Implementation Science Centers for Cancer Control (IS-C^3)
Developing and Advanced Centers
RFA-CA-19-005 and RFA-CA-19-006

Pre-Application Funding Opportunity Announcement (FOA) Webinar

Webinar Logistics

- *All lines will be in listen-only mode*
- *Make sure icons are selected for them to appear as a drop down option*
- *Submit questions at any time during the presentation. Type into the Q&A panel on the right hand side of the interface and press 'send'*

Webinar Presenters

Cynthia Vinson, PhD, MPH

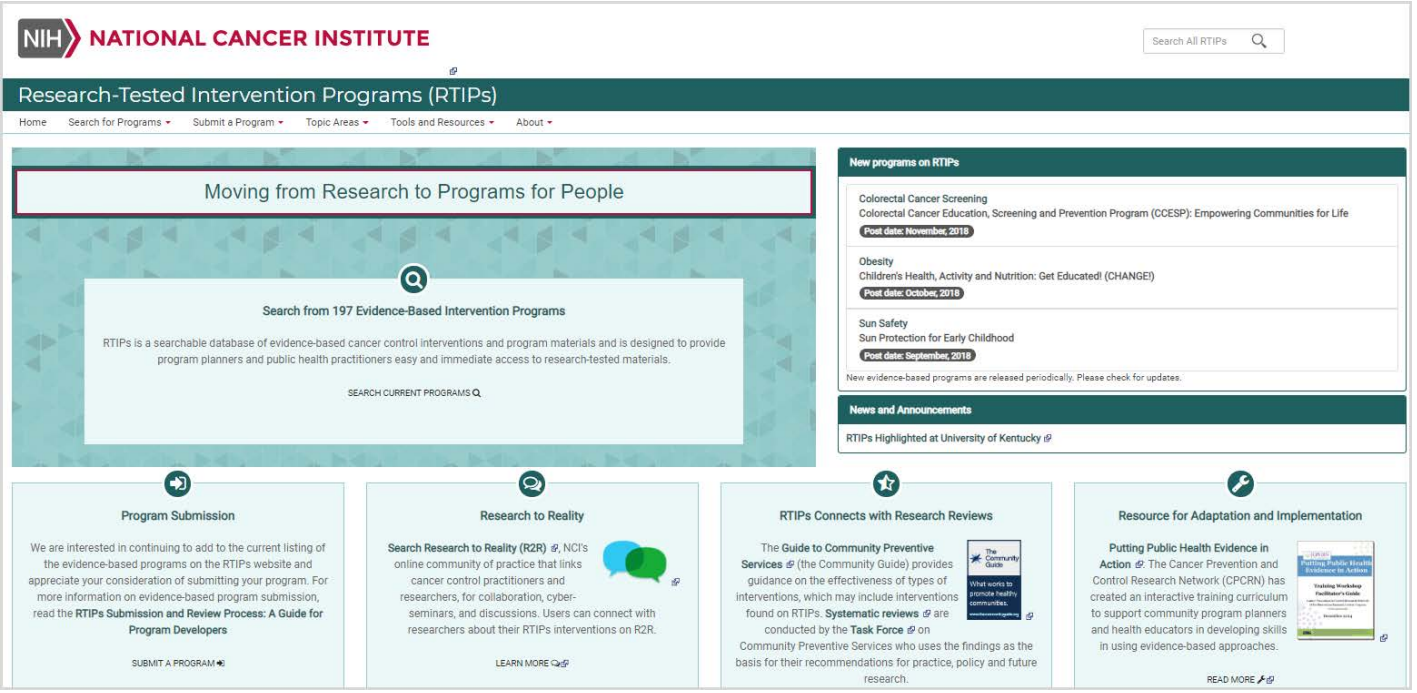
April Oh, PhD, MPH

Implementation Science Working Group Report: Implementation of Evidence-based Prevention and Screening Approaches

- **Issue**: Suboptimal uptake of evidence-based cancer prevention and screening programs, particularly among underserved populations.
- Can we better implement what has already been developed and tested?
- Effective scale-up of CRC screening and follow-up, HPV vaccination, and tobacco cessation interventions could result in:
  - 389,900 fewer new cancer cases annually
  - 318,500 fewer cancer deaths annually

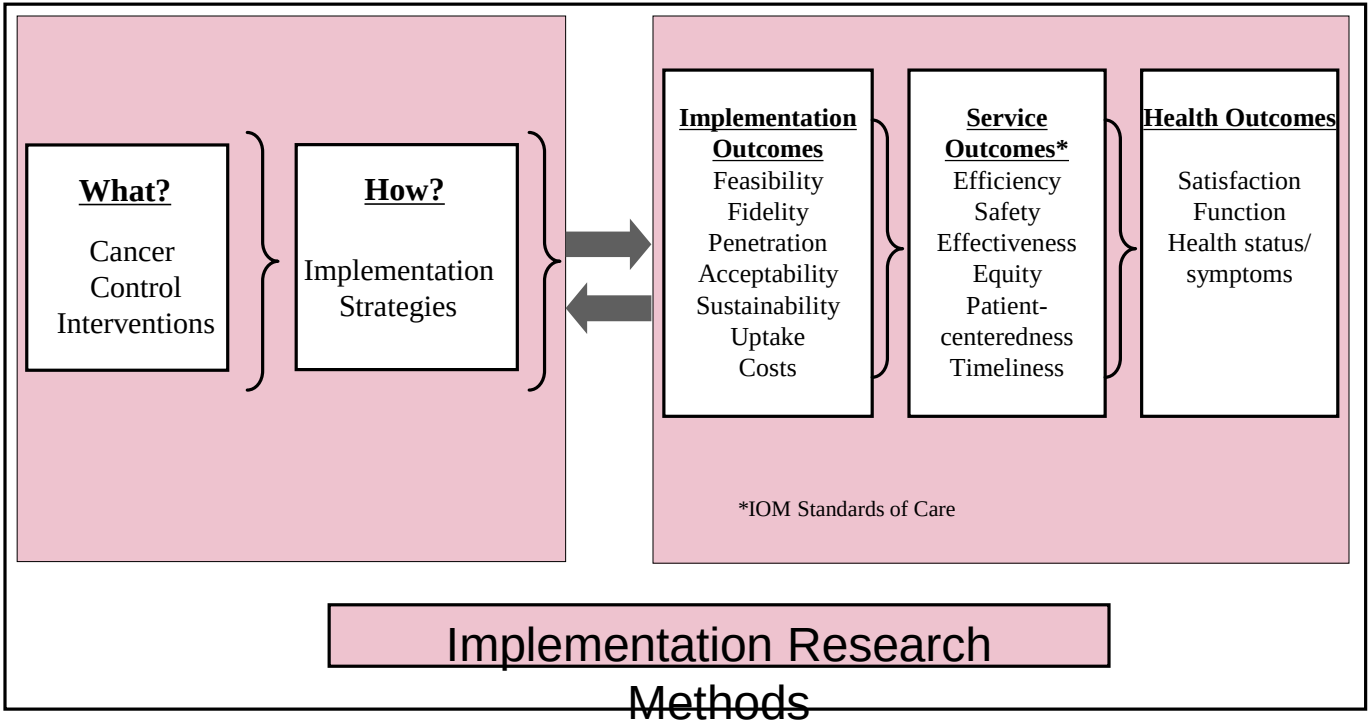
A robust knowledge base around implementation strategies would make significant progress toward this goal.

We have hundreds of evidence-based programs to implement



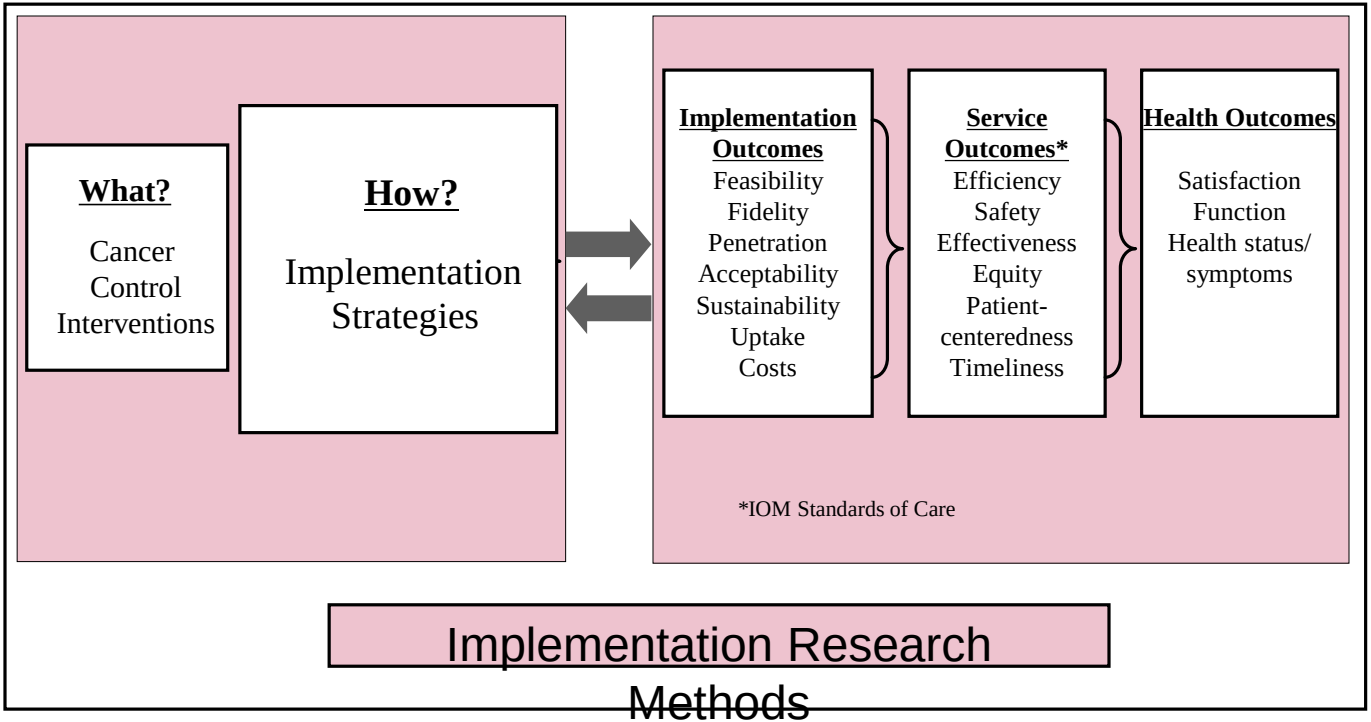
https://rtips.cancer.gov/rtips/index.do

But Need Implementation Science to Drive Population Benefit…



Proctor et al 2009 *Admin. & Pol. in Mental Health & Mental Health Services Research*

But Need Implementation Science to Drive Population Benefit…



Proctor et al 2009 *Admin. & Pol. in Mental Health & Mental Health Services Research*

Current Needs for Scaling Up Implementation Science

- Leveraging existing clinical and community sites where cancer control interventions are delivered to form an **"implementation laboratory"**
- Development and execution of **natural experiments** and **rapid-cycle testing** of innovative approaches to implementing evidence-based interventions
- Development and testing of **valid, reliable and pragmatic measures** of **implementation constructs** not currently available
- Generation of **pilot studies** in **emergent areas** of implementation science
  - E.g. implementation of precision medicine, de-implementation, local adaptation of interventions, mechanistic studies of implementation strategies
- **Nationwide support** for implementation scientists in cancer control,
  - annual meetings, education and mentoring support, technical assistance on proposals, collaborative workspace for innovative study concepts

Implementation Science Centers for Cancer Control (IS-C^3)

- **Developing Centers (RFA-CA-19-005):**
  - **Greater focus on emergent and less well-developed concepts** related to implementation science in cancer control.
  - Proposed research activities should be organized around a cohesive, **overarching "emerging" implementation science theme** that will frame the activities of each required center component and the research agenda that the center will complete.
  - Pilots developed in these centers should be considered more **high-risk/high-reward studies**.
  - The implementation laboratory in these centers will be **scaled appropriately** for the work proposed.
- **Advanced Centers (RFA-CA-19-006):**
  - **More established areas of implementation science**, for which scale, refinement and expansion of existing scientific and methodologic areas for implementation science in cancer control are achievable.
  - Proposed research activities are organized around a cohesive, **overarching "grand challenge" implementation science theme** that will frame the activities of each required center component and the research agenda that the center will complete.
  - These centers should **leverage existing efforts and clinical and community sites where implementation science** can be rapidly tested and advanced.

Award Information

- **Application Types Allowed:** New
- **Clinical Trials Optional**
- **Award Project Period:** Maximum of 5 years
- **Funds Available:**
  - **Developing Centers:**
    - $3M in FY2019
    - $600K direct costs/year
    - Up to 3 awards
  - **Advanced Centers:**
    - $5M in FY2019
    - $1.2M direct costs/year
    - Up to 4 awards

Key Dates

Timeline	Due Date
RFA Informational Webinar*	December 19, 2018, 3-4PM
Letter of Intent Due	January 11, 2019
Application Due Date	**February 11, 2019, by 5 PM local time**
Scientific Merit Review	April-May 2019
Advisory Council Review	August 2019
Earliest State Date	**September 2019**

*Please visit NOT-CA-19-013 for information on registration and subm

Key Definitions

- ***Implementation Science:*** the study of methods to promote the integration of research findings and evidence into public health, clinical practice and community settings. It seeks to understand the behavior of healthcare professionals and other stakeholders as a key variable in the sustainable uptake, adoption, and implementation of evidence-based interventions.
- ***IS-C^3 Program:*** Refers to the **combined activities of the Developing Centers (RFA-CA-19-005) and the Advanced Centers (RFA CA-19-006), and the NCI** to advance the science of implementation in cancer control through innovative pilots, additional field capacity development, implementation laboratories, improved methods and measurement, and consortium activities.

Key Definitions (Continued)

- ***Implementation Laboratory*:** A collaborative research concept specific to the IS-C^3. The "Implementation Laboratory" should reflect a collaboration between the Center awardee institution and an appropriate set of community and/or clinical sites. The collaborating sites may reflect **diverse settings (e.g., oncology care, primary care, community services)** but all are expected to share interest in and capacity to conduct **research consistent with the implementation science theme of the Center.** Each Implementation Laboratory should **enable a range of studies** focused on the **adoption, implementation, sustainment, and de-implementation** of various cancer control interventions. As appropriate, studies to be conducted may be **observational, experimental, and/or quasi-experimental**.

IS-C^3 Center Organization

- **Administrative Core**: manage and coordinate all Center research and activities, within a cohesive organizing framework, provide education on implementation science and knowledge, conduct evaluation, networking and dissemination.
- **Research Program**
  - Implementation Studies Unit
  - Methods Unit
- **Implementation Laboratory**: enable a range of observational and experimental and/or quasi-experimental pilot implementation studies to be tested within a set of clinical and/or community service settings that have shared interest in the Center theme, capacity for study participation, and engagement in improving cancer control across the continuum.

1. Administrative Core

Specific Aims: Succinctly describe the strategies and goals for managing the ISCCC and connecting the Center to the broader field of Implementation Science in Cancer Control

Subsections A-E

A. Operational Structure
B. Implementation Science Outreach
C. Network Unit
D. Evaluation Unit
E. Timeline, Milestones, Advisory Board

2. Research Program

Specific Aims: Succinctly describe the goals of the Research Program. Explain how the Research Program will, through the Implementation Studies and Methods Units, contribute to the development and oversight of the implementation science pilot studies, methods, and measurement studies, and other research activities of the ISCCC.

Subsections A-C Below:

A. Research Program Overview

B. Implementation Studies Unit

C. Methods Unit

PHS 398 Research Plan (Research Program)

Specific Aims: Succinctly describe the goals of the Research Program. Explain how the Research Program will, through the Implementation Studies and Methods Units, contribute to the development and oversight of the implementation science pilot studies, methods, and measurement studies, and other research activities of the ISCCC.

Research Strategy:

The Research Strategy must consist of Subsections A-C below:

Subsection A. Research Program Overview. This subsection should describe how the Research Program will develop and manage a set of scientific activities that will enhance knowledge on the center's implementation science theme through studies conducted within the Center's Implementation Laboratory. This description should summarize the initial research pilot studies, each of which should offer potential for future R01 applications, and how these studies will relate to and support one another as well as studies in other units. Applicants should describe how the Methods Unit and Implementation Studies Unit are integrated in the service of this Research Program and how the Research Program will relate to the Implementation Laboratory.

Subsection B. Implementation Studies Unit. This subsection

- *Initial Pilot Studies.* Describe at least two implementation
  - *Innovation:* Describe the unique and innovative co
  - *Approach:* Research studies proposed for the Adv
    - The content of the implementation studies should be directly linked to the Center's primary scientific theme and should show a clear rationale for why the studies are innovative and can overcome current limitations in implementation science knowledge. It is expected that these studies will have highly innovative cross-disciplinary linkages and high-risk/high-pay-off components designed to address priority implementation science challenges in cancer control. Describe the feasibility of the proposed research studies, the advantages of any new methodologies, potential pitfalls, and alternative approaches for the studies and how these might impact on progress in the overall Center.
- *Additional Innovative Study Ideas.* Describe at least two additional innovative study concepts related to the center theme that will be of smaller scope than those included above and may be considered as vehicles for junior investigators with little research experience that may lead to R03, R21, or R01 submissions by these investigators. How these studies will lead to further research and how they contribute to the overall focus of the advanced center should be described in this application.
- *Process for Developing, Reviewing, Choosing, and Managing Additional Studies.* While the Implementation Studies Unit will initially focus on conducting the initial pilot studies described within the application, the Unit will be expected to continue to develop additional pilot studies throughout the funding period. This section should describe the process for developing, reviewing, choosing and managing additional pilots of two different scales.

Implementation Studies Unit:

- ❑ Initial Pilot Studies
- ❑ Additional Innovative Study Ideas
- ❑ Process for Developing, Reviewing, Choosing, and Managing Additional Studies

Subsection C. Methods Unit. Using the headings provided, address the following aspects:

- *Strategies and Goals.* Describe the scientific goals that the methods unit will pursue, who will ensure these goals will be met, and how the Unit will contribute to individual Research Studies and to attaining the Center's objectives. Describe how the Methods Unit will function as an incubator for innovative approaches to studying the implementation science priorities related to the Center's theme (e.g., identify opportunities to rapidly refine/optimize data acquisition methods; apply innovative approaches to study design, participant selection/ engagement, ecologically valid assessment, and monitoring of study progress). Describe how the unit's efforts will accelerate study of implementation efforts in clinical and community settings (e.g., improving analysis of natural experiments, maximizing power in multi-level implementation studies, and other approaches that can b
  Unit will facilitate novel and convergent solutions to intrac
  implementation scientists, insights from key clinical and c
  behavioral and social science, health informatics, systems
- *Measurement and Methods Studies:* At least two methodo
  of their significance and methodological soundness. For
  research proposals but should be targeted to overcome o
  to the focus of the center and should include plans for int
  broader research community. Innovative cross-disciplinar
  encouraged. Each study should be described addressing
  - *Significance:* Describe overall goals and the impa
    section should also explain the contribution of the
    the Center and the appropriateness of the center
  - *Innovation:* Describe the unique and innovative m
    with the rest of the Center to achieve more than w
    transdisciplinary, convergent solutions to research
    of the ISCCC.
  - *Approach:* Methods studies proposed for the ISC
    design and analysis that will guide the design of f
    how it will ensure the high-quality completion of th
    the study. If this is an opportunity for junior invest
    study will take place and available resources to su
- *Development of Additional Methods and Measurement St*
  and methods studies over the study period that address a
  further research and how they contribute to the overall fo
- *Generate Innovative Research Methods and Chart Future*
  in the field. Detail the Unit's role in catalyzing, selecting, a
  new investigators, during the 5-year study period. Describ
  and analytic innovations and to identify and engage new
  bioinformatics, etc.
- *Operational Support to Implementation Pilot Studies*: Des
  support to the Center's investigators for the proposed pilo
  for methodological support for the research studies of the
  development, measurement, qualitative and mixed metho
- *Dissemination of Methodological Advances and other Cen*
- Describe how the Unit will function as a national consultation resource beyond the Center collaborations. Detail the Unit's role in facilitating the development and dissemination of measurement and methods resources. Address such aspects as:
  - New data collection/assessment approaches and analytic methods;
  - Common data elements for use in a range of implementation studies;
  - Data sets that can be shared for re-analysis/meta-analysis; or
  - Other common-source materials (including new methods and analytic strategies for mining and analyzing 'big data' from Implementation Laboratory data collection efforts).

Methods Unit:

- ❑ Strategies and Goals
- ❑ Measurement and Methods Studies
- ❑ Development of Additional Methods and Measurement Studies
- ❑ Generate Innovative Research Methods and Chart Future Directions
- ❑ Operational support to Implementation Pilot Studies
- ❑ Dissemination of Methodological Advances and resources

3. Implementation Laboratory

Specific Aims: Succinctly describe the composition and characteristics of the Implementation Laboratory. Explain how the Implementation Laboratory will be able to host a variety of innovative and priority implementation studies over the course of the study period that will contribute to the advancement of implementation science in cancer control broadly and to attaining ISCCC objectives.

Subsections A-D:

A. Implementation Laboratory Overview and Leadership

B. Implementation Membership

C. Data Management Unit

D. Practice Surveillance Unit

Some Tips

- Read the full announcement. For experienced investigators, the structure is likely different from what you may have been used to.
- Please pay attention to the clinical trials requirements
- Develop a cohesive narrative for your projects that clearly demonstrate how the projects and activities relate to the overarching implementation science theme
- Do not forget your letters of support for the implementation laboratories. Pay careful attention to the evaluation criteria for the laboratories.
- Identify the right team and expertise need and engage them early in the writing!!
- Read the review criteria.

Frequently Asked Questions

- Are Global (International) Activities within the scope of the RFAs?
- How many research studies should be proposed?
- What is the difference between the Developing and Advanced Centers?
- Do Implementation Laboratories need to have the combination of clinical and community settings/organizations?

Contacts:
Cynthia Vinson Cynthia.vinson@nih.gov
April Oh ohay@mail.nih.gov

For updates:
Subscribe to the Implementation Science Newsletter
Follow on Twitter @NCI_ImplSci

Question 1

- Does program have clear expectations about the organizational structure of the submissions and whether PIs need to have roles on all components of the proposed center? (e.g. Can the PI that is leading the Admin Core have a smaller role on the methods unit?)

Question 2

- May key personnel (co-investigators) be involved in the pilots as well as in other aspects of the proposal (e.g., methods unit?)

Question 3

- Should biosketches for faculty who will receive D/I research mentorship as part of the Center's activities be included in the application?

Question 4

- If an early stage investigator is the implementation pilot leader, would the policy be regarding “ESI applications with meritorious scores [being] prioritized for funding” count towards the pilot study?

Question 5

- How is program defining cancer control? Can implementation studies be proposed to span the cancer continuum from prevention to control or is Program's emphasis on studies of cancer patients (either survivors or those in current treatment)?

Question 6

- How narrowly should themes be defined?

Question 7

- How does Program envision the interaction between the Implementation Lab and the Implementation Studies/Methods Units, apart from funded pilot studies?

Question 8

- If an organization is planning to submit a P50 proposal for an advanced center and has also been invited to participate in another organization's advanced center application as a laboratory, is this permissible under the P50 announcement - assuming the two applications have different focus areas?

Question 9

- The RFA notes that applicants must describe at least two implementation studies intended to be conducted in the first two years of the study period. Does each of these studies need to be funded as a two-year pilot, or is there flexibility for the pilots to be awarded as one year or 18-month pilot projects?

- Is there a minimum time period required for future pilot implementation studies? Is there an anticipated minimum number of pilots to be supported in Years 3-5?

Question 10

- How many methodological research studies are expected to be conducted over the five-year period and is there flexibility in terms of the time period for these pilots? Is it anticipated that these pilots could potentially build on either the implementation studies pilots and/or other existing cancer control programs?

Question 11

- For the pilot project awards, do applicants need to provide a sum total of resources allocated for each pilot with a separate pilot project budget?

- Do centers have the flexibility to provide pilot awards through vouchers for discrete services (e.g., biostatistics support, machine learning, engineering resources, research coordinator)?

Question 12

- Can grantees who receive an award under this funding announcement use the NCI Cancer Control IRB as the single IRB of record?

Question 13

- Would a pilot study that includes randomization at the clinic level qualify as a "clinical trial" per the NIH definition?

Question 14

- If the first two years of a Center's research would not be considered a clinical trial, but the Center may want to support pilot projects that qualify as clinical trials in future years, should the application note "clinical trials" via delayed onset studies or can the initial application note "not clinical trials" and be adjusted when annual progress reports are submitted?

Question 15

- How does NCI intend to engage with Centers under the P50 mechanism? Will partnership/engagement be more limited than under the ‘U’ mechanisms often used for consortia?

Question 16

- Are program staff available for calls with PIs to discuss their specific proposals?

Question 17

- Would a P50 Center that has its population in a Low or Middle-Income Country (LMIC) be eligible for this funding announcement?

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

cancercontrol.cancer.gov/IS

1-800-4-CANCER

Produced December 2018