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

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

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

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

Mortality data from SEER Registry (2009-2013).
As mortality from cancer has fallen overall, rural-urban disparities are widening

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://aspe.hhs.gov/poverty-guidelines)  

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**


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

Be sure you are using the correct application forms.

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

<table>
<thead>
<tr>
<th>Section of Application</th>
<th>Page Limits</th>
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<tbody>
<tr>
<td>Specific Aims</td>
<td>1</td>
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<tr>
<td>Research Strategy</td>
<td>12</td>
</tr>
<tr>
<td>Biographical Sketch (each)</td>
<td>5</td>
</tr>
<tr>
<td>Follow instructions in Section IV. Application and Submission Information closely</td>
<td></td>
</tr>
</tbody>
</table>

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

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Questions?

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

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