Improving the Reach and Quality of Cancer Care in Rural Populations
Q & A

General

How many years can this R01 be funded for?
The scope of the proposed project should determine the project period. The maximum project period is 5 years.

Does my application need to include a data sharing plan?
Yes, all applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

How many projects does the NCI intend to fund?
Contingent on receiving funds and meritorious applications, NCI intends to fund an estimate of 8-10 awards, corresponding to a total of $7 million, for fiscal year 2019. Future year amounts will depend on annual appropriations.

Will this funding opportunity be available for another cycle in the future?
Currently, there is no plan to reissue the RFA. Applications for this RFA are due September 19, 2018 by 5:00pm local time of the applicant organization. Please see Part 1 of the RFA announcement under the heading "Key Dates". Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Are there plans for future RFAs/PAs in this area?
NCI's Division of Cancer Control and Population Sciences (DCCPS) has several open funding opportunities relevant to research in rural areas. Earlier this year, NCI-designated Cancer Centers were provided the opportunity to apply for administrative supplements. All active DCCPS funding opportunities can be found at: https://cancercontrol.cancer.gov/funding_apply.html
We would encourage potential applicants to review these announcements regularly and reach out to relevant program officials. We are also working closely with our agency partners and scientific experts to analyze the current evidence and to scale up our research efforts in rural cancer control.

Population

Is there a preference that the proposal focus on one or several cancer types?
No. The proposed project may focus on one or several cancer types.

What if I only use the 2010 Rural-Urban Commuting Codes (RUCA) to define the rural population in my study?
This FOA requires that applicants define the rural population for the proposed study based on the non-metropolitan 2013 Rural-Urban Continuum Codes (RUCC) as defined

at this link: https://www.ers.usda.gov/data-products/rural-urban-continuum-codes.aspx. Applications that only use RUCA to define their population of interest will not be responsive to this RFA. Applications may use other codes as applicable to the research questions of interest, but these other codes must be in addition to RUCC codes. For example, if questions are related to access and distance to care, applicants might use **both** the RUCC codes and RUCA codes to define the rural population and/or analyze the data.

Is this RFA focusing on research that takes place in AREAS that are rural and low income, or could it be in AREAS that are rural with PEOPLE who are low income?
Applicants are required to propose a study in a nonmetropolitan area as defined by the RUCC. Applicants are required to justify how the application addresses a primarily low income and/or underserved population/people and the related in challenges for cancer care delivery.

Must participants be proven to be low income or just come from county that is low income?
Applicants are required to justify how their application addresses a rural population that is also low income and/or underserved.

Research sites

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 Shobha Srinivasan at ss688k@nih.gov and Sallie Weaver at sallie.weaver@nih.gov as soon as possible to let them know you are planning to conduct your proposed study in NCORP. They will work with NCI NCORP staff to set up a call and outline the process.

Scope

Is it possible to include comparing data from a rural population to a non-rural population in another state as part of a mixed methods plan?
The FOA is focused on rural populations and interventions that address health care delivery for rural populations. It is not focused on further documenting rural-urban disparities and is not focused on studies that are primarily examining rural-urban comparisons. However, data from or comparisons of *rural* populations from other states within the US is certainly allowed.

Following up on previous question - can we compare data from low income rural population in one state to low income rural population in another state as long as we focus on codes 4-9?

Data from or comparisons of rural populations across counties and/or states within the US is certainly allowed.

What kind of public health activities are not included in this RFA?
This RFA encourages research in areas of the cancer care continuum following an abnormal screening test. This includes studies examining follow-up to an abnormal screening test, cancer diagnosis, treatment and/or survivorship focused on improving the reach and quality of cancer care (e.g., adherence to NCCN Guidelines). Though not an exhaustive list, example topics that are **not responsive** to this RFA include research examining interventions to promote cancer screening, physical activity interventions, or other primary risk reduction interventions targeting generally healthy populations that have not previously been diagnosed or treated for cancer. Responsive studies could examine, as a secondary aim, public heath activities such as ongoing surveillance or physical activity promotion during treatment and/or survivorship.

Review

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.

Do I need submit a letter of intent?
Investigators can assist NCI in selecting reviewers by submitting letters of intent and by specifying the expertise they think is necessary to evaluate the proposal in the PHS Assignment Request Form submitted with their application. Letters of intent should be sent to Shobha Srinivasan at ss688k@nih.gov at least 30 days before the application due date.

Is there any special consideration, in the review process, given to Early Stage Investigators (ESI) and/or first time R01 investigators?
We welcome applications from new and early stage investigators. Investigators who are new to the NIH application process may consider working with a team of people that has experience with the NIH grants process for mentoring and guidance. Peer reviewers look more at ESI's potential than achievement—they weigh your academic and research background heavily. Reviewers may expect new R01 investigators to have fewer preliminary data and publications than more established researchers do. When feasible, new and early-stage investigator applications are not interspersed with those of established investigators at the review meeting.

Other

How can I be sure if my study meets the definition of a clinical trial?
Please visit the following website for tools and resources that will help you determine if your study meets NIH's definition of a clinical trial: https://grants.nih.gov/policy/clinical-trials/definition.htm

In an observational study with the pilot aim do we have to use a pilot that was validated in another population if we are saying that we are using this study to truly understand the issues in this particular population?
This question does not provide enough detail to give a definitive answer. The applicant will have to provide the appropriate justification for the study. The reviewers would make the assessment.

Can recruitment to cancer clinical trials be included as an outcome measure as well, or would that make the application less competitive?
This FOA does not focus on issues related to recruitment and retention of participants to clinical trials or other research studies; therefore, studies that are primarily focused on examining these issues and outcomes would be considered non-responsive to the goals of this FOA and will not be reviewed. Responsive studies should delineate the challenges to and strategies for delivering high quality cancer care and treatment in rural areas, and develop and implement interventions in community and/or clinical settings Applications examining clinical trial recruitment as part of a broader study may be reviewed.

Would a project that focuses on quality of life for cancer survivors be responsive?
Studies focused on cancer survivors could be responsive to this RFA. However, this question does not provide enough detail to give a definitive answer. Please contact the Scientific Program Contact for this RFA, with questions specific to your proposed study.

What about referral for genetic evaluation for breast and ovarian cancer patients - since genetic mutations can impact care choices.
Studies focused on breast and/or ovarian cancer patients could be responsive to this RFA. However, this question does not provide enough detail to give a definitive answer. Please contact the Scientific Program Contact for this RFA, with questions specific to your proposed study.

What extent of pilot data is needed for the intervention component?
In general, pilot data should usually demonstrate proof-of-concept and may possibly provide insight on feasibility within the settings, populations, or contexts in which you plan to further test or implement your intervention. It is advisable to consult colleagues and mentors who can help you consider this question. You may also contact the NCI Scientific Program Contact to discuss your proposal in more detail.

Should pilot data be in rural or low income but not both?
A strong scientific premise will need to be provided for the project. Peer review will determine whether you have provided sufficient justification for the research you are proposing. Pilot data should align with your primary research questions of interest. In general, pilot data should usually demonstrate proof-of-concept and may possibly provide insight on feasibility within the settings, populations, or contexts in which you plan to further test or implement your intervention. It is advisable to consult colleagues

and mentors who can help you consider this question. You may also contact the NCI Scientific Program Contact to discuss your proposal in more detail.

Will slides be available for review after WebEx?
To request a copy of the webinar slides please send an email to Sallie Weaver at sallie.weaver@nih.gov. Please include “Request for rural RFA webinar slides” in the subject line of your email.

Who should I contact with other questions or to discuss my specific study idea?
Please contact Dr. Shobha Srinivasan, the Scientific Program Contact for this RFA, with additional questions or questions specific to your proposed study:

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