

# Intervening with Cancer Caregivers to Improve Patient Health Outcomes and Optimize Health Care Utilization

**PAR-19-352 (R01); PAR-19-355 (R21)**

Healthcare Delivery Research Program

Division of Cancer Control and Population Sciences

# Webinar presenter

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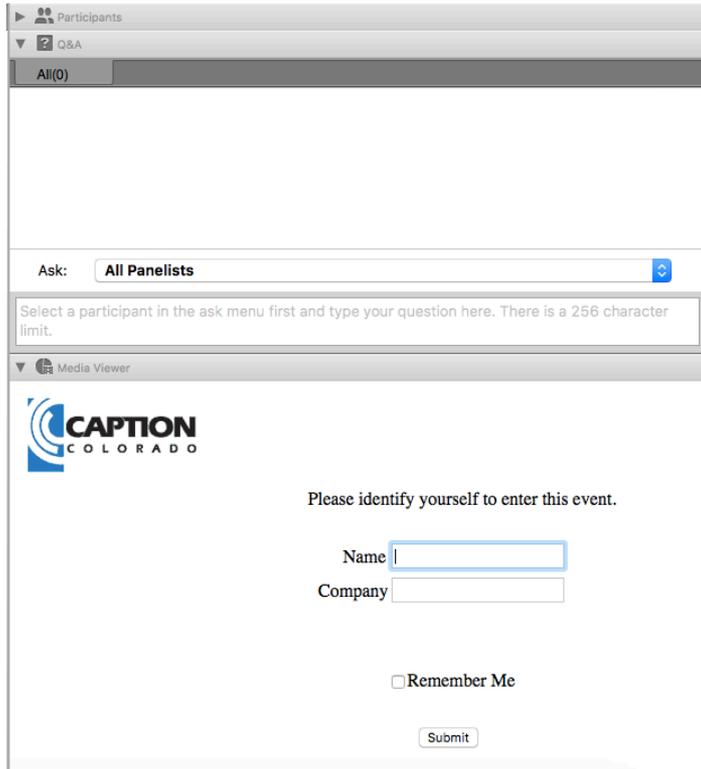
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# Using WebEx and webinar logistics



The screenshot displays the WebEx interface with three main sections:

- Participants:** A header with a person icon and the text "Participants".
- Q&A:** A section with a question mark icon and "Q&A". Below it is a tab labeled "All(0)". A dropdown menu is set to "All Panelists". A text box contains the instruction: "Select a participant in the ask menu first and type your question here. There is a 256 character limit."
- Media Viewer:** A section with a camera icon and "Media Viewer". It features the "CAPTION COLORADO" logo and the text "Please identify yourself to enter this event." Below this are input fields for "Name" and "Company", a "Remember Me" checkbox, and a "Submit" button.

- Submit questions at any time during the presentation
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- Closed captioning is available by selecting the Media Viewer Panel on the right hand side of your screen
- This webinar is being recorded

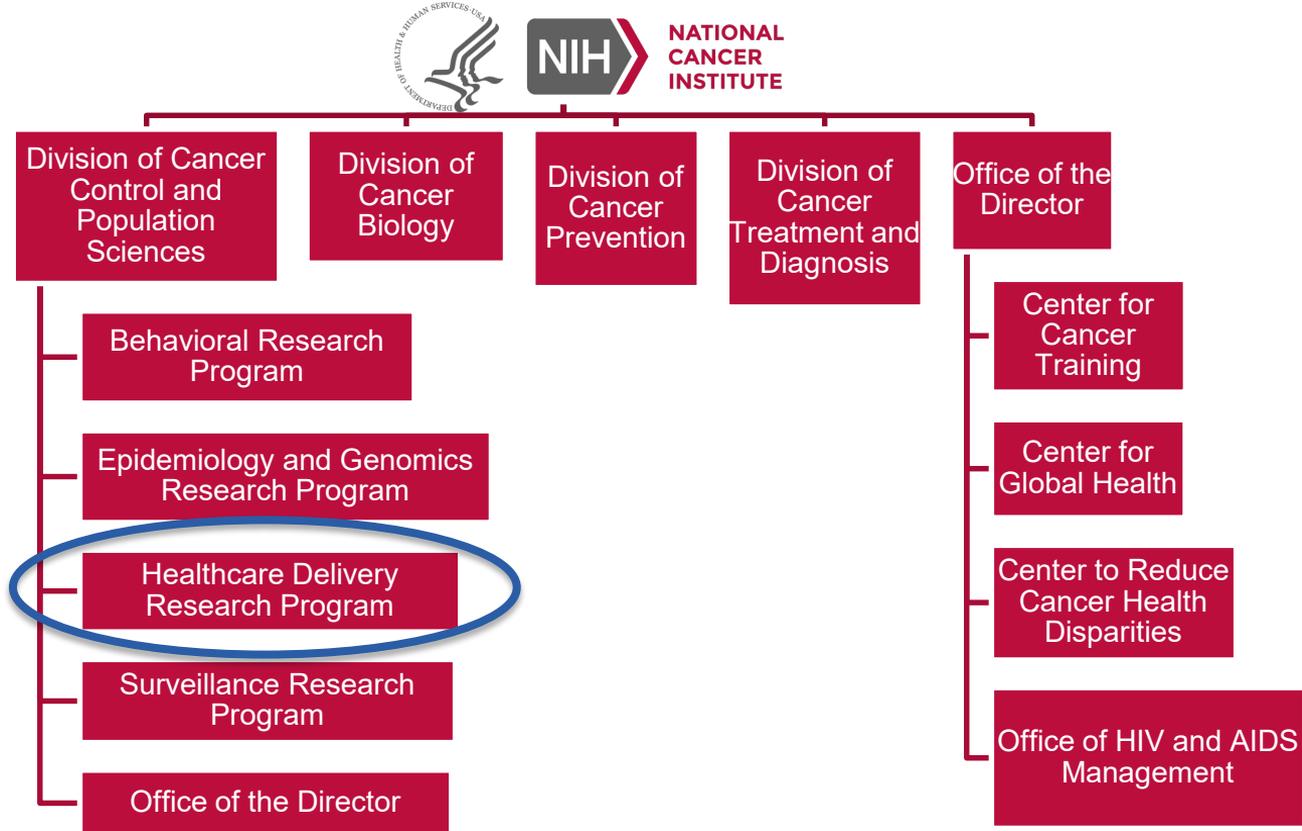
# Outline

- Background
- FOA Details
- Questions
  - **Note:** questions about specific aims or grant application details will not be addressed

# Background

*Healthcare Delivery Research Program*

# Organizational Chart of Extramural Divisions at NCI



# HEALTHCARE DELIVERY RESEARCH PROGRAM

Advancing innovative research to improve the delivery of cancer-related care.



## HEALTHCARE ASSESSMENT

Assess utilization, access, diffusion, and effectiveness in community settings



## HEALTH SYSTEMS & INTERVENTIONS

Observe and intervene on behavior and context



## OUTCOMES

Evaluate and improve patient experiences and health outcomes

# Informal Cancer Caregiving

# Informal Caregivers: Who are they?

- Individuals that assist family members/friends by providing care which is:
  - typically uncompensated
  - usually in the home setting
  - involves significant efforts for extended time



# Informal Caregivers: What do they do?

- Caregiving can require demanding tasks, including:
  - Monitoring for side effects
  - Managing symptom burden
  - Treatment decision-making
  - Care coordination
  - Triage
  - Administering medication
  - Technical medical tasks
  - Managing patient's financial and social obligations



# Cancer caregiving

- Unique aspects of caregiving in the context of cancer
  - Multi-modal therapies
  - High burden of care
  - Cancer care continuum
  - Recurrence, and fear of recurrence



# Research and Priorities in Cancer Caregiving

## Cancer Caregiving Report

National Alliance for Caregiving

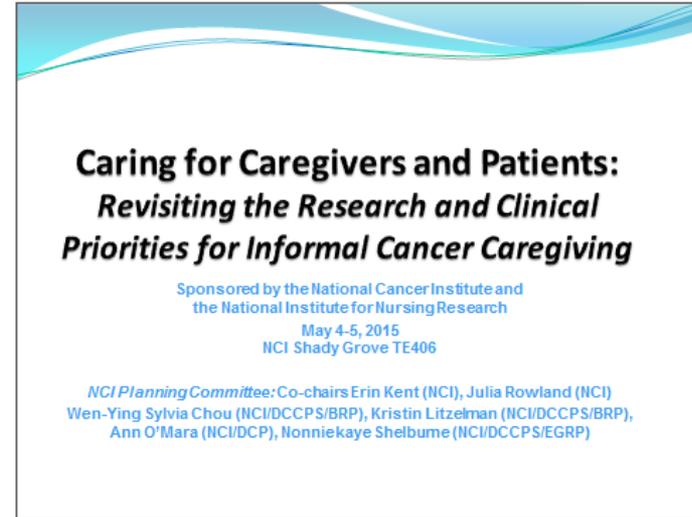
National Cancer Institute

Cancer Support Community



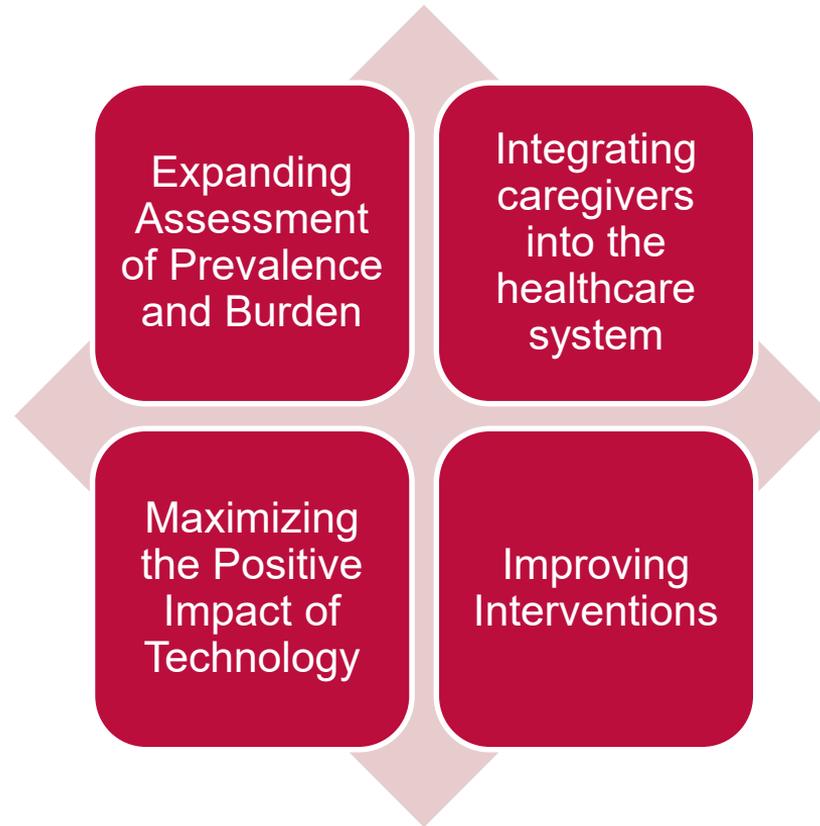
Hunt, G. G., Longacre, M. L., Kent, E. E., Weber-Raley, L. (2016) Cancer Caregiving in the U.S.: an Intense, Episodic, and Challenging Care Experience. National Alliance for Caregiving

## NCI and NINR Workshop



Kent, E.E., Rowland, J.H., Northouse, L., et al. (2016). Caring for caregivers and patients: Research and clinical priorities for informal cancer caregiving. *Cancer*.

# Key Recommendations



# Previous (Expired) FOA: Intervening with Cancer Caregivers

- PAR-18-246 and PAR-18-247 (previously PAR-16-317/318)
- Focused on interventions that examine strategies to support cancer caregivers to improve patient and caregiver outcomes
- Nine awards funded (4-R01s, 1-R37, 4-R21s)

# Current FOA Details

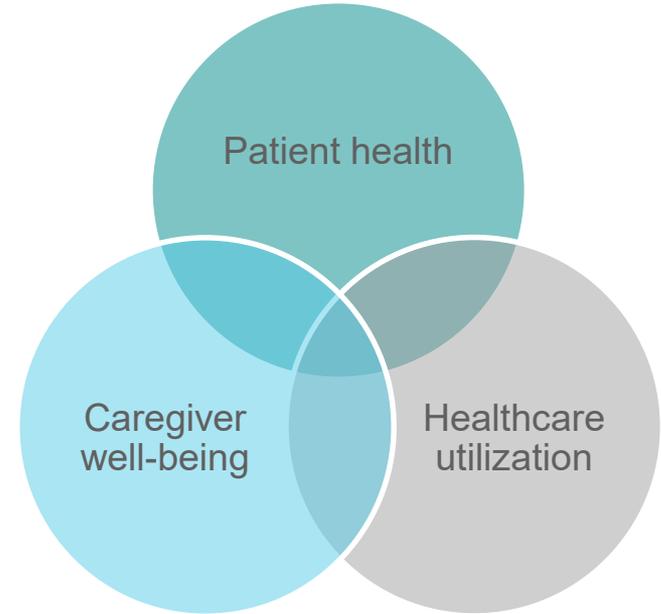
# Intervening with cancer caregivers to improve patient & caregiver health outcomes and optimize healthcare utilization

## PAR 19-352/355

**Purpose:** Support interventions that examine strategies to provide caregivers with training, promote coping skills, and ultimately help them manage their care

Outcomes of interventions should aim to:

1. Improve patient health
2. Improve caregiver well-being
3. Optimize healthcare utilization



# Grant mechanisms – R01 and R21

NIH Research Project Grant (R01)	NIH Exploratory/Developmental Grant (R21)
<ul style="list-style-type: none"><li>▪ Supports a discrete, specified, and circumscribed research project</li><li>▪ Most commonly used grant program</li><li>▪ No specific dollar limit<ul style="list-style-type: none"><li>▪ Advance permission required for <math>\geq</math>\$500K direct costs in any year</li></ul></li><li>▪ 3-5 years of funding</li></ul>	<ul style="list-style-type: none"><li>▪ Supports new, exploratory, and developmental research projects</li><li>▪ May be used for pilot and feasibility studies</li><li>▪ Combined budget for direct costs for the two-year project period usually may not exceed \$275,000</li><li>▪ Up to 2 years of funding</li></ul>

For more information: [grants.nih.gov/grants/funding/funding\\_program.htm#RSeries](https://grants.nih.gov/grants/funding/funding_program.htm#RSeries)

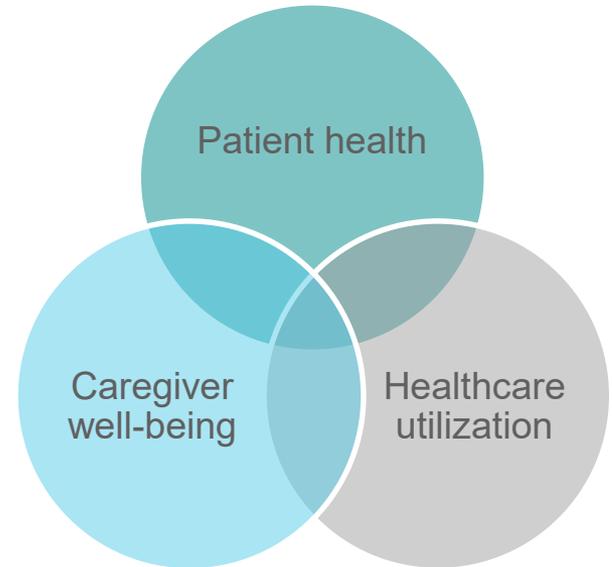
# Application requirements

- Interventions must be delivered at least to the caregiver, though can also be delivered to the patient/care recipient
- Applications should focus on caregivers of patients ages 21 and over at diagnosis (see [RFA-CA-19-033](#) for interventions focused on caregivers of pediatric cancer populations)
- Patients must be at point of diagnosis forward on the cancer control continuum. Studies conducted with patients in active treatment, transitioning into survivorship, with advanced cancer, or at end-of-life are acceptable

# Application requirements

Outcomes must focus on the following areas:

- At least **one cancer patient health outcome** (behavioral, physical, and/or psychosocial morbidity)
- At least **one caregiver well-being outcome** (behavioral, psychosocial, and/or physical)
- At least **one healthcare utilization outcome**



# Application considerations

- Research projects should aim to identify intervention components that make them effective (e.g., conceptual framework, timing of and content of intervention, intervention mode and dosage)
- Investigators are encouraged to consider **sustainability** and **scalability** in the development, design, and testing of interventions
- Transdisciplinary approaches that foster collaboration of **diverse stakeholders** (e.g., clinicians, researchers, caregivers) is encouraged
- Studies targeting or expanding inclusion of medically or minority underserved patient-caregiver populations are encouraged

# Application considerations

- Use of randomized controlled trials and/or pragmatic trial designs is strongly encouraged
- Applications may include mixed-methods approaches to determine the most effective components in the context of the intervention
- Applications may or may not include the development and testing of tools to evaluate caregiving, although the focus should be on the development and testing of an intervention

## Applications not appropriate for this FOA

- Applications focusing on caregivers of pediatric populations
- Applications proposing observational research only
- Applications focused on cancer patients or survivors only (do not include a caregiver population)

# Research strategy

- Specific aspects to be addressed:
  - A clear definition of the target cancer patient/caregiver population, as well as indication of how the project addresses persistent and salient problems for the specified population
  - Inclusion of a research team with appropriate caregiving science and health services expertise
  - A description of how the intervention will balance improvements targeted in all 3 outcome areas: (1) healthcare utilization; (2) caregiver well-being; and (3) patient health
  - A strategy for how the intervention, if successful, will be appropriately disseminated

# Review criteria specific to this FOA

- Significance:
  - Does the project address persistent and salient challenges that the targeted cancer patient/caregiver population faces? How amenable is the proposed intervention for dissemination/implementation?
- Investigator:
  - How strong is the research team, including representation of appropriate caregiving and health services expertise (broadly construed)?
- Approach:
  - Does the intervention appropriately balance improvements targeted in all three outcome areas: (1) health care utilization; (2) caregiver well-being; and (3) patient health?

# Application Requirements: Clinical Trials

- NIH requirements for clinical trials research applications were updated in January 2018. Please note the following policies:
  - Application form now consolidates all Human Subjects and Clinical Trial related information into one place and also expands information required for clinical trials applications (FORMS-E)
  - Investigators and staff must receive training in Good Clinical Practice
  - All sites participating in multi-site studies research will use a single IRB
  - All NIH-funded clinical trials are expected to register and submit results to Clinicaltrials.gov
- Information about the NIH Clinical Trial Requirements:  
<https://grants.nih.gov/policy/clinical-trials.htm>

# Application Requirements: Budget

- Budget should reflect the actual needs of the proposed project
- R01: Advance permission required for  $\geq$ \$500K direct costs in any year
- R21: The combined budget for direct costs for the two-year project period may not exceed \$275,000. No more than \$200,000 may be requested in any single year.

# Resources

- Read the FOA carefully:

<https://grants.nih.gov/grants/guide/pa-files/par-19-352.html>

<https://grants.nih.gov/grants/guide/pa-files/par-19-355.html>

- Application Due Dates:

- PAR-19-352 (R01): New, Renewal, and Resubmissions due **10/17/19**; thereafter standard due dates apply

- PAR-19-355 (R21): New submissions due **10/16/19**; Resubmissions due **11/16/19**; thereafter standard due dates apply

- Webinar and FAQ will posted on our website:

<https://healthcaredelivery.cancer.gov/media>

- Connect with us early:

Scientific contact: Michelle Mollica; [michelle.mollica@nih.gov](mailto:michelle.mollica@nih.gov)

# Summary

- PAR-19-352; PAR-19-355: Intervening with cancer caregivers to improve patient & caregiver health outcomes and optimize healthcare utilization (R01/R21)
- Purpose: Support interventions that examine strategies to provide caregivers with training, promote coping skills, and ultimately help them manage their care

# Questions?

Please type your questions in the Q & A section on WebEx

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