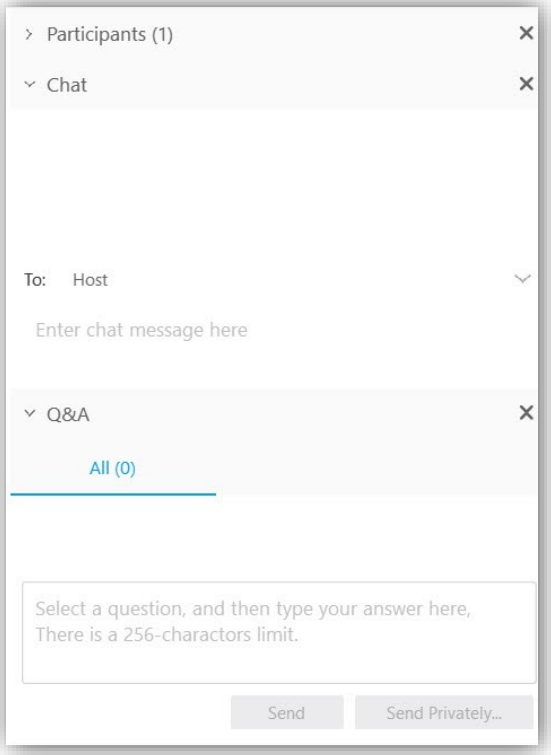
RURAL CANCER CONTROL RESEARCH

Improving the Reach and Quality of Cancer Care in Rural Populations
(R01 Clinical Trial Required)
RFA-CA-19-064

NIH NATIONAL CANCER INSTITUTE
Division of Cancer Control & Population Sciences

https://cancercontrol.cancer.gov

Using WebEx and Webinar Logistics



- All lines will be in listen-only mode
- Submit questions at any time using the Q&A or Chat Panel and select *All Panelists*
- You may need to activate the appropriate box using the floating navigation panel. Found on the center of your screen

- This webinar is being recorded

Webinar presenter

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On behalf of:

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Overview

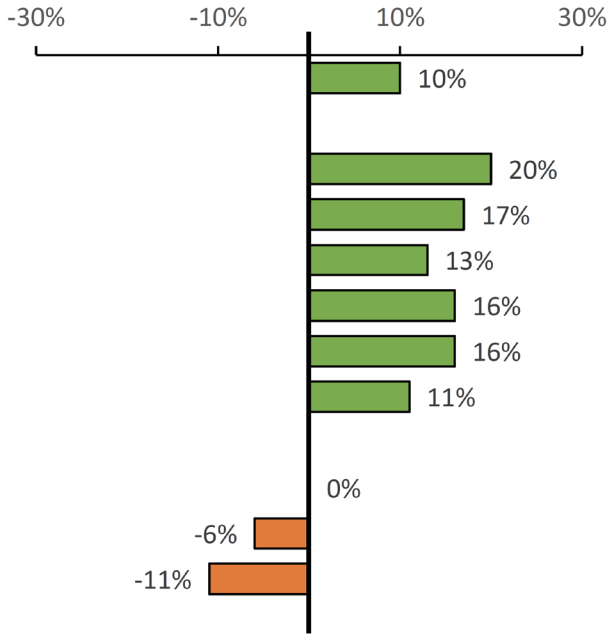
- Background
- Request for Applications (RFA) Details
  - Goals and scope of RFA
  - Application dates
  - Resources
- Questions
  - NOTE: Questions about specific aims will not be addressed

Background

Cancer mortality rates are higher for rural Americans

	Urban		Rural	
Cancer type	Rate	SE	Rate	SE
All cancers	**166**	**0.1**	**182**	**0.3**
Lung and bronchus	44	0.1	53	0.1
Oropharyngeal	2.4	0.0	2.8	0.0
Cervical (♀)	2	0.0	3	0.0
Colorectal	15	0.0	17	0.1
Kidney	4	0.0	4	0.0
Melanoma	3	0.0	3	0.0
Breast (♀)	22	0.1	22	0.1
Thyroid	1	0.0	0	0.0
Liver	6	0.0	6	0.0

Note. Mortality rates are per 100,000 people per year (cervical and breast cancer among women only).

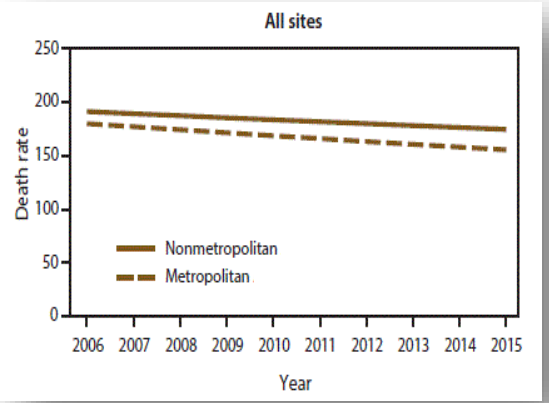


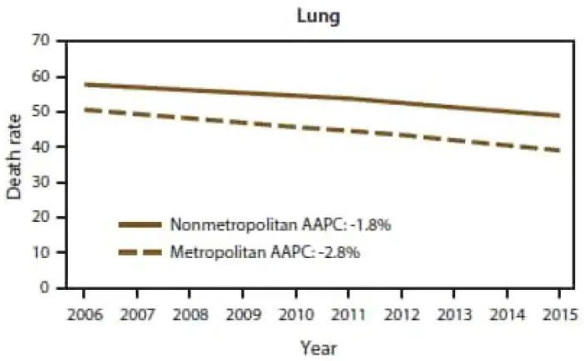
p<.05 for all cancer types except breast and thyroid.

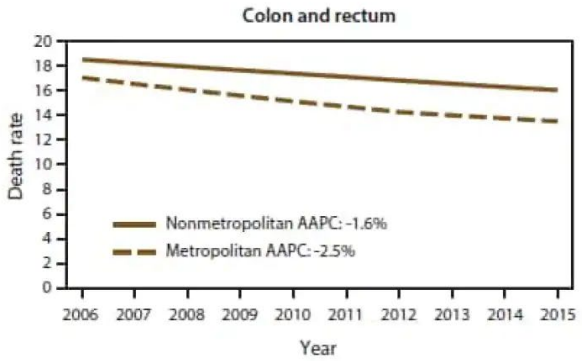
Mortality data from SEER Registry (2009-2013).

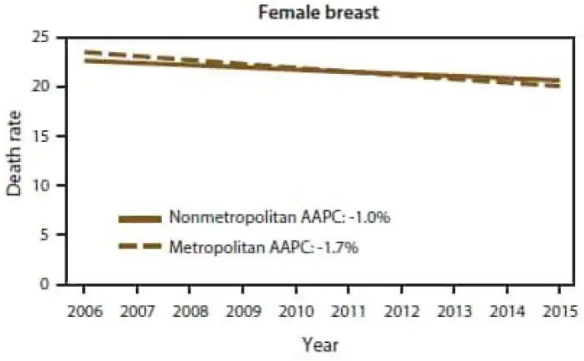
Blake et al. Making the Case for Investment in Rural Cancer Control: An Analysis of Rural Cancer Incidence, Mortality, and Funding Trends. Cancer epidemiology, biomarkers, and prevention. 2017;26(7): 992-997

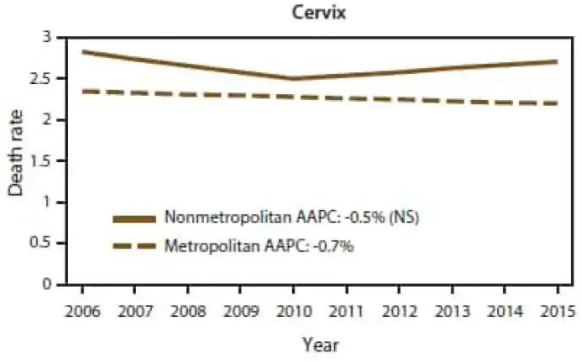
As mortality from cancer has fallen overall, rural-urban disparities are widening











Mortality data from CDC NCHS- US population. Henley SJ et al. Invasive Cancer Incidence, 2004–2013, and Deaths, 2006–2015, in Nonmetropolitan and Metropolitan Counties-United States. MMWR Surveill Summ 2017;66(14):1–13.

Request for Applications (RFA) Details

RFA Goal

Reduce the burden of cancer and improve the quality of cancer care in rural areas among low-income and/or underserved populations

R01s only, clinical trial required, two application types:

1. Observational research that includes intervention pilot testing to understand and address predictors of cancer care/treatment and outcomes in rural low-income and/or underserved populations **OR**

2. Intervention research to address known predictors of cancer care/treatment and outcomes in rural low-income and/or underserved populations

Focus: Strategies for addressing care quality and access related to cancer diagnosis, treatment and/or survivorship

- Develop, implement interventions in community and/or clinical settings
- May address quality of care indicators, health care delivery, barriers contributing to cancer burden in rural low-income/underserved populations

Focus: Observational Studies

- Observational studies – WITH PILOT TESTING include:
  - Understanding and addressing the predictive and/or mediating role of social determinants of health, barriers to care, and treatment
- At least ONE aim that is pilot testing an intervention
- **Budget:** Not to exceed $400k direct cost in any year
- **Maximum project period:** 5 years
- *Not focused on issues related to recruitment and retention of participants to clinical trials*

Focus: Intervention Studies

- Intervention research should address quality of care related to cancer diagnosis, treatment and/or survivorship
- Many existing interventions not ready for implementation
- So, proposals should seek to develop, adapt, and/or implement, and test interventions
- **Budget:** Less than $500k direct cost in any year
- **Maximum project period:** 5 years
- *Not focused on issues related to recruitment and retention of participants to clinical trials*

RFA Parameters

Requirements

- **RUCC:** Application must define the rural population for the proposed study based on the 2013 Rural-Urban Continuum Codes (RUCC)

- **Low Income:** Application must justify how study addresses a rural population that is also primarily low income
  https://aspe.hhs.gov/poverty-guidelines
  https://www.ers.usda.gov/topics/rural-economy-population/rural-poverty-well-being/#howis

Other issues to consider

- Can use other definitions of rural, but must be in addition to RUCC

Required rural definition:
2013 Rural Urban Continuum Code (RUCC), USDA

https://www.ers.usda.gov/data-products/rural-urban-continuum-codes/documentation/

Code	Definition	*k* in US	*N* in SEER
1	Counties in metro areas of 1 million+ population	472	54,360,203
2	Counties in metro areas of 250,000 to 1 million population	395	17,963,604
3	Counties in metro areas of <250,000 population	369	6,104,298
4	Urban population of 20,000+, adjacent to a metro	217	1,845,954
5	Urban population of 20,000+, not adjacent to a metro	92	1,374,217
6	Urban population of 2,500 to 19,999, adjacent to a metro	597	2,427,381
7	Urban population of 2,500 to 19,999, not adjacent to a metro	434	1,736,695
8	All rural or <2,500 urban population, adjacent to a metro	220	415,639
9	All rural or <2,500 urban population, not adjacent to a metro	425	492,659

Examples of activities covered

Barriers to accessing health services (e.g., financial hardships, such as being underinsured or uninsured; shortage of physicians; oncology specialists; distance from treatment facilities; no personal vehicle and/or lack of access to public transportation to reach services; place/built environment; prejudice/discrimination)

Evaluation of natural experiments, programs, and policies to improve care and access to treatment services in rural areas that may interact with the implementation of the intervention and potentially influence effectiveness

Role of social determinants of health, including socioeconomic factors, cultural differences that influence trust in and attitudes toward institutions, medical providers, and government-sponsored programs

Examples of activities covered (cont.)

Limitations in information technology that may limit access to patient portals, telehealth, or other proposed strategies to improve patient-provider communication and care in rural communities

IT-enabled, team-based care delivery models that could improve the delivery of guideline-concordant, high-quality cancer care among rural populations (e.g., studies of innovative care delivery interventions using telemedicine and other technologies or novel strategies designed to deliver comprehensive, coordinated, high-quality cancer-related care to rural low-income and/or underserved populations)

Improve primary/specialty collaborative care to enhance the dissemination of state of the art cancer care and follow-up

Collaborations

- Among cancer control research community and research communities less likely to be involved in such research, including demographers, geographers, transportation researchers, economists, and sociologists

- Relevant community stakeholders and rural health care delivery partners

- With organizations and programs with experience or infrastructure (e.g., telemedicine, social, clinical and behavioral health services) designed to address other health or social problems in rural populations

Applications considered non-responsive

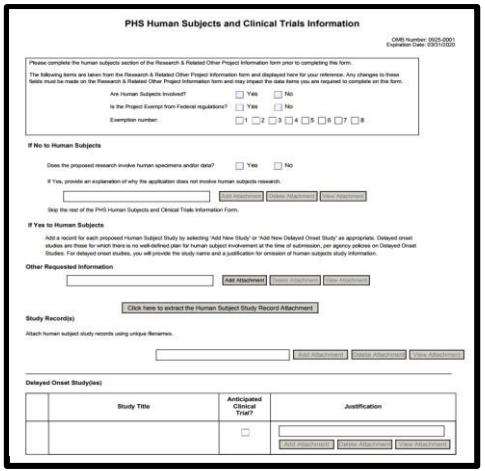
- Applications that fail to use RUCC codes to define the rural population of interest
- Applications focused on issues related to recruitment and retention of participants to clinical trials or other research studies
- Applications focused only on primary prevention interventions among healthy populations or screening without adequate attention to abnormal screening follow-up
- Studies of natural experiments, without an investigator-initiated intervention

Clinical Trials and FORMS-E

FORMS-E Application Packages is **REQUIRED** (including new Human Subjects and Clinical Trials form)

PHS Human Subjects
and Clinical Trials Information Form

- ✓ Consolidates information from multiple forms
- ✓ Incorporates structured data fields
- ✓ Collects information at the study-level


PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 03/31/2020

Please complete the human subjects section of the Research & Related Other Project Information form prior to completing this form.

The following items are taken from the Research & Related Other Project Information form and displayed here for your reference. Any changes to these fields must be made on the Research & Related Other Project Information form and may impact the data items you are required to complete on this form.

Are Human Subjects Involved? ☐ Yes ☐ No

Is the Project Exempt from Federal regulations? ☐ Yes ☐ No

Exemption number: ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8

If No to Human Subjects

Does the proposed research involve human specimens and/or data? ☐ Yes ☐ No

If Yes, provide an explanation of why the application does not involve human subjects research.

Add Attachment | Delete Attachment | View Attachment

Skip the rest of the PHS Human Subjects and Clinical Trials Information Form.

If Yes to Human Subjects

Add a record for each proposed Human Subject Study by selecting 'Add New Study' or 'Add New Delayed Onset Study' as appropriate. Delayed onset studies are those for which there is no well-defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide the study name and a justification for omission of human subjects study information.

Other Requested Information

Add Attachment | Delete Attachment | View Attachment

Click here to extract the Human Subject Study Record Attachment

Study Record(s)

Attach human subject study records using unique filenames.

Add Attachment | Delete Attachment | View Attachment

Delayed Onset Study(ies)

	Study Title	Anticipated Clinical Trial?	Justification
		☐	Add Attachment | Delete Attachment | View Attachment

Be sure you are using the correct application forms.

See https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm

Resources for clinical trials

Website on Clinical Trial Requirements:
https://grants.nih.gov/policy/clinical-trials.htm

Training Resources:
https://grants.nih.gov/policy/clinical-trials/training-resources.htm

- ✓ Slides
- ✓ Human Subjects/Clinical Trials Questionnaire
- ✓ Videos
- ✓ Training opportunities

Page limit for R01

Section of Application	Page Limits
Specific Aims	1
Research Strategy	12
Biographical Sketch (each)	5
Follow instructions in Section IV. Application and Submission Information closely	

Please contact: Shobha Srinivasan (ss688k@nih.gov) when you have the ONE page specific aims

Review Criteria

Overall impact

Scored review criteria

- Significance
- Investigators
- Innovation
- Approach
- Environment

Additional review criteria

- *Study timeline (for clinical trials)
- Protections for Human Subjects
- Inclusion
- Vertebrate Animals
- Biohazards

Additional review considerations

- All applications, regardless of amount of direct costs requested in any single year, must include a Data Sharing Plan

Important Dates

- Letter of intent/earliest submission date: December 15, 2019
- Application Due Date: January 15, 2020 by 5 p.m.
- Scientific merit review: May/June 2020
- Advisory council review: October 2020
- Earliest start date: December 2020
- Be sure to start the process early, read the RFA very carefully

Resources

- Today's webinar and FAQ will be posted on our websites:

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

  https://healthcaredelivery.cancer.gov/media

- Connect with RFA Program Contact early

Shobha Srinivasan, PhD

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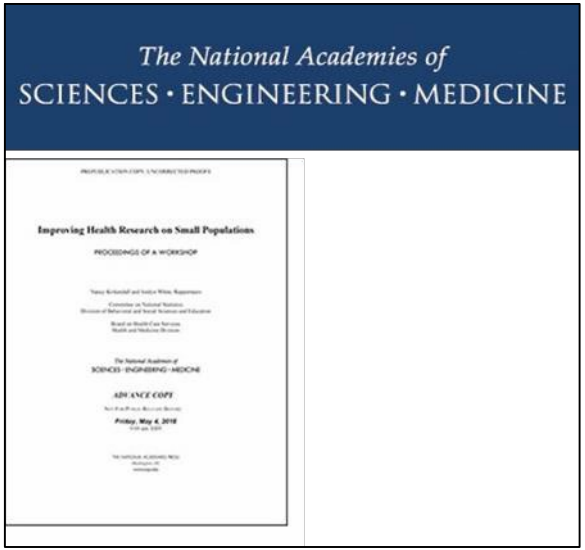
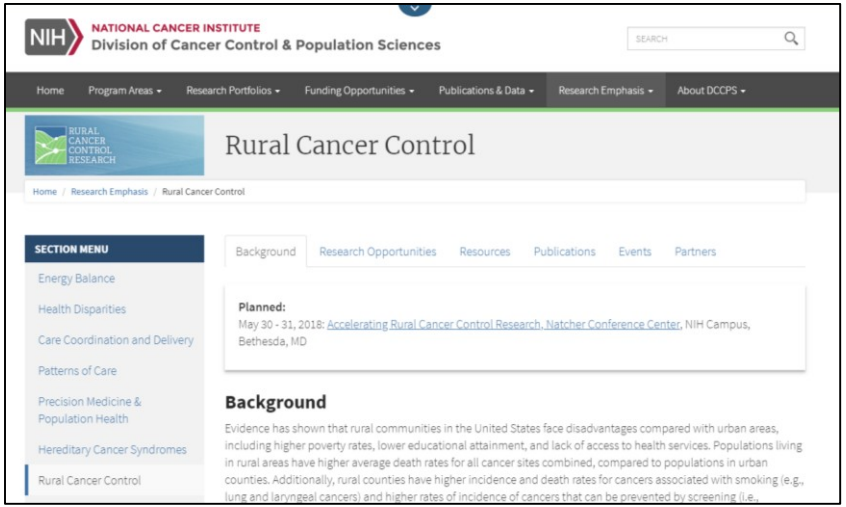
Additional resources



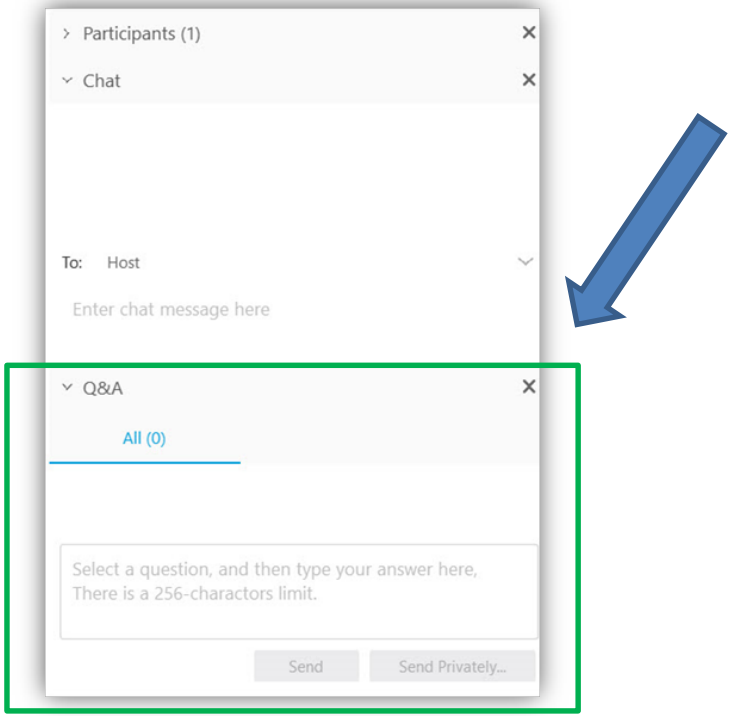
[Improving Health Research on Small Populations: Proceedings of a Workshop (January, 2018)]



[https://cancercontrol.cancer.gov/research-emphasis/rural.html]

Questions?

Please type your questions in the Q & A section on WebEx



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