RFA-CA-19-064
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 4 to 6 awards, corresponding to a total of $3 million, for fiscal year 2021. 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 January 15, 2020 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. You can find a list of relevant funding opportunity announcements at: https://cancercontrol.cancer.gov/research-emphasis/rural.html A list of all active DCCPS funding opportunities can be found at: https://cancercontrol.cancer.gov/funding_apply.html

If we submitted to the original RFA (RFA-CA-18-026), are we able to submit to this reissued RFA as a resubmission?
No, your application to the current RFA (RFA-CA-19-064) must be formatted as a new application. All applications to the RFA must comply with the requirements for a New Application. The following content is **NOT allowed** anywhere in a New A0 Application or its associated components (e.g., the appendix, letters of support, other attachments):

- Introduction page(s) to respond to critiques from a previous review
- Mention of previous overall or criterion scores or percentile
- Mention of comments made by previous reviewers
- Mention of how the application or project has been modified since its last submission
- Marks in the application to indicate where the application has been modified since its last submission

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.

Can the PI e-mail the letter of intent or does it have to be routed through the office of sponsorship?
Letters of intent may be directly emailed to: Dr. Shobha Srinivasan at ss688k@nih.gov.
At a minimum, letters of intent should include:

- Descriptive title of proposed research
- Name, address, and telephone number of the Principal Investigator(s)
- Names of other key personnel
- Participating institutions
- Number and title of the funding opportunity

Although a letter of intent 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

Is it possible to request a budget in excess of the stated caps, $400k and less than $500k?
No. Budgets for applications that propose an observational study with intervention pilot testing are limited to $400K direct costs per year. Budgets for applications that propose intervention projects are limited to less than $500K per year in direct costs. Budgets above these limits may not be requested.

Does the direct cost limit include consortium F&A or is consortium F&A on top of the direct cost limit?
No, the direct cost limit does not include consortium F&A costs. Consortium F&A costs are NOT included as part of the direct cost base when determining whether the application meets the direct cost limit for this RFA. You can find additional resources for developing an application budget here: https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/develop-your-budget.htm#consort.

Population

What urban rural continuum is required? 4-9?
This RFA 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. This RFA is focused on populations with non-metropolitan RUCC codes, so RUCC codes 4 through 9. Programmatically we will prioritize studies focused on the most rural populations—so those with RUCC codes of 7,8,9.

If your study population is rural (RUCC 4-9), but a health care system partner who

serves these rural patients is in an urban area is that OK?
For this RFA applicants are required to justify how the application addresses a primarily low income and/or underserved population and the related challenges for cancer care delivery. Applicant institutions are not required to be located in a rural area themselves. Applicant institutions that are not located in a rural area are are strongly encouraged to partner with rural stakeholders, including, but not limited to rural community-affiliated clinics or hospitals, state or county offices of rural health, departments of health, education, or human services, or other community organizations. Engagement of community advisors and rural-practicing clinicians are strongly encouraged.

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 use the Rural-Urban Commuting Codes (RUCA) or the Frontier and Remote Area Codes (FAR) to define the rural population in my study?
An application using only the RUCA codes to define the rural population of interest will be non-responsive and will not be reviewed. 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 may use other rural designation codes as applicable to the research questions of interest, but these other codes must be in addition to the 2013 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. Again, if the RUCC code for your targeted population is not included and discussed in the application, the application will not be responsive to the RFA and will not be reviewed. If research questions are focused on Frontier and Remote Areas, the 2010 Frontier and Remote Area Codes as defined by the following link may also be used: https://www.ers.usda.gov/data-products/frontier-and-remote-area-codes/.

I haven't looked at the RUCC codes yet, but would a U.S. territory in the Pacific likely qualify? Or are you looking for mainland studies?
Studies conducted in US Territories or Tribal lands that do not have 2013 RUCC codes may be eligible. The application still must clearly justify how the study addresses a population that is rural and low-income.

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.

When the eligibility criteria is income - does this have to be a screening criteria for study entry or is an application responsive if it compares urban versus rural and low SES versus higher SES.
Applicants are required to justify how their application addresses a rural population that is also low income and/or underserved. This RFA is not focused on rural-urban comparisons or low SES versus high SES studies. Rural-Urban comparison studies

are not allowed. There are other funding opportunity announcements available for projects focused on rural-urban comparisons.

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

Would applications that focus on survivorship and quality of life be considered?
The purpose of this RFA is to reduce the burden of cancer and improve the quality of cancer care in rural areas among low-income and/or underserved populations. For example, studies may address quality of care related to cancer diagnosis, treatment and/or survivorship. Studies focused on survivorship may be responsive. Studies that include quality of life as a secondary outcome may also be responsive. Applicants are encouraged to reach out to Shobha Srinivasan at ss688k@nih.gov and Sallie Weaver at sallie.weaver@nih.gov to discuss the specific aspects of their application.

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.

Would cancer prevention interventions (such as CRC screening) be ok?
Projects that will be viewed as non-responsive to this RFA include applicants focused on improving screening rates without a clear focus on addressing issues of follow-up to abnormal screening in rural low, income populations. There are other funding mechanisms available for studies focused on screening, which can be found here: https://cancercontrol.cancer.gov/funding_apply.html

Will supportive care interventions for rural cancer patients (who are receiving treatment) be seen as responsive to this RFA?
Studies of supportive care interventions may be responsive to this RFA.

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.

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.

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.

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.

Will slides be available for review after WebEx?
Slides and other materials will be posted to the following websites several weeks after the webinar:

- https://cancercontrol.cancer.gov/research-emphasis/rural.html
- https://healthcaredelivery.cancer.gov/media/webinars.html

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

Sallie Weaver, PhD, MHS
National Cancer Institute
Email: sallie.weaver@nih.gov
Phone: (240) 276-6254

Or

Shobha Srinivasan, PhD
National Cancer Institute
Email: ss688k@nih.gov
Phone: (240) 276-6938