

## **Frequently Asked Questions PAR-19-352; PAR-19-355**

### **Is a letter of intent (LOI) required? If so, what should be included in the LOI?**

An LOI is not required but strongly recommended for this PAR. LOIs should be sent at least one month prior to the receipt date.

LOIs should include the following:

- Descriptive title of the 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

The LOI should be sent by email, with the subject "Letter of Intent for PAR-19-352 (355)" to [michelle.mollica@nih.gov](mailto:michelle.mollica@nih.gov)

### **Is an Awaiting Receipt of Application (ARA) required for budgets that exceed \$500K direct costs in any of the grant years?**

Yes, for budgets that exceed \$500K in direct costs in any of the grant years, an ARA is required. In the Division of Cancer Control and Population Sciences, the ARA must be submitted at least 8 weeks prior to the submission date.

### **Who should I contact with further questions about this FOA?**

You should contact Michelle Mollica at [michelle.mollica@nih.gov](mailto:michelle.mollica@nih.gov) with any questions about applying for this FOA.

### **What study section will be reviewing applications to this PAR?**

Applications to this PAR will be reviewed by standing study sections within the Center for Scientific Review (CSR) that are deemed the best fit for each application.

**Are new applicants who have not had prior NIH funding before encouraged to apply?**

Yes, we welcome applications from new and early stage investigators. However, if you are new to the NIH application process, we strongly encourage you to consider working with someone who has experience with the NIH grants process, such as a colleague or expert at your institution. Additionally, we encourage you to speak with the scientific contact listed on the FOA.

**Are these applications to this FOA reviewed by a special emphasis panel?**

Yes. Review falls under the purview of the Center for Scientific Review (CSR) at NIH. The goal is to convene a special emphasis panel (SEP) with the relevant expertise necessary for a comprehensive review. Program Directors advise CSR on appropriate disciplines that should be represented on the SEP. Because this announcement focuses on informal cancer caregiving interventions, the panel will likely have expertise in nursing science, behavioral interventions, health services research, palliative care, and psychosocial oncology. Investigators can assist the CSR and Program by submitting letters of intent and by writing cover letters that specify the expertise you think necessary to evaluate your proposal.

**Can you please clarify the receipt dates?**

The original PAR had special receipt dates. Although there are unique receipt dates for this PAR to start, we then transition to standard receipt dates. Please review the FOA carefully for the receipt dates.

**Can you please clarify whether a proposal that was submitted to the previous PAR (18-246) would be considered a new submission or a resubmission for this new PAR?**

Applications to the previous PAR would be considered a resubmission for this new PAR.

**What is the review process after the scientific review panel? For example, to what extent does the percentile versus other considerations impact this program announcement?**

Applications reviewed by study sections receive a percentile score. Early stage investigators may receive special consideration in funding decisions.

### **Do R21s need to propose at least a two-arm RCT?**

R21s may, but are not required to, propose a two-arm RCT. The R21 is an exploratory mechanism, and as such, applicants can propose an acceptability/feasibility study with the intention of designing a larger study to test the intervention in development.

### **How much pilot or preliminary data is needed for the R01 application?**

Reviewers will evaluate the application for scientific merit, which includes an assessment of the rigor of the prior research (developed either by the applicant or cited from the literature) that supports the scientific premise for the proposed project. Additional preliminary data (developed by applicants as needed) should be sufficient to support any gaps in the premise of the proposed project and/or to demonstrate that your proposed research approach is potentially promising, sufficiently rigorous, and that the applicant and their team have the skills, experience, and environmental resources to address the study aims. You may also contact the NCI Scientific Program Contact to discuss your proposal in more detail.

### **Are multiple PI submissions possible and/or encouraged?**

Multiple PI submissions are acceptable, but not required.

### **I would like to use the NCI Community Oncology Research Program (NCORP) network to conduct my clinical trial in response to this funding announcement. Is there anything special I need to do if I am going to use the NCORP network?**

Yes, there are additional steps that need to occur if you are proposing to use the NCORP network to conduct your study and this process takes additional time. You must speak with NCI NCORP staff before submitting an application proposing a study in NCORP. Please send an email to Michelle Mollica at [michelle.mollica@nih.gov](mailto:michelle.mollica@nih.gov) as soon as possible to let us know you are planning to conduct your proposed study in NCORP. We will work with NCI NCORP staff to set up a call and outline the process.

### **How can I be sure if my study meets the definition of a clinical trial?**

Please visit the [NIH Clinical Trials website](#) for tools and resources that will help you determine if your study meets NIH's definition of a clinical trial.

**Are foreign institutions allowed to respond to this FOA?**

Foreign institutions and components are not eligible to apply to this FOA.

**Do applications need to include a data sharing plan?**

All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

**Are there any special IRB considerations for this FOA?**

This FOA follows standard requirements for IRB review and approval.

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**Are caregivers of pediatric or Adolescent and Young Adult (AYA) cancers included in this PAR?**

This PAR focuses on caregivers of individuals diagnosed with cancer at age 21 or older. We encourage you to review [RFA-CA-19-033](#) for an RFA focused on pediatric populations, which includes caregivers. This RFA focuses on interventions and may be targeted to the patient or to the patient/caregiver dyad.

**Are applications welcome across all cancer sites and phases of care?**

Yes, applications that include patients with all cancer sites are welcome, provided patients are over 21 at diagnosis, and all phases of care from cancer diagnosis onward.

**Given that interactions with caregivers often occur outside the healthcare system, is it appropriate to include these settings in an application?**

Caregiving occurs in many different settings, both inside and outside formal healthcare system settings. It is important to consider the scalability of the intervention and to include reliable and relevant measures of healthcare utilization. It is best to consult a Program Officer to determine if a particular topic and setting is responsive to the FOA.

### **Do applications need to recruit both patients and caregivers as participants into the study?**

To be considered responsive to this FOA, applications must include the caregiver as participants. Applications may or may not propose to recruit the patient/caregiver dyad.

### **The PAR requires that applications consider sustainability and scalability in the development, design, and testing of interventions. Do we have to submit an implementation science application?**

The PAR asks applicants to consider the potential for an intervention to be scaled and sustained. We are not requiring applicants to submit an implementation science-based application, although applications may address the potential for scalability and sustainability in the development, design, and testing of proposed interventions.

### **How broadly defined is “caregiver” in terms of this FOA?**

Informal/family cancer caregivers are individuals who manage care for cancer patients, usually a friend or family member. Investigators are encouraged to provide a rationale for their operational definition of a cancer caregiver as it corresponds to their application.

### **Do applications need to target all 3 types of outcomes (patient, caregiver, healthcare utilization)?**

Yes. It is up to the applicant to decide how to prioritize, but outcomes should be targeted and measured in all three areas.

### **How do you balance the three outcomes of caregiver well-being, patient health, and healthcare utilization? Can one be primary over another?**

One of the three could be primary, though in most cases patient and/or caregiver health should be considered primary. Prioritization should depend on the overall goal of the research, specific aims specified, and targeted clinical population included. It is always best to consult with the scientific contact of the FOA.

### **Are there suggestions for how specifically to measure healthcare utilization outcomes in applications to this FOA?**

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There are many possible measures of healthcare utilization and of the health system. Having expertise in health services research represented on the study team is beneficial. One might also consider seeking input from the healthcare system or hospital administrative leaders to discuss a proposed intervention and additional measures that, if collected, might foster and facilitate implementation of caregiving interventions. In addition, partnering with community-based organizations can help identify relevant measures of healthcare utilization that might ultimately improve implementation of caregiving interventions. Examining prior literature and preliminary evidence and letting theory guide the choice of constructs and measures are other useful approaches. An important consideration is that the FOA states *optimized* healthcare utilization as opposed to *reduced* healthcare utilization. For example, better support of caregivers might lead to increased preventive healthcare visits, which would mean increased, but perhaps ultimately more optimal, utilization.

### **Can the intervention or assessment improve outcomes for the patient and the caregiver?**

The application requires that the intervention must be delivered to at least the caregiver. It can also target the caregiver/care recipient dyad, but this is not required.

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