Accelerating Colorectal Cancer Screening and follow-up through Implementation Science (ACCSIS)

Pre-Application Funding Opportunity Announcement (FOA) Webinar
Using WebEx and 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

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Webinar Overview

1. **Background**
   - Cancer Moonshot℠ Initiative
   - Colorectal Cancer Screening

2. **Requests for Applications (RFAs)**
   - UG3/UH3 Exploratory/Developmental Research Projects
   - U24 Coordinating Center

3. **Select Application Information**

4. **Questions**
Beau Biden Cancer Moonshot<sup>SM</sup> Initiative

- In 2016, NCI convened Blue Ribbon Panel (BRP) to provide recommendations for achieving Beau Biden Cancer Moonshot<sup>SM</sup> Initiative.

- Goal: Make a decade’s worth of progress in cancer research in five years.

- BRP charged with assessing state-of-the-science in specific areas and identifying research opportunities that could lead to significant advances in understanding cancer and how to intervene.

https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative
Recommendation:
• Conduct implementation research to accelerate the adoption and deployment of sustainable, evidence-based cancer prevention and screening interventions at multiple levels and in different clinical and community settings.

• High priority areas included colorectal cancer (CRC) screening

https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/blue-ribbon-panel
Problem: Low Rates of CRC Screening

• Colorectal cancer (CRC) is the second leading cause of cancer deaths in the U.S.

• Low rates of CRC screening contribute to high CRC mortality rates.

• Current CRC screening rate in the U.S. is below 50%.

• National goals for CRC screening rate are 70.5% to 80% (Healthy People 2020, National Colorectal Cancer Roundtable).

• Rates for appropriate CRC follow-up and referral-to-care are also low.
Increasing CRC Screening

- Many evidence-based tests, interventions, and strategies demonstrated to reduce CRC-related mortality, including CRC screening, follow-up, and referral-to-care.

- CRC screening **tests** (e.g., fecal occult blood testing [FOBT], guaiac-fecal occult blood test [gFOBT], fecal immunochemical test [FIT], flexible sigmoidoscopy, and colonoscopy)

- Evidence-based **interventions** (e.g., NCI’s Research-Tested Interventions Program [RTIPs])

- **Implementation strategies** (e.g., supervision, technical assistance, coaching, payment/financing)
Multilevel Interventions to Increase CRC Screening

• Multilevel intervention: Interventions that address two or more levels of change.

• Levels:
  • Patient (e.g., access to care, fear of results)
  • Provider (e.g., limited shared decision-making skills, lack of time)
  • Clinic/System/Organizational-level (e.g., poor organizational culture or climate, conflicts in incentives)

• A priori hypotheses informed by existing literature and relevant frameworks, models, or theories.
Multilevel Interventions

CRC Screening & Follow-Up Practices

- FOBT*
- gFOBT
- FIT*
- Flexible Sigmoidoscopy
- Colonoscopy
- Guideline-concordant Follow-up

Implementation Strategies

**Examples:**
- Outreach/Media Navigation
- Health IT supports
- Pat/Prov Reminders
- Workflow Changes
- Staff Training
- Innovative Funding Models

**Targets:**
- Patient
- Provider
- Team
- Organization
- Community

Community and Healthcare Settings

**Contexts:**
- Primary Care Clinics
- Community Centers
- Integrated Health Systems
- Technology Platforms
- Home

**Strata:**
- FQHCs
- Metropolitan Areas
- Health Systems
- Rural Settings
- (State or County approaches)

*FOBT=Fecal occult blood test; FIT=Fecal Immunochemical Test
ACCSIS Overview

Coordinating Center (U24)

Program Steering Committee

Ethics/Regulatory/Data Sharing

Design/Analysis

Healthcare Systems/Community Partnerships

Implementation Science

Research Project (UG3/UH3)

Local Innovation Study

Research Project (UG3/UH3)

Local Innovation Study

Research Project (UG3/UH3)

Local Innovation Study
Overview of RFAs: UG3/UH3 & U24

- Overview of ACCSIS Program
  - ACCSIS Research Projects UG3/UH3 (RFA-CA-17-038)
  - ACCSIS Coordinating Center U24 (RFA-CA-17-039)

- Cooperative Agreements
  - NIH/NCI staff programmatic and scientific involvement

- Definitions (review announcements for details)
  - Multilevel intervention
  - Experimental study design
  - Quasi-experimental study design
UG3/UH3 ACCSIS Research Projects: Research Objectives

- **Expected Characteristics (see RFA for full list)**
  - Target population of individuals for whom CRC screening rates are below or well-below national standards
  - Addresses cancer health disparities
  - Cover sufficient geographic region to have impact
  - Appropriate selection of multilevel interventions
  - Process and outcome data at two or more levels, three or more time points, and at minimum 9-month follow-up time point
  - Outcome data includes (but not limited to) CRC screening rates and CRC follow-up rates (for positive screens)
  - Encouraged to incorporate elements of pragmatic trials (**PRECIS-2**).
  - Encouraged to collect qualitative and quantitative data

**RFA-CA-17-038**
UG3/UH3 ACCSIS Research Projects: Research Objectives

- Two-Phase Projects
  - Cooperative agreements granted for UG3 Planning-Exploratory Phase.
  - Most promising projects may be approved for UH3 Implementation Phase.

- UG3 Planning-Exploratory Phase
  - Pilot test and assess multilevel intervention.
  - Refine multilevel intervention based on pilot data.

- UH3 Implementation Phase
  - Use experimental or quasi-experimental design to test impact of multilevel intervention on rates of CRC screening, follow-up, and referral-to-care.
  - Identify locally-developed, innovative approaches to increase rates of CRC screening, follow-up, and referral-to-care.

RFA-CA-17-038
UG3/UH3 ACCSIS Research Projects: Research Strategy

1. Background and Significance
   • Define target population.
   • Justify and explain rationale for selection of target population.
   • Justify and explain rationale for selection and size of geographic region.

2. Preliminary Data
   • Summarize preliminary data used to inform selection of multilevel intervention components.
   • Summarize collaboration with stakeholders.
   • Summarize relevant literature informing selection of multilevel intervention.

3. Approach (see announcement for details)
   • UG3 Planning-Exploratory Phase
   • UH3 Implementation Phase

RFA-CA-17-038
Award Information: **UG3/UH3**

- **Funds Available:**
  - $2.4M in FY 2018 to fund three awards

- **Award Budget (Direct Costs):**
  - UG3: $500,000
  - UH3: $800,000/year
  - Designated PD/PI must commit a minimum of 1.8 person-months effort per year to the project. The PD/PI person-months effort cannot be reduced in later years of the award.
  - Must include travel budget for annual meetings.

- **Award Project Period:**
  - UG3: 1 year
  - UH3: 4 years

RFA-CA-17-038
U24 ACCSIS Coordinating Center: 
Research Objectives & Requirements

• **Scientific Responsibilities**
  • Assist Research Projects (e.g., pilot testing, refining, assessing multilevel interventions; technical assistance; guidance on methods).
  • Coordinate collaboration across Research Projects (e.g., selection, harmonization, collection, and analysis of common data elements).
  • Support Research Projects in identification of local practices.
  • Synthesize and share main findings and lessons learned.

• **Research Team Expertise**
  • CRC screening, follow-up, referral-to-care
  • Multilevel interventions, implementation science, study methods, research designs, history of collaboration, ethical/regulatory requirements, cancer health disparities

RFA-CA-17-039
U24 ACCSIS Coordinating Center: Research Strategy

A. Administrative Processes
   • Explain capabilities and experience of study team to coordinate large, multi-site research initiatives.
   • Describe organizational and governing structure.

B. Common Data Elements
   • Propose process for interacting with Research Projects and NCI to develop standardized frameworks and measures.

C. Evaluation of Locally-Developed Innovative Approaches
   • Propose process for supporting Research Projects in identifying, monitoring, and evaluating locally-developed innovative approaches to increase CRC screening, follow-up, and referral-to-care rates.

D. Data Sharing and Dissemination
   • Provide detailed plan for creating user-friendly data repository of Research Projects.
   • Propose process for sharing results with stakeholders groups.

RFA-CA-17-039
Award Information: **U24**

- **Funds Available:**
  - $600,000 in FY 2018 to one award

- **Award Budget (Direct Costs):**
  - $400,000/year
  - Contact PD/PI must commit a minimum of 2.4 person-months effort per year to the project. Commitment cannot be reduced in later years of the award. If a project includes multiple PDs/PIs, the total annual PD/PI effort must be at least 2.4 person-months and the contact PD/PI effort must be a minimum of 1.8 person-months.
  - Must include travel budget for annual meetings.

- **Award Project Period:**
  - 5 years
UG3/UH3 & U24 Resource Sharing Requirements

• Utilizing the provision outlined in the 21st Century Cures Act, NCI has established a data sharing policy for projects that are funded as part of the Beau Biden Cancer Moonshot\textsuperscript{SM} Initiative that requires applicants to submit a Public Access and Data Sharing Plan that:

  • (1) Describes their proposed process for making resulting Publications and to the extent possible, the Underlying Primary Data immediately and broadly available to the public;

  • (2) If applicable, provides a justification to NCI if such sharing is not possible. NCI will give competitive preference and funding priority to applications with a data sharing plan that complies with the strategy described here. The data sharing plan will become a term and condition of award.
Application Dates

• Application Due Date
  • January 18\textsuperscript{th}, 2018 by 5:00pm local time of applicant organization
  • One-time submission, no late applications

• Required Letter of Intent
  • Due December 18\textsuperscript{th}, 2017 to Sarah Kobrin: sarah.kobrin@nih.gov

• Earliest Start Date
  • September 2018
Select Additional Information

• Research Strategy is limited to 30 pages for each RFA.

• Eligibility:
  • Non-domestic (non-U.S.) Entities (Foreign Institutions) are not eligible to apply. Non-domestic (non-U.S.) components of U.S. Organizations are not eligible to apply. Foreign components, as defined in the NIH Grants Policy Statement, are not allowed.

• Can we apply for the UG3/UH3 and the U24?
  • Yes…but…any individual designated as a PD/PI on the UG3/UH3 is not eligible to serve as a PD/PI on the U24.
Resources

- Recording of webinar and FAQs
  - Posted on our website: *TBD*

- Moonshot/BRP Websites
  - [https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative](https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative)
  - [https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/blue-ribbon-panel](https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/blue-ribbon-panel)

- RFAs
Questions?

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

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