

NOT-CA-20-026 Notice of Special Interest : Research on Oral Anticancer Agents in the Contexts of Utilization, Adherence, and Health Care Delivery

Mechanism	R01, R21, P01 or R03 mechanisms
Leadership	Single or Multiple PI
Clinical Trial Requirement	Optional
Aims	<p>This NOSI invites research applications that characterize the patient and provider factors influencing utilization of oral anticancer agents; identify structural, systemic, and psychosocial barriers to adherence; and/or develop models and strategies to improve safe and effective delivery of oral anticancer agents. Areas of interest include, but are not limited to, research that fall in one or more of the following categories:</p> <ol style="list-style-type: none"> 1. Utilization <ul style="list-style-type: none"> • Identify current trends in utilization of newly approved molecularly targeted oral therapies • Describe patient, provider, and organizational characteristics associated with prescribing and use of molecularly targeted oral therapies 2. Adherence <ul style="list-style-type: none"> • Describe patients' perception of risks associated with oral anticancer agents, and how these risk perceptions influence adherence. • Identify daily decision points that influence adherence to oral anticancer therapy. 3. Care Delivery <ul style="list-style-type: none"> • Develop and test innovative intervention(s) in the care delivery setting to optimize patient treatment regimen adherence • Develop and test interventions to enhance patient reporting of side effects and timely system response
Budget Considerations	The application budget needs to reflect the actual needs of the proposed project.
Scientific Contacts	<p>Wendy Nelson Nelsonw@mail.nih.gov Kate Castro Kathleen.castro@nih.gov Kelly Filipski Kelly.Filipski@nih.gov</p>

Application FAQs

Do applications need to target all three focus areas: utilization, adherence and care delivery aims?

No, applications are not expected to address all areas.

How does this NOSI differ from the previous Program Announcements?

The oral anti-cancer agents Program Announcements expired in early 2020. This NOSI closely mirrors the previous PAs.

Can you please clarify whether a proposal that was submitted to the previous Program Announcement (18-004 and 18-014) would be considered a new submission or a resubmission for this NOSI?

Applicants should check the "Application Types Allowed" section of the PA/PAR to which they would submit their application. At least one of the FOAs; PAR-19-039 only allows resubmissions from PAR-18-018 and PAR-19-309.

What mechanisms are allowed through NOT-CA-20-026?

R01s, R21s, R03s, and P01s are responsive to this NOSI. Please see the list of related announcements for the funding opportunity announcements (FOAs) that support these mechanisms.

If I plan to request that my application be assigned to an Institute other than NCI, can I submit my application through this NOSI?

Since NCI is the only Institute participating on the NOSI, if you submit an application through this NOSI, it will likely be assigned to NCI.

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

Yes, for budgets of \$500K or more 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 NOSI?

Contact the appropriate Program Director depending on the focus area of your grant:

- Utilization - Kelly Filipski at Kelly.Filipski@nih.gov
- Adherence – Wendy Nelson at Nelsonw@mail.nih.gov
- Care delivery – Kate Castro at Kathleen.castro@nih.gov

What study section will be reviewing applications to this NOSI?

Applications to this NOSI 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.

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?

Applicants must check the FOA to which they are submitting to determine if multiple PI applications are allowed.

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 six weeks before submitting an application proposing a study in NCORP. Please send an email to Kate Castro at Kathleen.castro@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.

I didn't see receipt dates in the NOSI, when are applications due?

The NOSI directs applicants to several FOAs through which applications must be submitted. Applicants should follow the receipt dates and submission instructions in these FOAs.

If I plan to submit to a PAR not listed in the NOSI, can I mention in the abstract or specific aims that my application is responsive to NOT-CA-20-026?

No. Only applications submitted to one of the FOAs listed in the NOSI, and responsive to the objectives of the NOSI, may include mention that the application is being submitted in response to the Notice of Special Interest (NOSI) identified as NOT-CA-20-026.

Are foreign institutions allowed to respond to this FOA?

Applicants must check the PA to which they are submitting to determine if foreign institutions may apply.

Do applications need to include a data sharing plan?

Per the NIH policy notice, NOT-OD-03-032 applicants seeking \$500,000 or more in direct costs in any year of the proposed project must address a Data Sharing Plan.

Are there any special IRB considerations for this FOA?

This NOSI follows standard requirements for IRB review and approval

Research Scope FAQs

Is adjuvant endocrine therapy for breast cancer considered an oral anticancer agent?

Yes, endocrine therapy is an oral anticancer therapy.

Is an application required to have patient outcomes?

No, the outcomes should be relevant to the study aims and are not required to be patient-level outcomes.

Would an application be considered unresponsive if it does not focus on a molecularly targeted therapy?

No, investigators may focus on other oral anticancer agents.

Does NCI consider health information technology as a strategy in responding to this NOSI?

Yes, use of a health IT intervention would be responsive to this NOSI. Examples include use of mobile technology to improve adherence.

Would NCI consider studies evaluating policies and financial incentives already in place by CMS and other insurers?

Applicants should review NOT-OD-16-025, *Clarifying NIH Priorities for Health Economics Research*, to determine if the study fits with NIH mission.

Are you interested in the development of prediction models for adherence?

Yes, this is of interest and would be within scope for this NOSI
