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

Pre-Application Funding Opportunity Announcement (FOA) Webinar

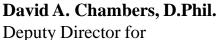
Using WebEx and Webinar Logistics

- 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

Sarah Kobrin, PhD, MPH

Branch Chief (Acting)
Health Systems and Interventions Research
Healthcare Delivery Research Program
kobrins@mail.nih.gov



Implementation Science dchamber@mail.nih.gov

Wynne E. Norton, PhD
Program Director
Implementation Science
wynne.norton@nih.gov







Webinar Overview

1. Background

- Cancer MoonshotSM 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 MoonshotSM Initiative

- In 2016, NCI convened Blue Ribbon Panel (BRP) to provide recommendations for achieving Beau Biden Cancer MoonshotSM Initiative.
- Goal: Make a decade's worth of progress in cancer research in five years.
- BRP charged with assessing state-ofthe-science in specific areas and identifying research opportunities that could lead to significant advances in understanding cancer and how to intervene.





BRP Implementation Science Working Group Report

Recommendation:

- Conduct implementation research to accelerate the adoption and deployment of sustainable, evidencebased 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], guaiacfecal 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
- Guidelineconcordant 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:

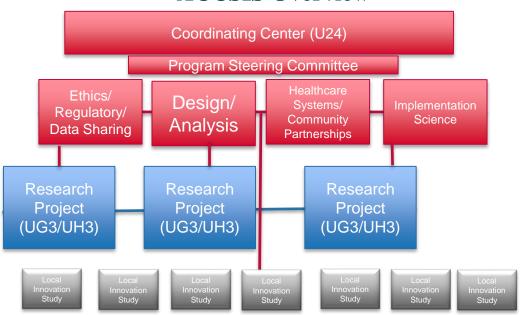
Primary Care Clinics
Community Centers
Integrated Health
Systems
Technology Platforms
Home

Strata:

FQHCs
Metropolitan Areas
Health Systems
Rural Settings
(State or County
approaches)

^{*}FOBT=Fecal occult blood test; FIT=Fecal Immunochemical Test

ACCSIS Overview



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 (<u>PRECIS-2</u>).
 - Encouraged to collect qualitative and quantitative data

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.



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



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



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



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.



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 or 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 <u>Beau</u>
 <u>Biden Cancer MoonshotSM Initiative</u> 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 18th, 2018 by 5:00pm local time of applicant organization
 - One-time submission, no late applications
- Required Letter of Intent
 - Due December 18th, 2017 to Sarah Kobrin: <u>sarah.kobrin@nih.gov</u>
- 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/blue-ribbon-panel
- RFAs
 - UG3/UH3: https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-17-038.html
 - U24: https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-17-039.html

Questions?

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

- Program Directors:
 - Sarah Kobrin: <u>sarah.kobrin@nih.gov</u>
 - Wynne Norton: <u>wynne.norton@nih.gov</u>
 - David Chambers: <u>dchamber@mail.nih.gov</u>

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

https://healthcaredelivery.cancer.gov/media/

1-800-4-CANCER

Produced November 2017