

SO | Science Of Behavior Change

Technical Assistance Webinar for Use-Inspired Research to Optimize Adherence, Behavior Change Interventions, and Outcomes: Competing Revision (R01, U01, R34) & Exploratory/Developmental (R21) Applications

October 30, 2017, 12 p.m. Eastern

#### Webinar Logistics

- This webinar is being recorded
- Submit questions using the chat box
- Audio options:
  - Select "call using computer" (VOIP)
  - Select "call me" and enter your number to have the system call you
  - Select "I will call in" to dial in yourself
- Please remain on mute for the duration of the webinar

#### Presenters



Jonathan W. King National Institute on Aging



Paige A. Green National Cancer Institute



Melissa W. Riddle
National Institute of Dental and
Craniofacial Research



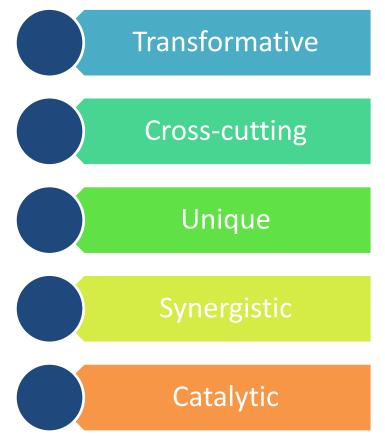
Will M. Aklin National Institute on Drug Abuse

#### Agenda

- 1. SOBC Background
- 2. SOBC Measures Repository
- 3. Competing Revision (R01, U01, R34) Funding Opportunity Announcements (FOAs)
- 4. Exploratory/Developmental (R21) FOA
- 5. SOBC Resources
- 6. Questions from Webinar Participants

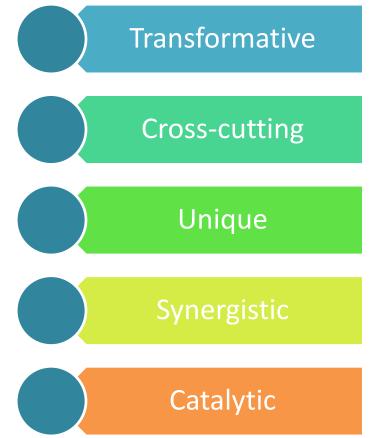
#### SOBC BACKGROUND

#### The NIH Common Fund



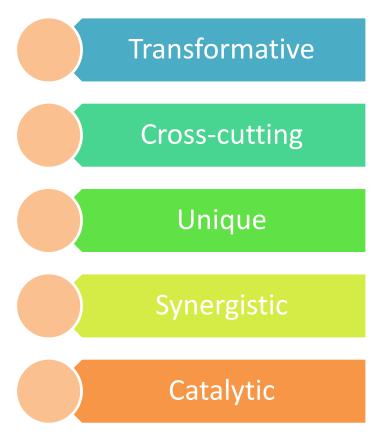
Change paradigms, develop innovative tools and technologies, and/or provide fundamental foundations for research that can be used by the broad biomedical research community

### The Science of Behavior Change Program



Infuse the study of mechanisms of behavior change across NIH institutes, behaviors, diseases, and translational stages

#### The Science of Behavior Change Program

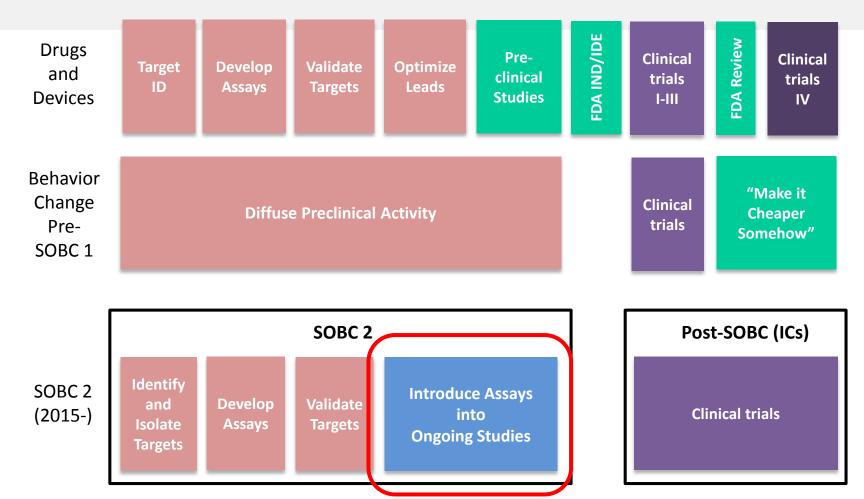


Establish an experimental medicine approach to behavior change research

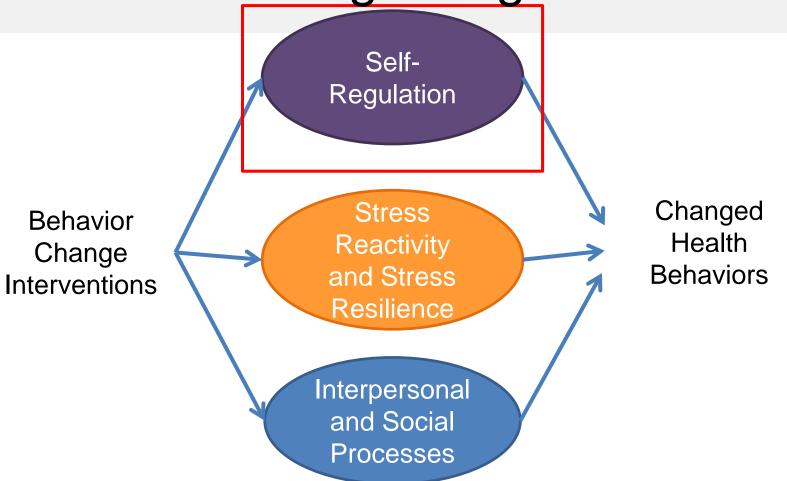
#### Experimental Medicine Approach

- What are the processes or mechanisms that drive health behavior change?
- Answering this question requires:
  - Hypotheses about targets (processes/mechanisms) that drive behavior
  - Experimental methods for engaging the target
  - Valid measures of target engagement

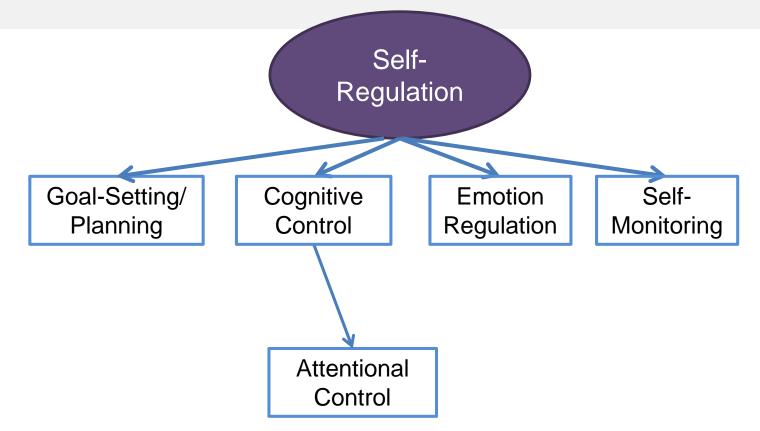
#### Intervention Development Pipelines



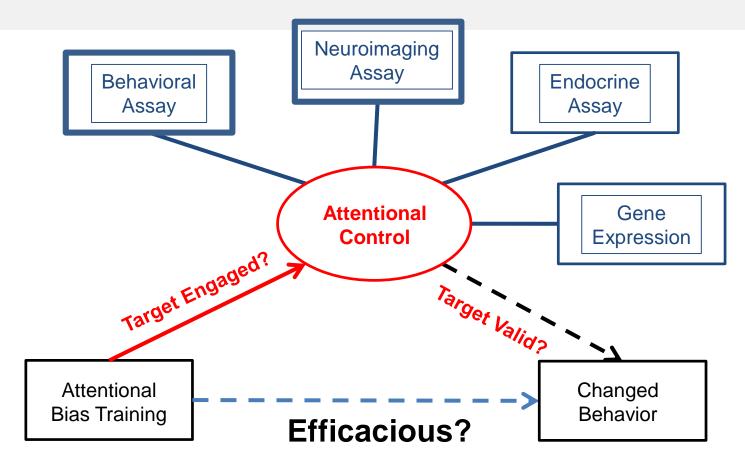
Behavior Change Target Domains



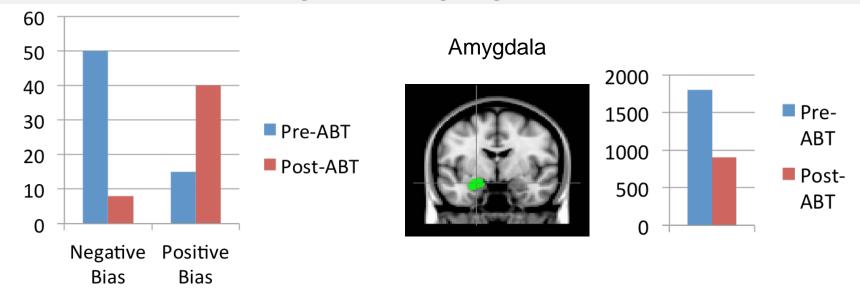
### Self-Regulation Target Processes



#### Causal Mechanisms and Behavior Change



### Developing Attentional Assays and Verifying Target Engagement



Attentional bias training is intended to decrease attention to negative and increase attention to positive affective stimuli in the at-risk daughters of women with recurrent major depressive disorder. Successful training:

- 1. decreases negative attention bias (left), and
- 2. is associated with decreased reactivity in the amygdala (right) during an emotional interference task.

## **DEVELOPING ASSAYS**

Identify Mechanism

Measure Mechanism

Influence Mechanism





#### The SOBC Research Network

- The SOBC experimental medicine approach aims to identify, measure, and influence key mechanisms underlying successful change in health behaviors
- Identify potential targets for behavioral change interventions in three broad domains:
  - Self-regulation
  - Stress reactivity and stress resilience
  - Interpersonal and social processes

# SOBC Research Network: Target Validation Activities

- Identify a set of putative targets implicated in medical regimen adherence and at least one other health behavior
- Leverage existing or develop new experimental or intervention approaches to engage identified targets

## SOBC Research Network: Target Validation Activities

- Identify or develop appropriate assays (measures) to permit verification of target engagement
- 4. Test the degree to which engaging identified targets produces a desired change in medical regimen adherence and at least one other health behavior

#### SOBC MEASURES REPOSITORY

#### **SOBC** Measures Repository

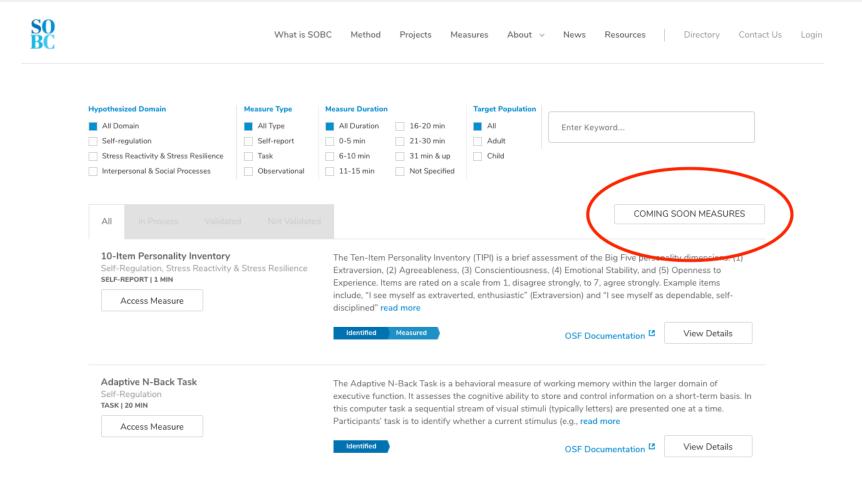
- 63 SOBC Measures Repository assays, including experimental manipulations and measures, from the three SOBC domains
- Accessible through the SOBC Research Network Open Science Framework (OSF) at <a href="https://osf.io/zp7b4">https://osf.io/zp7b4</a>

#### **SOBC** Measures Repository

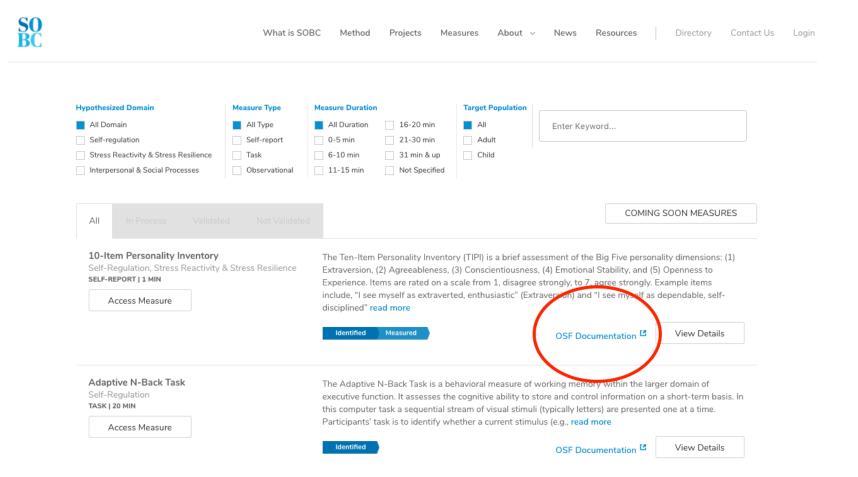
Hypothesized Domain	Measure Duration	
☐ All Domain	□ All Duration	☐ 16 – 20 min
☐ Self-regulation	☐ 0-5 min	☐ 21-30 min
☐ Stress Reactivity & Stress Resilience	☐ 6-10 min	□ 31 min & up
☐ Interpersonal & Social Processes	□ 11 – 15 min	☐ Not Specified
Measure Type	Target Population	
☐ All Type	All Population	
☐ Self-report	□ Adult	
☐ Task	☐ Child	
□ Observational		

https://scienceofbehaviorchange.org/measures SOBC Research Network Open Science Framework (OSF) https://osf.io/zp7b4

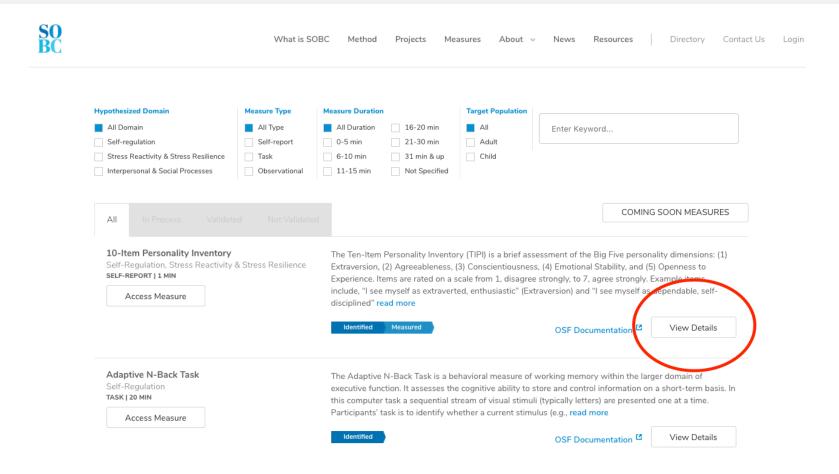
#### Measures Repository: Coming Soon Measures



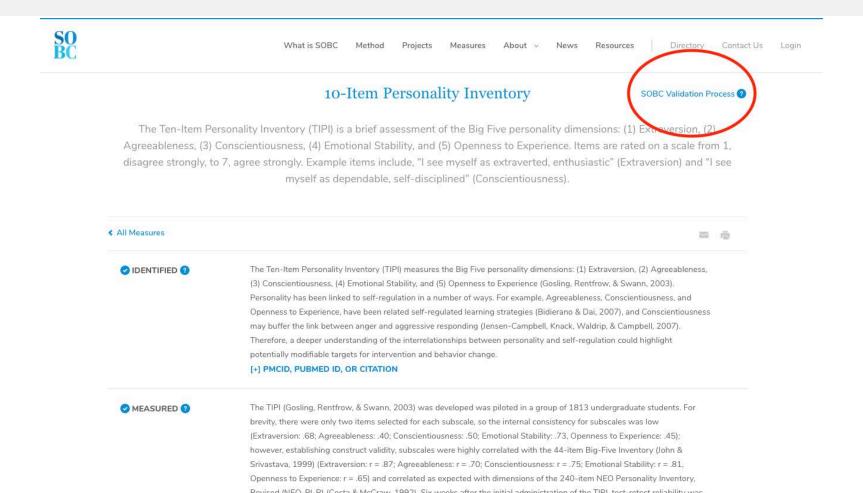
#### Measures Repository: OSF Documentation



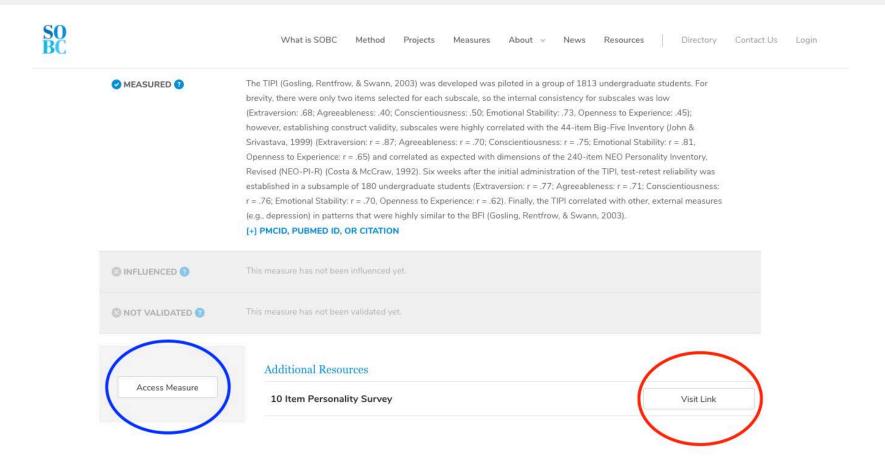
#### Measures Repository: View Details



#### Measures Repository: Validation Process



#### Measures Repository: Access Measure



COMPETING REVISION
(R01, U01, R34)
FUNDING OPPORTUNITY
ANNOUNCEMENTS

#### Revision Purpose

RFA-RM-17-022 • RFA-RM-17-023 • RFA-RM-17-024

Solicit competing revision applications to eligible NIHsupported clinical trials awarded as either:

- 1. Research project **R01** grants (RFA-RM-17-022)
- 2. Research project **U01** cooperative agreements (RFA-RM-17-023)
- 3. Research project **R34** grants (RFA-RM-17-024)

#### **Revision Goal**

RFA-RM-17-022 • RFA-RM-17-023 • RFA-RM-17-024

- Accelerate the adaptation, validation, and translation of assays in the SOBC Measures Repository for use in ongoing clinical trials
- Integrate assays in the SOBC Measures Repository into active NIH-supported clinical trials of drugs, devices, procedures, or behavioral modifications

#### Revision Objective

RFA-RM-17-022 • RFA-RM-17-023 • RFA-RM-17-024

 Encourage the adaptation, validation, and verification of assays in the SOBC Measures Repository meant to engage and verify engagement of behavior change targets hypothesized to be malleable, and responsible for behavior change

## Parent Award Eligibility

RFA-RM-17-022 • RFA-RM-17-023 • RFA-RM-17-024

- Relevant, active R01, U01, and R34 awards across all stages of clinical trial development potentially are eligible
- Confer with the parent award Program Official at the Institute/Center/Office that administers the R01, U01, R34 award

#### Revision Application Scope

RFA-RM-17-022 • RFA-RM-17-023 • RFA-RM-17-024

Required elements of the proposed revision activity and aims include:

- 1. A well-justified scientific rationale or theory for the selection of the putative target/mechanism of action
- 2. One or more assays from the SOBC Measures Repository
- 3. A behavior change outcome relevant to the parent trial

### Revision Application Scope

RFA-RM-17-022 • RFA-RM-17-023 • RFA-RM-17-024

Activities and aims of the revision application must:

- Identify a putative target(s)/mechanism(s) of action in one of the three SOBC Program target domains implicated in a behavioral outcome relevant to the purpose, goals, or outcomes of the parent trial
- 2. Engage the identified target(s) or verify target engagement by using one or more assays from the SOBC Measures Repository

## Revision Application Scope

RFA-RM-17-022 • RFA-RM-17-023 • RFA-RM-17-024

Encouraged but not required are activities/aims that:

3. Test the degree to which engaging the putative target produces a desired change in a behavioral outcome relevant to the purpose, goals, or outcomes of the parent trial

## Revision Application Responsiveness RFA-RM-17-022 • RFA-RM-17-023 • RFA-RM-17-024

#### Responsive applications will propose to:

- Identify a putative target(s)/mechanism(s) of action in one of the three SOBC Program target domains implicated in a behavioral outcome relevant to the purpose, goals, or outcomes of the parent trial
- Use one or more assays from the SOBC Measures Repository to engage the identified target(s) or verify target engagement

## Revision Application Budget

RFA-RM-17-022 • RFA-RM-17-023 • RFA-RM-17-024

- R01 and U01: Limited to \$500,000 per year in direct costs
- R34: Limited to \$225,000 per year in direct costs
- Cannot exceed the budget of the parent award
- Reflect the actual needs of the proposed revision activities/aims
- Reflect requirement to attend the annual SOBC Research Network Steering Committee meeting in Fiscal Year 2019

# Revision Application Project Period RFA-RM-17-022 • RFA-RM-17-023 • RFA-RM-17-024

- Maximum allowed project period is 2 years
- Scope of proposed project should determine length of project period
- Project period of revision application cannot extend beyond the end date of the parent award

## Revision Application Data Sharing Plan

RFA-RM-17-022 • RFA-RM-17-023 • RFA-RM-17-024

- Regardless of the amount of direct costs requested for any one year, all applications are expected to include a Data Sharing Plan
  - Commitment to data sharing
  - Explanation of data sharing procedures
- All awardees are required to have an Open Science Framework (OSF) account and a public facing OSF study page linked to the SOBC OSF site

#### Revision Application Review Information

RFA-RM-17-022 • RFA-RM-17-023 • RFA-RM-17-024

- Applications will be reviewed by a Special Emphasis Panel convened by the NIH Center for Scientific Review
- Reviewers will evaluate the potential of the application to advance implementation of a mechanisms-focused, experimental medicine approach to behavior change research
- Specific scored review criteria for Significance, Innovation, and Approach are delineated in the SOBC competing revision FOAs

# EXPLORATORY/DEVELOPMENTAL (R21) FUNDING OPPORTUNITY ANNOUNCEMENT

### R21 Purpose & Objective

RFA-RM-17-028

- Solicit exploratory and developmental research project applications (R21) to advance a mechanisms-focused, experimental medicine approach to behavior change research
- Encourage the adoption, validation, and verification of assays from the SOBC Measures Repository meant to engage and verify engagement of behavior change targets hypothesized to be malleable, and responsible for behavior change

#### R21 Goal

RFA-RM-17-028

Leverage SOBC Measures Repository assays of putative targets in three SOBC domains to:

- Engage a selected putative target(s)/mechanism(s) of action or verify target engagement of the selected target(s)/mechanism(s) of action, and
- 2. Test the degree to which engaging the putative target(s)/mechanism(s) of action produces a short-term desired change in a health behavior

## R21 Application Responsiveness

RFA-RM-17-028

#### Responsive R21 applications will:

- Identify a putative target(s)/mechanism(s) of action in one of the three SOBC Program target domains implicated in a desired change in a health behavior
- 2. Use one or more assay from the SOBC Measures Repository to engage the identified target(s) or verify target engagement
- 3. Test the degree to which engaging the putative target produces a short-term desired change in a health behavior

## R21 Application Budget

RFA-RM-17-028

- Direct costs for the 2-year project period may not exceed \$275,000
  - No more than \$200,000 may be requested in any single year
- Reflect the actual needs of the proposed revision activities/aims
- Reflect requirement to attend the annual SOBC Research Network Steering Committee meeting in Fiscal Year 2019

## REA-RM-17-028

- Scope of proposed project should determine length of project period
- Maximum allowed project period is 2 years

# R21 Application Data Sharing Plan RFA-RM-17-028

- Regardless of the amount of direct costs requested for any one year, all applications are expected to include a Data Sharing Plan
  - Commitment to data sharing
  - Explanation of data sharing procedures
- All awardees are required to have an Open Science Framework (OSF) account and a public facing OSF study page linked to the SOBC OSF site

# R21 Application Review Information RFA-RM-17-028

- Applications will be reviewed by a Special Emphasis Panel convened by the NIH Center for Scientific Review
- Reviewers will evaluate the potential of the application to advance implementation of a mechanisms-focused, experimental medicine approach to behavior change research
- Specific scored review criteria for Significance, Innovation, and Approach are delineated in the R21 FOA

#### SOBC RESOURCES

#### Read the FOAs Carefully

- RFA-RM-17-022 (R01 Revisions)
  - https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-17-022.html
- RFA-RM-17-023 (U01 Revisions)
  - https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-17-023.html
- RFA-RM-17-024 (R34 Revisions)
  - https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-17-024.html
- RFA-RM-17-028 (R21)
  - https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-17-028.html

#### **Important Dates**

- Earliest Submission Date November 5, 2017
- Letter of Intent Due Date November 5, 2017
- Application Due Date December 5, 2017 by 5:00 p.m. local time of applicant organization
- Expiration Date December 6, 2017

#### Use the SOBC Common Fund Program Website



https://commonfund.nih.gov/behaviorchange

#### Use the SOBC Measures Repository



What is SOBC Method Projects Measures About v News Resources Directory Contact Us Login

#### The Measures

The SOBC Measures Repository was newly launched in early September 2017! There are currently 63 measures available. More measures will be added over the coming months, and the domain categorization is being updated regularly as information is received. Please continue to check back as we continually refresh the site.

The SOBC Research Network has identified specific potential targets for behavior change interventions in the three broad domains of self-regulation, stress reactivity and stress resilience, and interpersonal and social processes. If an SOBC investigator can verify that a measure (also termed an assay) does reflect the activity of the target, that target is deemed to have been measured. Further work may show that one or more manipulations can change the measured activity of a target, meaning that target has been influenced (or engaged). A final step in the process is to validate that influencing the target process can lead to a change in behavior. Visit the Method page to learn more about the methods and domains.

Rigor and transparency are core principles of the Science of Behavior Change Research Network. The SOBC Repository is the source for behavioral science measures that have been validated (or are in the process of being validated) in accordance with the SOBC Experimental Medicine Approach. The Open Science Framework (OSF) hosts the full details of the validation process for each measure posted in the SOBC Repository, to increase the openness and transparency of our science.

For questions or technical assistance, please contact the SOBC Resource and Coordinating Center by emailing info@scienceofbehaviorchange.org.

https://scienceofbehaviorchange.org/measures/ Questions: info@scienceofbehaviorchange.org

#### Connect with SOBC Program Staff

#### **FOA Scientific Contacts**

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- Melissa W. Riddle <u>melissa.riddle@nih.gov</u> 301-451-3888

#### **SOBC Working Group**

https://commonfund.nih.gov/behaviorchange/members

# QUESTIONS FROM WEBINAR PARTICIPANTS

#### Letter of Intent

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel

- Participating institution(s)
- Number and title of this funding opportunity

Send to: Will M. Aklin National Institute on Drug Abuse <a href="mailto:aklinwm@nida.nih.gov">aklinwm@nida.nih.gov</a>
301-827-5909