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^{SM} 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^{SM} Initiative

- In 2016, NCI convened Blue Ribbon Panel (BRP) to provide recommendations for achieving Beau Biden Cancer Moonshot^{SM} 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

BRP Implementation Science Working Group Report

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)

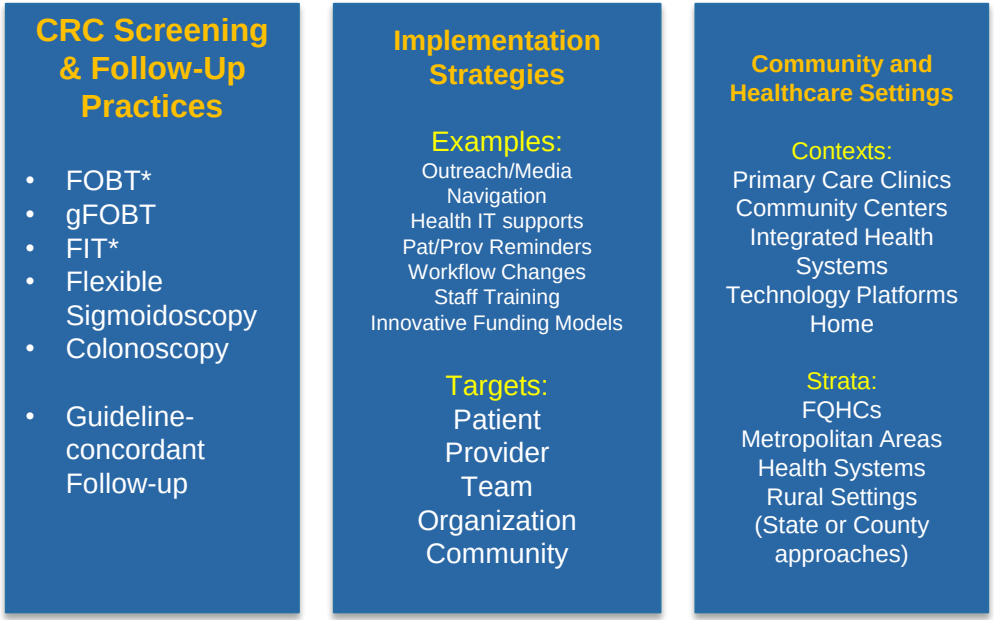
Multilevel Interventions to Increase CRC Screening

- 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)

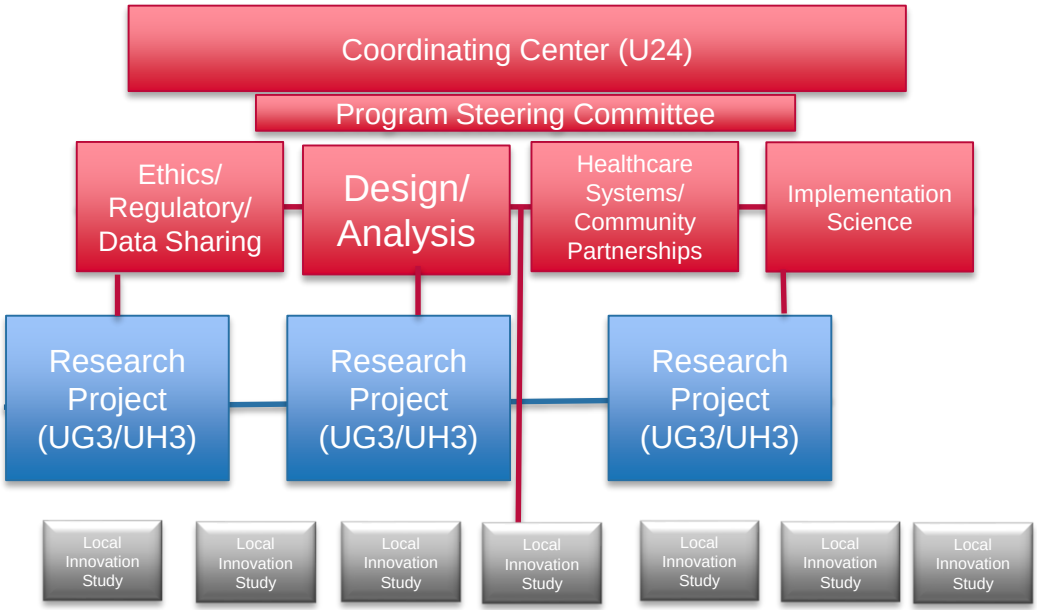
- *A priori* hypotheses informed by existing literature and relevant frameworks, models, or theories.

Multilevel Interventions



*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 (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.

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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

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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

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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.

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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

RFA-CA-17-039

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℠ 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 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: 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/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

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

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

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