RFA-CA-20-051

Social and Behavioral Intervention Research to Address Modifiable Risk Factors for Cancer in Rural Populations (R01 Clinical Trial Required)

Frequently Asked Questions (FAQs) following December 11, 2020 Pre-application Webinar

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BUDGET & TIMELINE

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.

How long can the study be? Many interventions take longer to modify risk factors.
The maximum project and budget period is 5 years.

How many grants does the NCI intend to fund?
NCI will fund 6-7 total awards across two receipt dates, with all projects funded in FY22.

How much budget should be allocated for local community partners?
All aspects of the budget request should represent the actual needs of the proposed project. For the purpose of this RFA, NCI encourages applicants to secure strong letters of support and to consider establishing a Community Advisory Board, as appropriate. NCI would like to see local/community organizations' participation in the studies reflected in subawards, stipends, incentives, or similar arrangements to demonstrate adequate and meaningful participation.

Given the current conditions and the likely start in December 2022, how much thought should be given to alternative approaches to account for the effects of the pandemic?
It is fine to include alternative approaches or contingency plans if you anticipate delays in start up due to pandemic closures.

Is NCI's investment of $7M per year for the full project period? Because each award will be $5-5.5M.
NCI's investment is $7M per year starting in FY22. The full investment will be approximately $35M over 5 years, depending on the total costs per year per project, and the length of each project.

Is the $7M investment total for each of the two submissions or is it the total for both?
NCI's investment is $7M in FY22. $7M is the total across both receipt dates – not $7M for each receipt date.

What is the total duration allowed and is $1.1M the limit for the total project award?
The maximum budget and project period is 5 years. Applications can request up to $700K per year in direct costs. With indirect costs added, NCI expects that total costs for each award will be between $1-1.1M per year, but each institution's indirect costs are different.

Is the length of the project fixed at five years, or can it be longer?
The maximum project period is 5 years.

How many years are allowed per project? Is it just one year? I'm confused because you mention the direct costs of $700K per year but the total cost to be $1.1M per award.
The maximum budget and project period is 5 years. Applications can request up to $700K per year in direct costs. With indirect costs added, NCI expects that total costs for each award will be between $1-1.1M per year.

SCOPE

There is increasing understanding between the use of alcohol and cancer. Would alcohol intake reduction interventions be responsive?
Yes.

Is focusing on tobacco only ok?
Yes.

Can the intervention focus on multiple risk factors for cancer (e.g., obesity and HPV)?
Yes.

Will applications focused on neighborhood disadvantage index as a risk factor for cancer in rural populations be considered?
Yes, but there must be an intervention component focused on modifiable risk factors for cancer.

Can the outcome be a surrogate, such as change in BMI, or does the application have to show a change in a cancer of interest?
Outcomes can be changes in behavioral risk factors for cancer.

Can the intervention be for cancer screening?
Cancer screening/early detection studies are generally considered secondary prevention – not primary prevention—and therefore are not the focus of the RFA. Screening interventions may be considered within scope if they focus on follow-up to abnormal screening in rural populations, but consultation with an NCI program director is advised.

Would a focus on second primary cancer be within scope?
Yes, it could be, as long as the focus is on the primary prevention of a second cancer(s).

Are there any concerns about partnering with faith-based organizations?
No.

Would depression be an appropriate target if it has been shown to influence cancer-related outcomes such as mortality and/or health care utilization and costs?
No. Depression outcomes are not within the scope of the RFA.

To confirm, the interventions are limited to primary prevention only, and cannot include screening?
Correct.

Is medical treatment for obesity in rural areas considered responsive?
Possibly, but please discuss your specific aims with an NCI program director.

Will investigations involving more than one disease, or more than one population, be considered responsive?
Yes, but the intervention must focus on primary cancer prevention in rural populations.

Are activities to reduce tobacco use (i.e., counseling, use of tobacco helplines, etc.) considered primary prevention for purposes of this RFA?
Yes.

When you state "diet, physical activity, and weight," does that mean we must look at all three? Or can an applicant focus on one of the domains?
One or more. Applications are not required to address all three.

How important are issues related to sustainability of an intervention?
Sustainability is not a scored review criterion that is specific to the RFA, but applicants would likely benefit from addressing sustainability in the applications.

Does the proposal have to target one particular type of cancer, or can it just be focused on diet, activity, and weight?
The intervention should be tied to primary cancer prevention for one or more cancers. Primary outcomes can be changes in diet, physical activity, and/or weight.

Is it expected that applications will focus on one or more than one outcome?
Either.

Does primary prevention include chemoprevention?
Not for the purpose of this RFA.

POPULATIONS

Please define rural.

This RFA requires that applicants define the rural population(s) for the proposed study based on the non-metropolitan 2013 Rural-Urban Continuum Codes (RUCC) 4-9, 2010 Rural Urban Commuting Area (RUCA) codes 4-10, or 2010 Frontier and Remote Area (FAR) level 4.

Given that this RFA is focused on primary prevention, would interventions that target caregivers (rather than cancer patients) be responsive? If so, would it also be responsive to include both caregivers and their care recipients (i.e., patients undergoing cancer treatment)?
The rural populations targeted by the interventions could include caregivers, but the intervention must be focused on social and behavioral research to reduce modifiable risk factors for cancer. Patients undergoing treatment would not be an acceptable intervention target unless the intervention is designed to prevent secondary cancers.

Do all sites need to be rural or can sites be a mix of rural and urban for comparisons across settings?
Both intervention sites and control sites should either be rural or serve rural populations. The intent of the RFA is not to examine rural-urban comparisons. Applicant institutions are not required to be located in a rural area themselves. Applicant institutions that are not located in a rural area 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 is strongly encouraged.

Do all sites in the study need to be RUCC 4+? For example, could we use funds for a comparison group in RUCC <4?
Both intervention sites and control sites should either be rural or serve rural populations. The intent of the RFA is not to examine rural-urban comparisons.

Is low SES and/or racial/ethnic minority research a requirement or desired population to target when we focus on rural areas?
This is not required, but NCI is interested in health disparities research to disentangle the effects of SES, race/ethnicity, and rurality on primary cancer prevention.

Can proposals include rural versus urban comparisons?
No. Both intervention sites and control sites should either be rural or serve rural populations. The intent of the RFA is not to examine rural-urban comparisons.

Can the RFA support comparative research (rural versus urban comparisons?)
No. Both intervention sites and control sites should either be rural or serve rural populations. The intent of the RFA is not to examine rural-urban comparisons.

If we partner with FQHCs that are not in the defined RUCC codes but serve a population residing in RUCC 4-9 will that be responsive?
Yes.

Could we target people with overweight and pre-diabetes (going through a remote diabetes prevention program) as those with increased risk of cancer?
Yes.

Could the proposal use the US Census definition of rural (<2500)?
No. For the purpose of this RFA, applicants must define the rural population(s) for the proposed study using the non-metropolitan 2013 Rural-Urban Continuum Codes (RUCC) 4-9, 2010 Rural Urban Commuting Area (RUCA) codes 4-10, or 2010 Frontier and Remote Area (FAR) level 4.

Would a community pharmacy be considered a feasible partner?
Yes.

APPLICATION REQUIREMENTS

If we would like to adapt the model used in Australia in melanoma prevention in the US, can we have an MPI from Australia?
No. Foreign components are not permitted on this RFA.

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 include a data sharing plan.

Is there a definition of a local organization? Is a rural satellite practice that is affiliated with our home academic medical center a "local organization?"
The RFA does not provide a definition for local organization. Applicants will be expected to adequately justify collaborations with local entities. Yes, a rural satellite practice would be considered a local organization.

Is the January 2022 receipt date only open to resubmissions?
No. Both new applications and resubmissions will be accepted.

Is there a downside to submitting more than one application per institution?
No.

If not funded on the first round, could one resubmit in round 2?
Yes. That is why the RFA includes two receipt dates and accepts resubmissions.

Will post-submission preliminary data (as a result of COVID-19) be accepted for this RFA?
NIH is granting maximum flexibility for COVID-related delays; however, it is strongly encouraged that preliminary/pilot data be included with the original submission. Pilot/preliminary data are required for R01 submissions.

REVIEW & SCORING

Will early investigator status be considered?
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 an ESI's potential than achievement—they weigh your academic and research background heavily. Reviewers may expect ESIs 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. ESI applications may be clustered in review.

Will ESI applications with meritorious scores be prioritized for this funding?
ESI status will be considered but not prioritized during funding decisions.

Can you provide more information on the likely expertise of the reviewers on the SEP?
The review will be conducted by NCI's Division of Extramural Activities. Reviewers may have expertise in cancer prevention and control, behavioral and social sciences, community engagement, and rural health.

Will applications to this RFA be reviewed by standing study sections? No. Applications will be evaluated for scientific and technical merit by a special emphasis panel convened by the NCI Division of Extramural Activities.

Will standard NCI paylines be applied to these awards?
These applications will receive an overall impact score but not a percentile, so paylines will not apply. Only the most meritorious applications will be funded.

GENERAL

Please provide a link to the CEBP commentary mentioned in the Webinar.
https://cebp.aacrjournals.org/content/26/7/992