UH2/UH3 Target Validation Projects Pre-application Technical Assistance Webinar

for:
RFA-RM-14-018
RFA-RM-14-019
RFA-RM-14-020

January 21, 2015 1:30 p.m. EST
The NIH Science of Behavior Change
Common Fund Program

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A trans-NIH initiative to establish an “experimental medicine” approach to behavior change research
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

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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

- Target engaged?
- Target valid?

Intervention → Putative Target

Traditional efficacy test → Outcome: Behavior Change
Implications for Measures Development:
Ensure valid measurement of target engagement

Putative Target

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

- Target engaged?
- Target valid?

Intervention → Behavior Change
The UH2/UH3 Teams

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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.
Who Should Apply?

- The choice of which RFA to apply for should be left to the scientific discretion of the investigative team.
- Investigators can apply for more than one RFA if the projects are scientifically distinct.
- The RFAs are not mechanisms to complete independent research projects, but are vehicles to promote diverse, interdisciplinary research and collaboration.
Who Should Apply?

• Scientists with expertise in the target domain who are:
  – Interested in working across disciplines to develop and refine tools for testing mechanistic hypotheses about behavior change
  – Willing to provide the field with necessary tools to advance behavior change intervention science

• Teams should demonstrate that they collectively bring together the expertise needed to lead this work

• Teams have the flexibility to engage additional consultants and experts for collaborative activities and pilot projects after award
The UH2/UH3 Target Validation Activities

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Target Validation Activities

1. Identify a set of putative targets (processes/mechanisms) implicated in medical regimen adherence and at least one other health behavior;

2. Leverage existing or develop new experimental or intervention approaches to engage identified targets;

3. Identify or develop appropriate assays (measures) to permit verification of target engagement;

4. *Teams that advance to the UH3 Phase will:* Test the degree to which engaging identified targets produces a desired change in medical regimen adherence and at least one other health behavior.
Target Validation Activities

UH2/UH3 awards provide great flexibility. Possible activities include:

- Workshops
- Experimental studies
- Development of behavioral and neurobiological assays
- Development of self-report instruments
- Consultations with measurement specialists across multiple disciplines
- Secondary or meta-analysis of existing data
Applicants specify milestones for the UH2 phase:
• Quantifiable metrics should be fully explained
• Additional milestones may be negotiated after funding

Milestones may include:
• Demonstration that selected targets are:
  1. promising as drivers of adherence to medical regimens and another health behavior
  2. measureable in multiple ways and at multiple levels (psychological, behavioral, social, biological
  3. relevant to at least two clinical endpoints or disease conditions
  4. malleable
Target Validation Activities: Milestones & UH3 Transition

Milestones may include:

• Development of aims for the UH3 Phase including plans for
  1. testing the degree to which engaging identified targets produces a desired change in medical regimen adherence and another health behavior
  2. refining manipulation/intervention approaches aiming for optimal target engagement
  3. refining assays that optimize measurement of target engagement
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**Paige Green McDonald, PhD, MPH**  
Chief, Basic Biobehavioral and Psychological Sciences Branch  
Behavioral Research Program  
National Cancer Institute
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**
• Each of these domains encompasses a large number of potential targets.

• Applicants must make the case for the selection of targets on which they propose to focus.

• See the specific RFAs for how each domain is defined and follow up with scientific contacts with your domain-specific questions.
Overarching Goals

To identify the most appropriate assessments & manipulations of targets in each of these domains for behavior change science, and determine:

– The extent to which various measures within that domain are tapping distinct or overlapping mechanisms involved in behavior change

– Whether measures are performing similarly across populations, context, laboratories, and age groups
The NIH *Science of Behavior Change* Common Fund Program

Melissa Riddle, PhD  
Chief, Behavioral and Social Sciences Research Branch  
Behavioral Research Program  
National Institute of Dental and Craniofacial Research
The UH2/UH3s will be Cooperative Agreements

- In addition to Program Officer, an NIH Project Scientist will be assigned to each UH2/UH3
  - 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 UH2/UH3s will be Cooperative Agreements

- 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 RCC and SOBC Team
The UH2/UH3 RFAs: 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 contact in the RFA!
The UH2/UH3 RFAs: Review

- Applications will be judged on scientific merit.
- Review panels will reflect the interdisciplinary nature of the RFAs.
- Administrative review for transition to UH3:
  - Investigators will be expected to have materials prepared for the transition from the UH2 to the UH3 mechanism several months in advance of the deadline to allow time for administrative review and to prevent a gap in funding.
  - Project Officers will examine the status of research projects in the UH2 phase to estimate the number of projects that are likely to be approved for the UH3 phase.
Scientific Contacts

RFA-RM-14-018 Interpersonal & Social Processes
Melissa Riddle: riddleme@mail.nih.gov
Rebecca Ferrer: ferrerra@mail.nih.gov

RFA-RM-14-019 Stress
Paige McDonald: mcdonalp@mail.nih.gov
Minda Lynch: mlynch1@mail.nih.gov

RFA-RM-14-020 Self-regulation
Lis Nielsen: nielsenli@nia.nih.gov
Christine Hunter: ch514c@nih.gov
Lisa Onken: lisa.onken@nih.gov
Important Dates

• February 20, 2015: Letter of Intent Due Date
• March 20, 2015: Application Due Date
QUESTIONS?

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