

Social and Behavioral Intervention Research to Address Modifiable Risk Factors for Cancer in Rural Populations

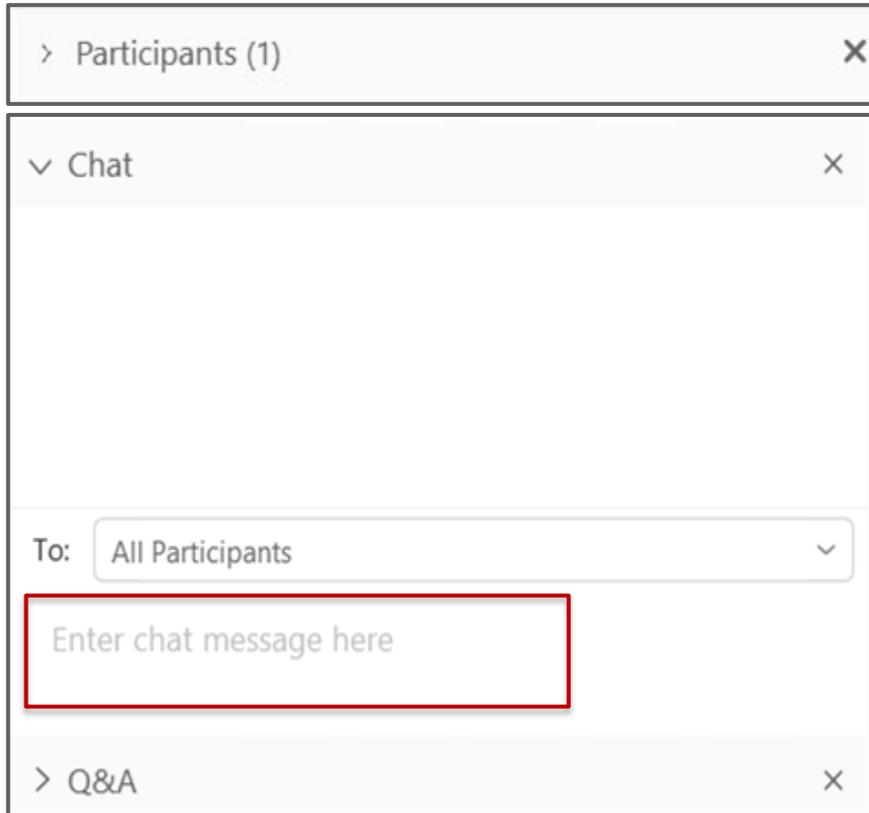
(R01 Clinical Trial Required)

RFA-CA-20-051

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Using WebEx and Webinar Logistics



- Submit questions at any time using the Chat Panel and select All Participants.
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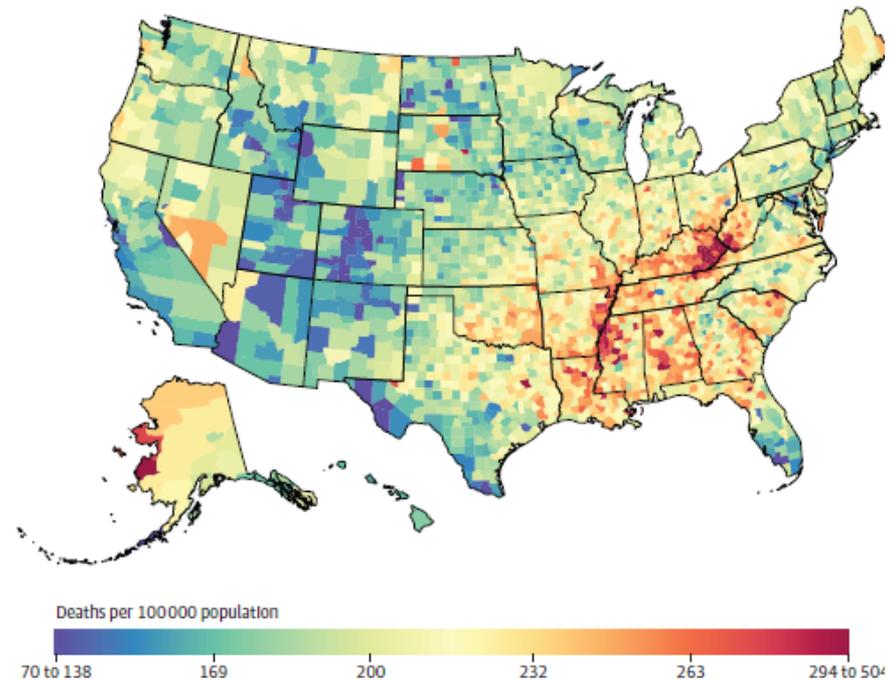
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Background: Rural Cancer Burden

- Individuals in rural counties have an 8% higher overall cancer mortality than those in urban areas.
- A rural-urban disparity in mortality has been observed for lung, colorectal, prostate, and cervical cancers.
- There are higher cancer incidence rates in rural areas for many preventable cancers including lung, cervical, colorectal, oropharyngeal, and melanoma.

Figure 1. County-Level Mortality From Neoplasms

A Age-standardized mortality rate from neoplasms, both sexes, 2014



NCI Leadership in Rural Cancer Control

Year	Activity
2016-2017	Emphasis on rural cancer disparities, <i>Cancer Currents</i> blogs
May 2017	NCI Research Conference: “Rural Cancer Control: Challenges & Opportunities,” University of Memphis SPH, Memphis, TN
June 2017	<i>CEBP</i> commentary: “Making the Case for Investment in Rural Cancer Control: An Analysis of Rural Cancer Incidence, Mortality, and Funding Trends”
October 2017	NCI Workshop: “Understanding Definitions of Rural/Rurality: Implications for Rural Cancer Control,” NCI Shady Grove
May 2018	NCI Research Conference: “Accelerating Rural Cancer Control,” Natcher Auditorium
FY18 and FY19	P30 rural administrative supplements
April 2018 and September 2019	RFA: “Improving the Reach and Quality of Cancer Care in Rural Populations”

DCCPS Rural Funding Initiatives Across the Cancer Control Continuum

Cancer Control Continuum	Funding Initiative		
	P30 Rural Supplements (FY18 & FY19)	Rural RFA (FY19 & FY21)	Current RFA (FY22)
[Capacity Building]	✓		
Prevention			✓
Detection			
Diagnosis		✓	
Treatment		✓	
Survivorship		✓	

Challenges & Strengths

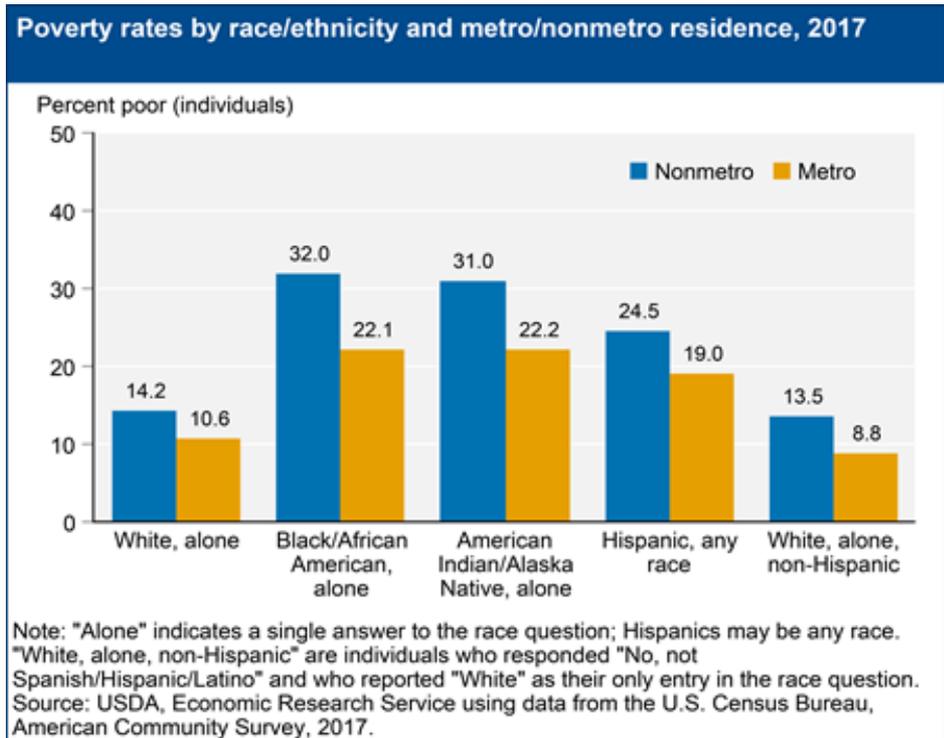
Rural Challenges

- Higher poverty rates than urban areas
- Lower educational attainment
- Higher proportion of elderly
- Few resources for public health infrastructure
- Higher proportion of uninsured
- Geographic and social isolation
- Insufficient transportation
- Insufficient broadband access
- Higher medical mistrust
- Cancer-related fatalism
- Hospital closures
- Lack of access to health services; HPSAs

Rural Strengths

Individual, organizational, community, and cultural assets may be leveraged to inform intervention development

- Strong relationships and social networks
- Social support
- Resilience
- Values such as self-sufficiency, independence, and autonomy
- Strong local- and community-based organizations
- Connectivity across sectors/community cohesion



Rural-Urban Disparities in Behavioral Risk Factors for Cancer

- **Tobacco**
 - Higher rates of cigarette smoking and smokeless tobacco use
 - Rural youth are more likely to use tobacco products and use them more frequently than urban peers
- **Diet, Physical Activity & Weight**
 - Higher rates of obesity, lower rates of physical activity, and poorer diets in rural adults and youth
- **Alcohol**
 - Higher rates of alcohol abstinence in rural areas, but those who *do* drink have a higher prevalence of current alcohol disorder and of individuals exceeding daily alcohol limits
- **UV Exposure and Sun Protective Behavior**
 - Less likely to wear sunscreen, and higher indoor tanning use among rural teens
- **HPV Vaccination**
 - Rural HPV vaccination rates are 10% lower than in urban areas
 - Rural populations are less likely to know that HPV causes cervical cancer
 - Strong provider recommendations for HPV vaccination are less common in rural than urban areas

RFA Objective

To solicit applications to develop, adapt, and test individual-, community- or multi-level interventions to address modifiable risk factors for cancer in rural populations (defined as USDA RUCC or RUCA non-metropolitan areas or FAR rural areas).

- Proposals should focus on **primary prevention**, targeting one or more of the modifiable risk factors that contribute to cancer disparities in rural populations
- Proposals should assess and address myriad social determinants of health, cultural factors, policies, and health care and technology access barriers that may contribute to rural cancer disparities.
- FOA also encourages implementation science research, to incorporate efficacious cancer control interventions into broader, sustainable health programs that are designed to reach rural populations and allow local customization and adaptation.
- Applicants are strongly encouraged to collaborate with organizations and programs with experience or infrastructure (e.g., telemedicine, behavioral health services) designed to address other health or social problems in rural populations that could afford substantial opportunities to cancer prevention and control investigators.
 - Examples include, but are not limited to, Federally Qualified Health Centers, community health centers, rural health centers, and community organizations.

Example Applications May Target:

- Behavioral risk factors for cancer in rural populations (primary outcomes)
 - Tobacco use
 - Diet, Physical Activity, and Weight
 - Alcohol consumption
 - UV exposure and sun-protective behavior
 - HPV vaccination
- Social determinants and structural/system characteristics that contribute to rural disparities in behavioral risk factors for cancer (secondary outcome measures or mediators of effect)
 - Economic and spatial barriers to healthy food access and/or physical activity in low density rural environments
 - Technology, communication, and health information inequalities that may contribute to cancer disparities in rural populations

Study Designs

- The RFA is labeled “Clinical Trial Required” in order to solicit intervention applications that meet the NIH definition of a clinical trial:
 1. Human subjects
 2. Prospectively assigned to one or more interventions
 3. Health-related biomedical or behavioral outcome
- Applications may propose either pragmatic or explanatory trials to test effects in real-world/usual conditions or under ideal/controlled conditions.
 - Experimental or quasi-experimental study designs
- Applications may propose individual, clinic, and/or community-level units of analysis
 - Individual or cluster randomization

- Investigators may propose a study design in which:
 - **groups or clusters are assigned** to study arms and individual observations are analyzed to evaluate the effect of the intervention, or
 - **participants are assigned individually** to study arms but receive at least some of their intervention in a group format or through a shared facilitator.
- Proposed designs might include parallel group- or cluster-randomized trials, stepped-wedge group- or cluster- randomized trials, individually randomized group-treatment trials, multiple baseline designs, time-series designs, and other quasi-experimental designs.
- Applicants must show that their methods are appropriate given their plans for assignment of participants and delivery of interventions.
- **ODP does not award grants. Applications must also be relevant to the objectives outlined by NCI.**
- Additional information: <https://researchmethodsresources.nih.gov/>.

Scored Review Criteria Specific to RFA

■ Significance

- Will this project, if successful, contribute to reducing modifiable risk factors for cancer in rural populations in the US?
- Will the evidence generated by this project improve scientific knowledge for cancer prevention and control researchers who hope to conduct primary cancer prevention research with rural populations in the US?

■ Approach

- Are the proposed interventions sufficiently supported by existing evidence and preliminary data?
- Do the targeted social and/or behavioral endpoint(s) represent an extant disparity in the rural population(s) under study?
- Is the research design appropriate to estimate the effect of the intervention on the targeted social and/or behavioral outcome(s)?

■ Environment

- Have the investigators demonstrated that local organizations or programs can contribute meaningfully to intervention development, recruitment, and delivery?

RFA Details

- *Review:* Special review criteria are required.
 1. Applicants must clearly define and describe the rural population(s) in which the intervention research will be conducted. Rural populations must be geographically defined using the USDA Economic Research Service's Rural-Urban Continuum Codes (RUCC) or Rural-Urban Commuting Area (RUCA) codes for non-metropolitan areas, or Frontier and Remote Area (FAR) codes.
 - **RUCC 4-9; RUCA 4-10; FAR Level 4**
 2. Applicants must collaborate with local organizations or programs with the relevant experience and infrastructure to participate meaningfully in intervention development and delivery in rural areas.
- *Receipt:* March 15, 2021 and January 18, 2022 (to allow for resubmissions)
 - Project and Budget start dates: December 2021 and September 2022
- Budget – Direct costs up to \$700K per year
 - We anticipate ~\$1.1M total costs per award with indirects and standard policy cuts.
- *Referral:* NCI DEA

RFA Details (Cont.)

- Letter of Intent
 - Not required but strongly encouraged
 - Due ~February 12, 2021 and ~December 17, 2021 (30 days prior to receipt dates)
 - Send to kelly.blake@nih.gov
 - Include:
 - Descriptive title of 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 the RFA

- No Awaiting Receipt of Application (ARA) required.

Thank you!

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240-281-5934

Q&A Session

**U.S. Department of Health and Human Services
National Institutes of Health | National Cancer Institute**

<https://cancercontrol.cancer.gov/brp>

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