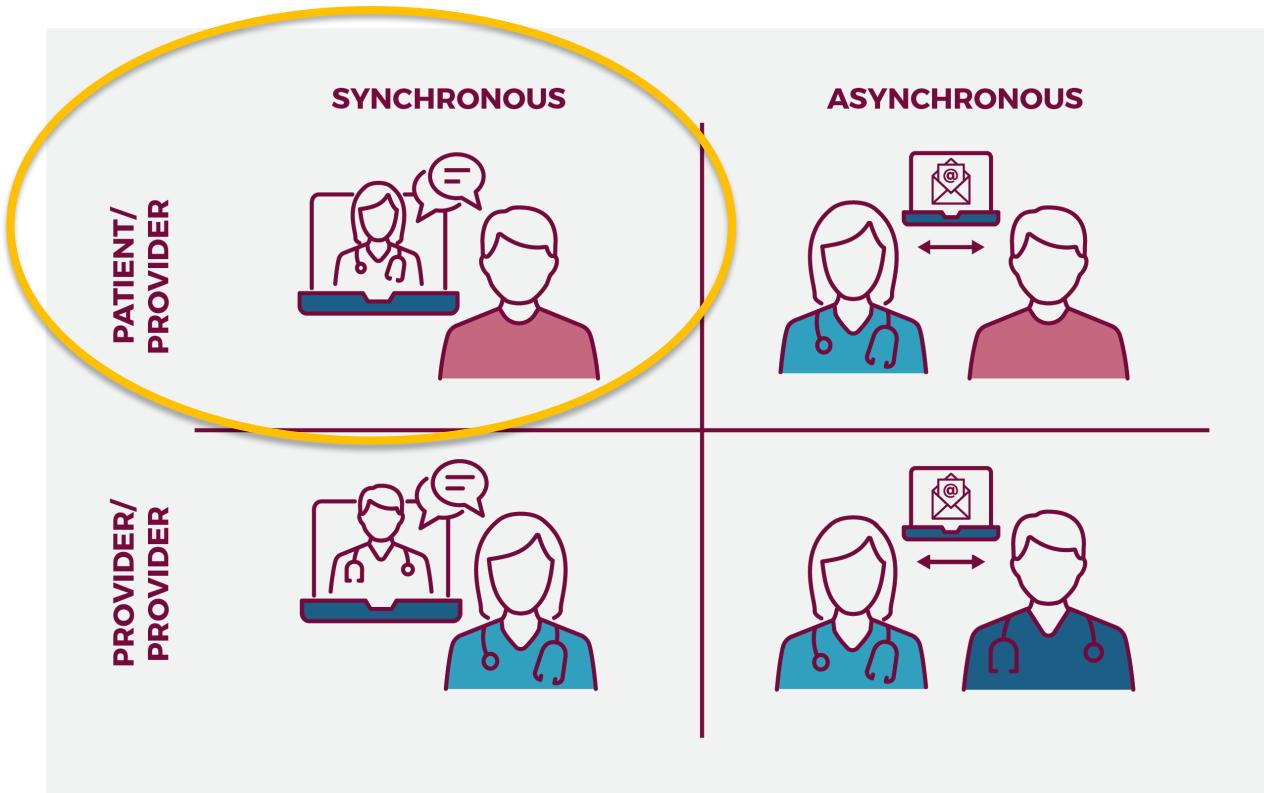
- Research has shown cancer-focused telehealth can improve:
 - Healthcare access and quality
 - Patient/provider communication
 - Health-related quality of life
- Very few findings have been translated and adopted into sustained clinical practice
- Research has focused on targeted interventions, not evaluating as a mode of care delivery



Telehealth: Interaction and Communication Type



Telehealth: Interaction and Communication Type



Opportunity for Telehealth Adoption due to COVID-19

- During the pandemic, in-person care delivery has rapidly transitioned to telehealth
 - Increased use in primary care, specialty care, and oncology settings
 - Virtual visits reimbursed equivalent to in-person visit
- Opportunity to improve cancer care by researching telehealth approaches
 - Foster research examining new tools, methods and technology
 - Address processes and outcomes of cancer-related care
 - Identify unique needs and opportunities for underserved populations
 - Assess telehealth's sustained utility, post COVID-19

What is Needed

- Rapid development of a telehealth-focused evidence base across the cancer care continuum, investigating:
 - Telehealth as a modality of cancer care delivery
 - Large, pragmatic trials to establish evidence-based telehealth practices
 - Innovative technology and research methods
 - Access to care and ways to reduce health disparities



Funding Opportunity Announcement (FOA): **RFA-CA-21-029**

Centers on Telehealth Research for Cancer-Related Care

RFA Goals

- Create national centers for advancing a telehealth research agenda focused on improving cancer-related care and outcomes across the cancer control continuum
- Generate and disseminate a robust evidence base for patient-centered, sustainable synchronous patient-provider telehealth models of cancer care delivery
- Foster innovations to improve cancer care delivery by researching real-time, patient-provider telehealth communication using new tools, research methods, and technologies

P50 Telehealth Centers Impact

- Collectively, the P50 Centers on Telehealth Research for Cancer-Related Care will represent a national initiative at the forefront of cancer-related telehealth research committed to improving:
 - **access to care**
 - **care quality**
 - **patient-provider communication**
 - **health outcomes across the cancer control continuum**



Why a P50? A Need for Specialized Centers

- Provides an infrastructure to conduct multiple studies
- Focuses on the development and dissemination of new telehealth-focused care delivery methods and research designs
- Promotes cross-center collaboration and learning opportunities
- Provides flexibility to adapt and study changes in the healthcare, policy, and technology environments
- Can conduct research to build a cancer-focused telehealth evidence base

RFA-CA-21-029: Overarching Requirements

- **Patient-provider synchronous telehealth communication** must be the focal point for all proposed research activities.

- **Research Theme:** An overarching, unifying theme that will frame all proposed scientific activities

- Approaches can be methodological, conceptual or technological
- Content (examples): health economics, quality improvement research, health communication, data science, human-centered design

- **Clear Cancer Research Focus:**

Goal is to develop a telehealth evidence base targeting critical cancer-related care delivery and associated health outcomes.



RFA-CA-21-029: Overarching Requirements

- **Access to Care and Health Disparities:** Emphasize opportunities to identify and address identified disparities in access to and receipt of telehealth services and/or cancer-related care among disparate populations.
- **Collaboration & Dissemination:** Centers are expected to build research capacity, collaborate on common data elements, exchange measures and metrics, and disseminate findings, tools, and resources with other funded centers and across the broader clinical care and cancer control research communities.
- **Telehealth Environment:** Make use of evolving technology, clinical care guidelines, novel research methods, and changes in healthcare context (e.g., policy, reimbursement/financing, access to care)

RFA-CA-21-029

Application Components: Key Elements and Highlights

Application

- Please read the FOA ([RFI-CA-21-029](#)) carefully before applying
- The application **must** include each of the following components:

Component	Page Limit
Overall	12 pages
Administrative Core	12 pages
Research and Methods Core	12 pages
Clinical Practice Network	12 pages
Pragmatic Trial	12 pages

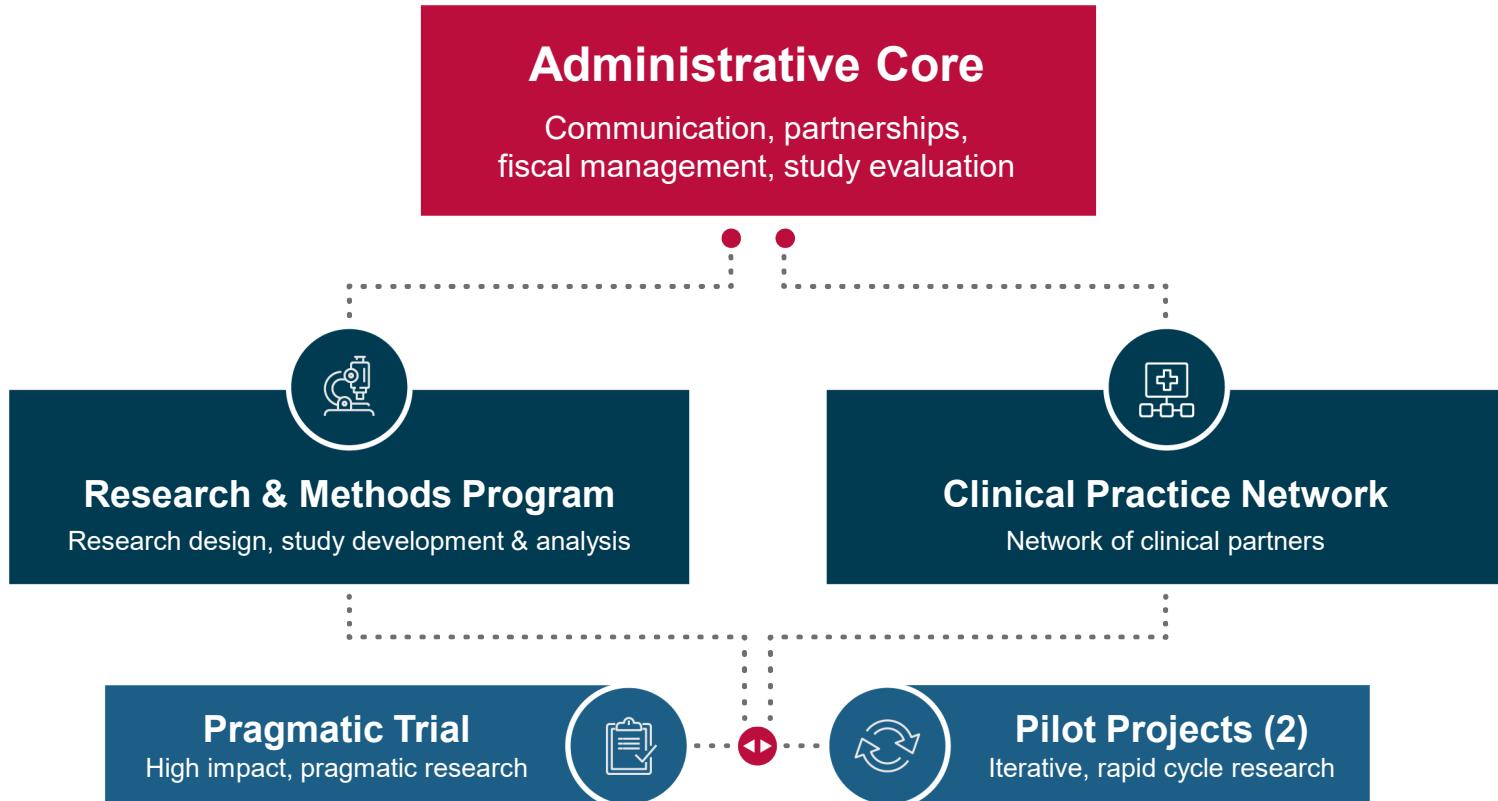
Overall Component (Key Elements)

- The **specific aims** should outline the overall vision and goals for the proposed Center on Telehealth Research for Cancer-Related Care.
- **Main Narrative of the Overall Component**
 - Center Overview
 - Investigative Team
 - Center Organization and Integration
 - Commitment to Improving Access to Care
 - Centers on Telehealth Research for Cancer-Related Care Collaboration
 - Letters of Support
 - Data Sharing Plan (included in the Overall component, but should cover all the activities [Cores and Research] of the Center

Overall (Highlights)

- Center's purpose and overall goals and overarching research theme
- Rationale and justification for a Center approach, including an organizing framework
- Summarize expected outcomes and dissemination of evidence-based model of cancer-focused telehealth
- Detailed plan for sharing resources with the clinical care and cancer control communities
- Describe interdisciplinary team approach
- Promote collaboration with other NCI-funded telehealth research centers

Telehealth Center Structure



Administrative Core (Key Elements)

- **Specific Aims:** Describe the aims of the Administrative Core and how these will advance the Center's organizational and fiscal functioning, research capacity to implement the proposed research studies, and dissemination goals.
- **Research Strategy:**
 - Administrative Core Overview
 - Operational Structure
 - Investigative Team
 - Research Experiences for Early-Stage Investigators
 - Center Evaluation
- **Timelines and Milestones**

Administrative Core (Highlights)

- Manage and coordinate all Center research and activities (e.g., fiscal management, evaluation, communication, and dissemination)
- Center evaluation, including research and public health impact
- Develop methods and processes for monitoring scientific, dissemination, fiscal progress and milestones for all Center activities
- Establish an External Advisory Board of key stakeholders
- Opportunities for graduate students, postdoctoral researchers, and early-stage investigators

Clinical Practice Network (Key Elements)

- **Specific Aims:** Describe the aims of the Clinical Practice Network and how it will advance the Center's research goals and broader dissemination of evidence-based telehealth models of cancer care delivery.
- **Research Strategy**
 - Clinical Practice Network Overview
 - Clinical Practice Network Sites
 - Investigative Team
 - Network Infrastructure and Telehealth Capacity
 - Data Collection and Management
 - Clinical Practice Network Surveillance

Clinical Practice Network (Highlights)

Group of clinical practices that will serve as the environment in which the Center's research will be conducted and evaluated.

- Must demonstrate that the selected clinical sites have the electronic infrastructure, staffing, patient population, and resources needed to engage in both the proposed research activities
- Must have an identified and engaged Clinical Practice Network activated by the end of year 1 of the project period.
- Discuss the inclusion of diverse patient populations that will facilitate addressing issues of health disparities and access to care
- Monitor and evaluate evolving telehealth technology, clinical care guidelines, policy, and digital divide issues

Research and Methods Core (Key Elements)

- **Specific Aims:** Describe the aims of the Research and Methods Core, and how it will advance the Center's research theme, overall goals, research activities, and dissemination of evidence-based telehealth models of cancer care delivery.
- **Research Strategy:**
 - Research and Methods Core Overview
 - Investigative Team
 - Development and Operational Support of Research Projects
 - Generate Innovative Research Methods and Evaluation Measures
 - Dissemination of Methodological Advances and Other Center-generated Resources
 - Evaluation of the Center's Research Productivity and Impact
 - Pilot Studies

Research and Methods Core (Highlights)

- Expertise in innovative study designs and methodological approaches that reflect the Center's research theme
 - Develop, implement, and evaluate rapid-cycle pilot studies
 - Provide expert study design and research methods support to the design and execution of the pragmatic trial
- Consider the target and outcomes of the intervention at multiple levels (e.g., patient, provider, and practice)
- Apply valid, reliable, and feasible measures of telehealth and cancer care delivery to assess outcomes at multiple levels; create new measures as needed
- Contribute to Center evaluation and related dissemination strategies
- Interface with the Clinical Practice Network to conduct pragmatic trial and pilot studies

Research and Methods Core: Pilot Studies (Key Elements)

- Centers must conduct two rapid-cycle pilot studies focusing on cutting-edge scientific questions within the Center's broader proposed research theme. In this section, describe one pilot intended to be conducted within the first 2 years of the study period that advances the research theme of the Center.
 - Significance
 - Innovation
 - Approach
 - Investigators
 - Environment
- Process for Developing, Reviewing, Choosing, and Managing Additional Studies (no later than year 4)

Research Methods: Pilot Studies (Highlights)

- To be developed and launched sequentially over the grant period
- Leverage existing Center infrastructure (Clinical Practice Network), staffing, resources, and stakeholders
- Generate preliminary findings on high-impact topics or signal important telehealth-focused intervention adaptations
- Encouraged: Innovative cross-disciplinary linkages and high-risk/high-pay-off studies designed to advance innovative telehealth research

Pragmatic Trial (Key Elements)

- **Specific Aims:** The specific aims should provide a concise description of the goals of the pragmatic trial to be conducted within the Clinical Practice Network.
- **Research Strategy**
 - Significance
 - Innovation
 - Approach. [The approach should justify the scale and scope of the trial.]
 - Investigative Team
 - Environment

Pragmatic Trial (Highlights)

- Each Center will conduct a pragmatic randomized controlled trial (RCT) for the purpose of generating telehealth-focused evidence reflecting the Center's overall research theme.
- Intervention outcomes **must** include: patient-reported outcomes, healthcare utilization, and clinical outcomes.
- The generated evidence-based telehealth approaches should be transferable, scalable, and sustainable.
- Plan for monitoring, evaluating, and intervening on issues related to health disparities, including access to care, digital divide challenges, and receipt of telehealth services.

Non-Responsive Applications

- No evidence that the Center has identified and secured clinical sites with synchronous, patient-provider telehealth capabilities.
- Does not propose one pragmatic trial and two rapid-cycle pilot studies.
- Does not include a detailed plan to monitor, evaluate, and address health disparities and access to care issues in proposed studies.
- Does not provide a comprehensive plan to monitor and evaluate changes in telehealth care delivery over the course of the award.
- Does not provide evidence that the infrastructure needed to administer telehealth as part of usual care delivery is available, adequately functioning, and can be maintained over the funding period.
- Does not have a cancer-relevant research focus.

Additional Details for RFA-CA-21-029

Key Dates for RFA-CA-21-029

Activity	Deadline
Letter of Intent Due	June 20, 2021
Application Due Date	July 20, 2021
Scientific Merit Review	November 2021
Advisory Council Review	January 2022
Earliest Start Date	April 2022

Strongly Recommended: Letter of Intent

(30 days prior to application due date)

Include:

- Descriptive title of proposed activity
- 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

Send to:

- Roxanne E. Jensen, PhD
National Cancer Institute
Email: roxanne.Jensen@nih.gov

Although a LOI is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NCI staff to estimate the potential review workload and plan the review.

Budget and Project Period

- NCI intends to commit \$3.36M in FY 2022 to fund three awards
- The budget should reflect the actual needs of the proposed project
- Budget is limited to \$800,000 in direct costs per year
- Project Period: Maximum 5 years



Leadership Commitment Requirements

Role	Minimum Effort (Person Months)
Center Director* ^{\$}	3 PM per year , applies to each individual listed as a Center PD/PI in a multiple PD/PI Center.
Administrative Core Leadership	1.2 PM per year , combined effort if multiple leaders
Research Methods Core Leadership	1.8 PM per year , combined effort if multiple leaders
Clinical Practice Network Leadership	1.8 PM per year , combined effort if multiple leaders
Pragmatic Trial Project Leadership	1.8 PM per year , combined effort if multiple leaders

* Must be the leader of the Administrative Core and Pragmatic Trial

^{\$} Investigators can only serve as a PI/multi-PI on one Center. However, investigators may have other roles (i.e., co-leader, Core director, consultant) on other P50 Centers.

Application Review Information: Review Panel Convened by NCI

Overall Impact – Overall Score

- **Criterion Scores** will be assigned to:
 - Significance, Investigator(s), Innovation, Approach (including clinical trial features), Environment

Additional Review Criteria:

- Study Timeline and Milestones; Protection of Human Subjects; Inclusion of Women, Minorities, and Individuals Across the Lifespan; Data and Resource Sharing Plans; Budget and Period of Support

Center Components:

- Reviewers will assign **one overall adjectival rating** for each component (Administrative Core, Research and Methods Core, Clinical Practice Network, and Pragmatic Trial).

Tips

- Read the full announcement. Even for experienced investigators the structure is likely different from what you have seen in other funding announcements.
- Pay attention to the **clinical trials requirements**.
- Develop a **cohesive narrative for your projects** that clearly demonstrate how activities tie into an overarching research theme.
- Submit a **letter of support** (Clinical Practice Network: required).
- Pay careful attention to the evaluation criteria for all Center components and research studies. **We strongly recommend reading the review criteria**.
- Identify the **appropriate expertise** for team members and engage them early in the writing.

Additional Resources

- Webinar and FAQ will be posted online:
<https://healthcaredelivery.cancer.gov/telehealth/>
- **Scientific/Research Contacts**
 - Robin C. Vanderpool, Dr.P.H.: robin.vanderpool@nih.gov
 - Roxanne E. Jensen, Ph.D.: roxanne.jensen@nih.gov
- **Financial/Grants Management Contact**
 - Dawn Mitchum: dm437a@nih.gov



Questions?

Please enter questions into the chat box.



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