U24
Science of Behavior Change
Resource and Coordinating Center
Pre-application Technical Assistance Webinar
for:
RFA-RM-14-017
February 5, 2015
1:30 p.m. EST
The NIH *Science of Behavior Change* Common Fund Program

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SOBC is a trans-NIH initiative to establish an "experimental medicine" approach to behavior change research
The NIH *Science of Behavior Change* Common Fund Program

SOBC program consists of three FOAs for *target validation projects* (covered in a previous webinar and reviewed here) and a *U24 Resource and Coordinating Center* (today’s main topic)
The UH2/UH3 RFAs

• Call for *teams of scientists* to conduct *target validation activities* to develop the tools required to implement a *mechanisms-focused, experimental medicine approach* to behavior change research

• Focus on targets in *three broad domains* hypothesized to be relevant to multiple health behaviors implicated in multiple clinical endpoints
  – *Self-regulation*
  – *Stress reactivity and stress resilience*
  – *Interpersonal and social processes*
The UH2/UH3 “Experimental Medicine” Approach

• Call for teams of scientists to conduct target validation activities to develop the tools required to implement a mechanisms-focused, experimental medicine approach to behavior change research

• Focus on targets in three broad domains hypothesized to be relevant to multiple health behaviors implicated in multiple clinical endpoints
  – Self-regulation
  – Stress reactivity and stress resilience
  – Interpersonal and social processes
An Experimental Medicine Approach to Behavior Change

• Seeks to answer the question:
  – “What are the processes/mechanisms that drive behavior change?”

• Requires:
  – Hypotheses about targets (processes/mechanisms) that drive behavior change
  – Experimental methods for engaging the target
  – Valid measures of target engagement
Implications for Intervention Development:
Tests hypotheses for how an intervention causes behavior change

Identifying Hypothesized Mechanisms

- Putative Target
- Intervention
- Outcome: Behavior Change

Target engaged?
Target valid?
Traditional efficacy test
Implications for Measures Development:
Ensure valid measurement of target engagement

Developing Tools:
Measures & Manipulations

- Behavioral measure/assay
- Neuroimaging measure/assay
- Self-report measure/assay
- Biological measure/assay

- Target engaged?
- Target valid?
- Intervention
- Behavior Change
The UH2/UH3 Teams

- Call for **teams of scientists** to conduct **target validation activities** to develop the tools required to implement a mechanisms-focused, **experimental medicine approach** to behavior change research
- Focus on targets in **three broad domains** hypothesized to be relevant to multiple health behaviors implicated in multiple clinical endpoints
  - **Self-regulation**
  - **Stress reactivity and stress resilience**
  - **Interpersonal and social processes**
Teams of Scientists

• Developing appropriate tools for this approach requires a broad range of expertise:
  
  – **Basic Researchers in the Behavioral Sciences**: To identify candidate measures of processes that are thought to be causally linked to health behaviors and conduct tests to verify that these processes can be manipulated
  
  – **Intervention Scientists**: To conduct the theory testing and experimentation that constitutes *Stage 0-1* research in the behavioral intervention development pipeline

• **UH2/UH3 teams** may span labs, disciplines, and institutions to bring together the expertise needed to achieve the target validation aims proposed.
The NIH *Science of Behavior Change* Common Fund Program

Wendy Weber, ND, Ph.D., MPH
Chief, Clinical Research in Complementary and Integrative Health Branch, National Center for Complementary and Integrative Health
What Will the RCC Do?

• The overall goal of the RCC will be to provide national leadership to coordinate the projects and initiatives of SOBC.

• There are five key objectives for the RCC, and your strategy for fulfilling these objectives will be the core of your application.

• The RCC *is not* equivalent to the coordinating center for a conventional multi-site RCT.
RCC Objective 1: Registry

- Establish a public registry of validated assays and experimental methods for inducing and measuring specified behavior change targets
- Collaborate with target validation project scientists and others in identification and documentation of assays and methods
- Actively curate and maintain the registry
RCC Objective 2: Guidelines

• Develop, adapt, and adopt technical guidelines and best practices for the validation of assays of behavior change targets
• Collaborate with target validation project scientists and others in development and documentation of guidelines and best practices
• Maintain and evolve guidelines as needed
RCC Objective 3: Disseminate Program

- Disseminate widely the assays and methods registry to research community and public
- Disseminate widely the guidelines and best practices developed in SOBC program
- Use multiple methods to disseminate experimental medicine approach, including but not limited to, publications, presentations, training, engaging research communities
RCC Objective 4: Systematic Review

- Conduct systematic reviews of the behavior change literature and specifically the medical regimen adherence literature to identify additional potential targets for future validation or research.
Who should apply?

- Coordinate activities between multiple awardees working on a single target class (the target validation projects) and across target class projects
- The RCC will serve as the central resource for the organization of the meetings and other activities of SOBC, including its External Scientific Panel, its Steering Committee, and any additional subcommittees of the Steering Committee.
SOBC Program Governance

• All awards funded under this FOA and its companions will be cooperative agreements.

• Close interaction with NIH and the Target Validation Project awardees (~6) will be required for the success of the SOBC program.

• The RCC will directly support the **SOBC Research Steering Committee** as well as the **SOBC External Scientific Panel**.
SOBC Research
Steering Committee

- The Steering Committee will address issues that span across Target Validation Projects (TVPs) and assist in the dissemination of all deliverables.
- The Steering Committee will include one investigator from each TVP, the NIH Project Scientist for each TVP, the *Director of the RCC*, the NIH Project Scientist of the RCC, and other representatives from NIH as needed.
• An External Scientific Panel (ESP) will review the progress of all components of the program and provide recommendations to the NIH.
• The ESP will have 6-8 permanent members selected and invited by the NIH, but membership may be changed as needed.
• The ESP will meet once yearly in conjunction with the annual in-person Steering Committee meeting coordinated by the RCC.
The RCC Director (or co-Directors, if multiple PIs proposed) must devote at least 20 percent effort (2.4 person months).

RCC Director will Chair the Steering Committee for the first year; others may serve thereafter.
Elaine Collier, MD
Senior Advisor to Director
National Center for Advancing Translational Sciences

The NIH Science of Behavior Change Common Fund Program
Who Should Apply?

• Scientists who wish to shape and provide national leadership to the new Science of Behavior Change, working in conjunction with:
  – Researchers who have demonstrated excellence in the curation, creation, and dissemination of tools and procedures to extramural researchers
  – Content domain experts and others who can facilitate the integrative analysis of data collected by and for the Target Validation Projects
The U24 RCC will be a Cooperative Agreement

• In addition to Program Officer, an NIH Project Scientist will be assigned to the U24 RCC
  – Selected because of relevant scientific content-area expertise and experience
  – Responsible for facilitating interactions and collaborations among awardees
  – Has substantial scientific involvement (collaboration) and participate in consensus post-award decisions
The U24 RCC will be a Cooperative Agreement

- Maximize the funded collective
- Create collaborative network of PIs
- Capitalize on opportunities to generate larger projects and datasets than typically possible
- Encourage awardees to consider cross-project consultation, collaboration, and data harmonization efforts as appropriate
- Facilitate collaboration with Target Validation Projects and SOBC Team
The U24 RCC: Application Process and Review

- Applications will be judged on scientific merit.
- Review panel will reflect the interdisciplinary nature of the U24 RCC RFA and the Target Validation Project (UH2/UH3) RFAS.
- Note that there are specific additional review criteria for Significance, Investigators, and Approach.
The U24 RFA:
Tips for Applicants

- **Read the FAQs** – This document will be updated as questions come in.
- **Read Section IV of the RFA: Application and Submission Information** – this tells you what you are expected to include in each section of the proposal.
- **Read Section V of the RFA: Application Review Information** - this tells you what the reviewers will be evaluating.
- **Read the Section VI** on Cooperative Agreement Terms and Conditions – this tells you how the SOBC Team will work with you over the years of the award.
- **Communicate** with the scientific contacts listed!
QUESTIONS?

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