Science of Behavior Change Research Network Kick-off Meeting

Meeting Summary

December 3-4, 2015

Bethesda, Maryland

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Acronym Definitions

Acronym	Definition
ABC	Appetite, Behavior, and Cortisol Studies
APS	Association for Psychological Science
EFT	episodic future thinking
fMRI	functional magnetic resonance imaging
FOA	funding opportunity announcement
IRB	Institutional Review Board
NIH	National Institutes of Health
RAINBOW	Research Aimed at Improving Both Health and Weight
RCC	Resource and Coordinating Center
SOBC	Science of Behavior Change

Executive Summary

The National Institutes of Health (NIH) Science of Behavior Change (SOBC) Common Fund Program aims to improve our understanding of human behavior change across a broad range of health-related behaviors. On December 3 and 4, 2015, the SOBC Program held a kick-off meeting of the SOBC Research Network. The SOBC Research Network comprises a Resource and Coordinating Center (RCC) and eight cooperative agreement target validation projects focusing on assay development and target validation in three behavior change domains: interpersonal and social processes, stress reactivity and stress resilience, and self-regulation. The purposes of the meeting were to officially launch the SOBC Research Network, introduce the awardees to each other and relevant NIH staff, share research plans, exchange ideas and methods, and identify areas of potential synergy.

Resource and Coordinating Center

The purpose of the RCC is to provide strategic leadership, efficient coordination, inspired support, and dissemination of SOBC methods, tools, and findings. Specifically, the RCC will provide assistance for systematic reviews; statistical support; dissemination of protocols, data, and findings; enhanced collaboration tools; and identification of potential areas of synthesis across projects. The RCC will oversee three target domain subcommittees and five service domain subcommittees of the Research Network Steering Committee. The intention of the subcommittees is to provide support services to the individual projects, to the Network as a whole, and to promote communication with and dissemination to the broader research community.

Target Validation Projects by Domain

Self-regulation Projects

Five of the target validation projects focus on a wide range of self-regulation targets, such as delay discounting, mindfulness, and self-efficacy. Recognizing the proliferation of self-regulation constructs across disparate fields of research, the project led by Lisa Marsch and Russell Poldrack seeks to define an ontology of self-regulation processes, which will help align various research efforts. Once the putative behavior change targets are defined, the study will determine whether interventions can engage the targets and affect changes in medical regimen adherence and health behavior among smokers and obese or overweight individuals.

The project led by Leonard Epstein and Warren Bickel focuses on delay discounting as a target for one type of self-regulation that can improve health behaviors and medical regimen adherence in pre-diabetic patients to prevent the onset of type 2 diabetes. Alison Miller's project uses a conceptual model of self-regulation as a mechanism of behavior change in which a self-regulation intervention acts on the targets of executive function, food bias, emotional regulation, and motivation to affect proximal validation targets, which in turn, directly influence health outcomes, such as obesity and chronic disease. Because healthy habits often develop during childhood, this study has the potential to impact health outcomes for a broad population.

The project led by Jun Ma and Leanne Williams leverages an existing randomized controlled trial of two proven behavioral therapies to treat adults with comorbid obesity and depression. Although these behavioral therapies demonstrate efficacy, they are not efficacious in all patients and a poor mechanistic understanding hinders their optimal use. The goal of this project is to establish self-regulation targets and assays to facilitate mechanism-driven tailoring in behavioral therapies across a range of comorbidities. Similarly, the self-regulation project led by Eric Loucks, Jean King, and Willoughby Britton recognizes that a better mechanistic understanding of mindfulness processes is needed in order to develop more personalized and effective interventions. This study will consider a range of mindfulness measures and health outcomes in four ongoing or nascent trials. The investigators hypothesize that targets in the self-regulation domains of cognitive processes, emotional regulation, and self-referential processing are influenced by mindfulness-based interventions, and that targeting these domains with customized interventions will increase effectiveness.

Stress Reactivity and Stress Resilience Projects

Two projects address stress reactivity and stress resilience. Because prolonged and frequent responses to everyday stress can impact health, the project led by David Almeida, Joshua Smyth, and Martin Sliwinski aims to develop a within-person approach to measuring everyday stress and to intervene to help individuals meet recommended levels of physical activity and sleep. Ultimately, the project will provide a stress measurement platform that enables a range of interventions.

Johannes Haushofer's project will take place in a population in Kenya with high infant and maternal mortality and diarrheal disease caused in large part by behavioral patterns. The investigators seek to understand how acute and chronic stress affect medical regimen adherence. By inducing stress, they will evaluate three behavioral targets: temporal discounting, self-efficacy, and constraints on cognitive function. Finally, in a series of laboratory and field experiments, the investigators will attempt to engage the targets and assess behavioral and clinical outcomes.

Interpersonal and Social Processes Project

Amy Slep, Richard Heyman, and their colleagues are focusing on interpersonal and social processes targets. This project seeks to improve health behaviors by reducing coercive conflicts in two types of dyads: parent/child dyads and romantic partners. The study design involves random assignment of interventions and control regimens, so all participants will receive both the intervention and control. Because the gold standard for collecting this type of observational data takes several months, the research team will develop and test new measurement methods. These methods will then be available for subsequent use by other researchers.

Synergies and Opportunities for Cross-network Collaboration

Throughout the meeting, participants identified areas of synergy and opportunities for collaboration across projects. One recurring theme was the need to integrate multiple putative mechanisms into cohesive constructs. The groups identified many opportunities to share specific measurement techniques and interventions that would be useful in multiple projects.

For example, laboratory developed assays from one study could be used by another in its field component. By the end of the meeting, each investigative team developed a list of the resources and expertise that can contribute to the network, as well as a list of resources desired from others. The RCC is taking steps to ensure that the collaboration is sustained and that the projects continue to enrich each other as they continue their work.

Meeting Summary

The National Institutes of Health (NIH) Science of Behavior Change (SOBC) Common Fund Program held a kick-off meeting of the SOBC Research Network on December 3 and 4, 2015. The SOBC Research Network comprises nine cooperative agreements in response to four related Funding Opportunity Announcements (FOAs): one U24 Resource and Coordinating Center (RCC) and eight UH2/UH3 target validation projects focusing on assay development and target validation in three behavior change domains: interpersonal and social processes, stress reactivity and stress resilience, and self-regulation.[1] The purposes of the meeting were to officially launch the SOBC Research Network, introduce the awardees to each other and relevant NIH staff, share research plans, exchange ideas and methods, and identify areas of potential synergy.

The meeting began with an overview and history of the SOBC Program. The RCC and each UH2/UH3 investigative team presented their respective projects and identified potential synergies in group discussions. A structured speed dating activity facilitated by the RCC provided an opportunity for participants to exchange specific skills and resources to enhance the projects. On the second day, the investigative teams discussed the proposed subcommittees in rotating breakout sessions. NIH staff provided details about applying to transition to the UH3 phase and discussed strategies to disseminate research from the SOBC network and conduct outreach to the broader research community.

This document summarizes the meeting's main presentations and discussions. The meeting agenda and list of participants are appended.

SOBC Program Overview

Jonathan W. King, National Institute on Aging, and Melissa Riddle, National Institute of Dental and Craniofacial Research

The SOBC Program began with two scientific meetings in 2009 and approval as a Common Fund Program in 2010. The late Richard Suzman, former Director of the Division of Behavioral and Social Research, National Institute on Aging, and the late Varda Shoham, special advisor for translational research at the National Institute of Mental Health, along with representatives from 19 Institutes, Centers, and Offices across the NIH, provided critical leadership and scientific direction to the SOBC Program. The SOBC Program is predicated on the recognition that poor health behaviors (e.g., smoking, poor diet, inactivity, low medication adherence) cost lives and that behavior change interventions can improve health outcomes. One challenge, however, is the common isolation of basic scientific domains that could inform the

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[1] The U24 FOA can be found at http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-14-017.html and the UH2/UH3 FOAs can be found at http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-14-018.html, http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-14-019.html, and http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-14-020.html

development of interventions development. Even more frequent is the Balkanization of problematic health behaviors in clinical research. The first stage of the SOBC Program sought to capitalize on emerging basic science to accelerate the study of common mechanisms of behavior change. The first stage of the program supported laboratory and field studies to define common behavior change mechanisms and how they are engaged in different contexts. The SOBC Program also sponsored a number of scientific meetings that helped break down disciplinary boundaries, foster collaboration, and expand perspectives on the mechanisms of behavior change.

In 2014 an Expert Review Panel evaluated the first stage of the SOBC Program and issued key recommendations for a possible continuation. These included (1) support research to identify key targets of behavioral interventions, develop robust methods to measure them, and validate them in multiple contexts; (2) support use-inspired basic research; (3) develop and build an SOBC registry of studies and trials to include mediators, moderators, mechanisms, measures, and effect sizes; and (4) develop a plan for sustainability of SOBC after Common Fund support expires. The Common Fund approved the continuation of the SOBC Program to promote a mechanisms-focused, experimental medicine approach to behavior change research and to develop the tools required to implement such an approach. The experimental medicine approach involves: identifying an intervention target, developing assays (measures) to permit verification of the target, engaging the target through experimentation or intervention, and testing the degree to which target engagement produces the desired behavior change.

At present, behavior change intervention research consists of diffuse clinical activity followed by clinical trials and in cost reduction efforts for the intervention to increase the likelihood of dissemination. But these efforts are not maximally productive since they proceed without sufficient information on what parts of the intervention really drive the desired change. The SOBC Research Network will define and operationalize a new development pipeline whereby researchers systematically identify and isolate targets, develop and validate assays, and introduce these measures to ongoing studies and clinical trials to define a more systematic and effective approach, akin to the drug development pipeline.

The SOBC Program used three target classes to organize the funding opportunities: self-regulation, stress reactivity and stress resilience, and interpersonal and social processes. Determining causal mechanisms of behavior change involve direct testing and validation of a putative target—an intermediate target such as attentional control—that can explain how or why a particular intervention is efficacious in changing a behavior.

Procedures to Apply for Transition to UH3 Phase
Wendy Weber, National Center for Complementary and Integrative Health, and Jonathan W. King, National Institute on Aging

The NIH Common Fund is operated by the Office of Strategic Coordination in NIH's Office of the Director. Common Fund programs are expected to be transformative, catalytic, synergistic, cross-cutting, and unique. The vision of the Common Fund is to catalyze research through short-term (5 to 10 year) investments in high-risk, enabling, or emerging scientific

opportunities. Resources or infrastructure generated in Common Fund programs will transition to other sources of support at the conclusion of Common Fund support.

The UH2/UH3 awards are phased cooperative agreements. The "U" indicates that the award is a cooperative agreement, a funding mechanism that provides assistance to the awardee and involves significant programmatic input from NIH staff. "H2" indicates the exploratory/developmental phase, and "H3" indicates the implementation phase. Exploratory projects do not automatically proceed to the implementation phase, and the Common Fund does not guarantee support of the UH3 phase (years 4 and 5) for all projects; however, there will be opportunities for individual Institutes, Centers, and Offices to contribute towards funding the UH3 phase of one or more meritorious projects.

Investigators of each project must submit a UH3 Transition Request, which will be due in April 2018. Each investigative team will receive a letter detailing the process and requirements several months in advance of the deadline. Review criteria will include completion of the UH2 milestones, development of satisfactory aims for the UH3 phase, and demonstrated engagement with the Research Network. The administering Institute or Center will provide feedback on the continued scientific relevance of the project. All transition requests will be administratively reviewed at the NIH.

SOBC Program Outreach
Lisbeth Nielsen, National Institute on Aging

One important goal of the SOBC Program is to disseminate findings and methods and promote the experimental medicine approach to behavior change to the broader research community. The proposed SOBC Subcommittee on Outreach, Dissemination, and Publications will focus on these efforts for the Network. There are, however, some near-term opportunities with professional societies. For example, the Association for Psychological Science (APS) Annual Convention in May 2016 will feature a [theme track on the science of behavior change](#), co-sponsored by the NIH SOBC Program, during which investigators and representatives from the SOBC Program will be featured. SOBC investigators planning to attend the APS meeting are encouraged to participate. The SOBC Program also plans to host a scientific symposium at the APS meeting to highlight key findings of the first stage of the program. Investigators are encouraged to identify and share other dissemination opportunities with the Network.

The cooperative agreement funding mechanism allows NIH Project Scientists to co-author peer-reviewed publications with investigators. Project teams interested in co-publishing with their Project Scientists should be aware of the needed approval process to avoid delays.

Resource and Coordinating Center Overview
Karina Davison and Donald Edmondson, Columbia University

The purpose of the Resource and Coordinating Center (RCC) is to provide strategic leadership, efficient coordination, inspired support, and dissemination of the innovative SOBC methods and findings. The RCC strives to help the Network continually improve its approach. Coordination

will benefit individual projects. Specifically, the RCC will provide assistance for systematic reviews; statistical support; dissemination of protocols, data, and findings; enhanced collaboration tools; and identification of potential areas of synthesis across projects.

Organizational Structure

The SOBC Research Network will be overseen by the SOBC Steering Committee. Voting members of the Committee include the Principal Investigators (PIs) and Project Scientists from each Network award. Additional investigators and NIH staff will join as appropriate. Eight subcommittees, three focusing on target domains and five on service domains, will report to the Steering Committee. Each subcommittee should have some representation from each of the individual target validation projects: this could be a PI, co-investigator, or key personnel member. The target domain subcommittees (self-regulation, interpersonal and social processes, stress reactivity and stress resilience) will comprise investigators with relevant expertise with the goal of encouraging collaboration and synergies. The service domain subcommittees are described below. The Steering Committee can change or disband a subcommittee if it ceases to be useful.

Systematic Review Subcommittee

The systematic review subcommittee will identify high priority topics for the SOBC Research Network as a whole. It might also provide assistance to Network investigators performing quick literature searches to inform operational decisions or conducting comprehensive meta-analyses of questions of broader importance. Through the subcommittee, Network investigators have access to a Cochrane librarian and meta-analysis experts who will assist with creating searches, systematic review processes and reporting, and meta-analyses.

Protocol Development and Methods Subcommittee[2]

This proposed subcommittee will identify opportunities for cross-network synthesis of assays and provide support for study design and analysis. In order to maximize overall SOBC Research Network impact on behavior science, the subcommittee will identify best practices and methods within individual studies and look for synergy across studies. RCC investigators will contribute statistical consultations, power analysis support, and Institutional Review Board (IRB) support, if needed. Experts in adaptive designs, current randomized clinical trial analytical methods, and multilevel models are available. These services will be available at all stages of the scientific process. Subcommittee members will discuss protocol assumptions that may be unique or shared across studies to identify opportunities for synthesis.

Data Sharing and Replication Subcommittee

The data sharing and replication subcommittee will host Network data on a secure website and develop processes for sharing within and outside the Network. In the early stages, this subcommittee will address regulatory challenges. Later it will help facilitate replication by

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[2] Discussion at and after the meeting resulted in the decision to combine the proposed Protocol Development and Methods and Technical Guideline Development subcommittees.

identifying replication sites and populations. This subcommittee will also provide support for data visualization and final analyses.

Technical Guideline Development Subcommittee
This subcommittee will develop processes for evaluating SOBC evidence, including guideline development and sensitivity analyses. In the UH3 phase, it will play a role in dissemination of the most successful assays, targets, and target engagement processes. This subcommittee will also help set the future research directions.

Outreach, Dissemination, and Publications Subcommittee
This subcommittee will serve both internal and external roles. Internally, it will provide manuscript copyediting services and host the SOBC Registry—a repository of data, assays, interventions, best practices, and guidelines. Externally, the subcommittee will facilitate communications with news media, conferences, and other outlets.

Means of Coordination
Sarah Greene, Rapid Science

The RCC will provide tools to facilitate collaboration across the projects. Communication alone is not enough: information is often lost in informal interactions. Rapid Science is a social media platform that will foster the exchange of ideas, archive information in a searchable format, give provenance to ideas, and widen the audience. Rapid Science will be the go-to place for information on the SOBC Research Network, expectations, new findings, meetings, and resources. Greene provided a live demonstration of Rapid Science, some of which is currently operational. Additional site features will launch in about 6 months. A key point is that the value of the platform depends on what the users put into it.

Self-regulation Projects—Part I

Delay Discounting as a Target for Self-regulation in Pre-diabetes
Leonard Epstein, University at Buffalo, and Warren Bickel, Virginia Tech Carilion Research Institute

Pre-diabetic individuals must implement lifestyle changes in order to reduce their risk of developing type 2 diabetes. Type 2 diabetics, however, tend to excessively discount the future. High discount rates, or preferring small short-term gains over more beneficial long-term gains, are associated with poor health behaviors and increase the risk of disease progression. Pre-diabetics who discount the future more highly are less likely to improve their diets, exercise, lose weight, and adhere to medication regimens, thereby increasing their risk of developing type 2 diabetes and comorbidities. Interventions to reduce discounting may improve health outcomes in pre-diabetic populations.

Specific Aims
This project aims to (1) identify an intervention target, (2) engage the target with an intervention, (3) test the stability of the intervention, and (4) determine whether target

engagement changes behavior. To identify a target, the investigators will examine how well delay discounting, executive function, and functional magnetic resonance imaging (fMRI) neural activation during discounting tasks predict medication adherence, diet, physical activity, and blood glucose in a cross-sectional sample of 100 pre-diabetic participants. The investigators will then determine whether episodic future thinking (EFT)—a form of prospection—reduces delay discounting, energy intake, and fMRI-measured brain activation in a randomized laboratory study of 64 participants.

The third aim is to test the ability of EFT to protect against poverty, a condition associated with increased discount rates. Using a randomized 2 x 2 design, the investigators will test the effects of EFT versus a control in poverty-simulated and neutral settings on delay discounting response and fMRI brain activation. Finally, in the UH3 phase, the investigators plan to conduct a randomized field experiment to determine whether EFT impacts delay discounting, diet, physical activity, medication adherence, and clinical outcomes.

Possible Roadblocks to Success
Recruitment is unlikely to be a major barrier; however, participant retention is a concern. To proactively mitigate attrition, the investigators will provide fair compensation and completion bonuses, utilize multiple methods of contact, issue appointment reminder phone calls and emails, and provide travel compensation when necessary.

Applying Novel Technologies and Methods to Inform the Ontology of Self-regulation
Lisa Marsch, Dartmouth College

A broad set of constructs of self-regulation have been studied across multiple distinct literatures with little crosstalk. The number of measures for identically-named constructs is increasing, and different measures are often used in different studies of the same putative constructs. Research has tended to focus on a small set of potential mechanisms at a specific level of analysis. Meanwhile, little research has established temporal precedence of a broad array of potential mechanisms. This project seeks to systematically and empirically integrate concepts across the divergent self-regulation literatures to identify putative mechanisms of behavior change. The goal is to develop an overarching ontology of self-regulatory processes.

Specific Aims
The first aim is to identify an array of putative targets within the self-regulation domain implicated in medical regimen adherence and health behavior across three levels of analysis: psychological, behavioral, and biological. Building on previous efforts, the investigators will integrate concepts from different literatures to develop an ontology of self-regulation processes. They will catalog tasks in the self-regulation literature, implement tasks via online testing, and conduct a small imaging study (N=36) to identify biological correlates in normal controls.

The second aim is to evaluate the extent to which it is possible to engage and manipulate putative targets within the self-regulation domain in both laboratory and field settings. In the laboratory component, 50 smokers and 50 obese or overweight individuals will complete the

tasks identified in the first aim. A comparable sample of 100 individuals will participate in a mobile-based behavioral assessment and intervention program under real-world conditions.

The third aim will identify or develop measures and methods to permit verification of target engagement within the self-regulation domain. This effort will look for patterns across assays, populations, and topics.

Pending successful completion of the aims, investigators will evaluate the degree to which engaging targets produce a desired change in medical regimen adherence and health behavior among smokers and obese or overweight individuals. The goal is to evaluate whether a 4-week intervention period leads to improvement in at least two health behaviors.

Possible Roadblocks to Success
The project has an ambitious plan and timeline, with multiple activities taking place concurrently at multiple institutions. Coordination of activities of various subgroups on the project team will be challenging but feasible, particularly given the geographic separation of investigative teams.

Group Discussion
Participants identified several commonalities between the two projects, including the foci on obesity, temporal discounting, and global interventions. Moreover, both studies include imaging, laboratory, and field research components. One difference is that the Epstein and Bickel project focuses on a particular manipulation, whereas the Marsch and Poldrack project will test many manipulations in the laboratory setting and apply the most promising manipulations to the field study.

Each project has or will have resources to offer the broader research community. Epstein, Bickel, and colleagues have developed a method to measure discounting in less than one minute. It is freely available for others to use. The ontology that Marsch and colleagues will develop will be broadly useful to other researchers; there was agreement that the use of multiple terms with the same meaning hinders progress in the field.

Meeting participants discussed the need to study the concepts of reward reinforcement and self-control and to find ways to integrate these into a single conceptual model. Bickel commented that the reinforcement value of different activities varies based on the temporal window. For example, employment and family offer valuable reinforcement over extended time horizons and might sometimes be unenjoyable in the short-term. Drugs, on the other hand, offer short-term reinforcement. Shortening the temporal window may increase the influence of value from short-term reinforcement. This perspective may allow mechanistic integration, for example, between addiction and anhedonia. Another participant added that external factors, such as stress, may influence delay discounting responses.

Self-regulation Projects—Part II

Targeting Self-regulation to Promote Adherence and Health Behaviors in Children
Alison Miller, University of Michigan

The study of self-regulation in children focuses mainly on food reward and emotional regulation. Although some children practice self-regulation, it is uncommon except when socially conditioned, such as in the presence of parents. Like in adults, self-regulation in children is associated with a range of functional areas, including some health outcomes. Yet few studies have systematically investigated how different aspects of self-regulation relate to health-related behaviors in children, and whether this pathway operates for all children.

This project uses a conceptual model of self-regulation as a mechanism of behavior change in which a self-regulation intervention acts on a self-regulation target (executive function, food bias, emotional regulation, and motivation) to affect proximal validation targets. The proximal validation targets then directly influence health outcomes, such as obesity and chronic disease.

In the UH2 phase, the project will use obesity as a model, leveraging the ongoing Appetite, Behavior, and Cortisol (ABC) Studies. Launched in 2009, ABC is a longitudinal cohort study of more than 300 low-income children aged 9 to 11 measuring eating behavior, self-regulation, and stress in relation to obesity risk. In the UH3 phase, the project will shift its focus to medication adherence, recruiting from a pediatric population with chronic illness at the University of Michigan Medical Center. A variety of interventions will be tested.

Specific Aims
The UH2 hypotheses are (1) interventions will improve proximal self-regulation targets, (2) self-regulation targets will associate with identified health behaviors related to obesity risk, and (3) child and family factors may moderate intervention effects. In this context, Specific Aim 1 is to field-test measures of self-regulation targets in children from ABC cohorts, Aim 2 is to validate measures of self-regulation targets with health behaviors, and Aim 3 is to implement interventions to change self-regulation targets and evaluate using a multiphase optimization strategy design.

Potential Roadblocks to Success
Potential challenges include participant burden, child/parent engagement, technological challenges, and intervention crossover effects. The investigators have proposed a number of potential solutions to these challenges and seek additional feedback from meeting participants.

Engaging Self-regulation Targets to Understand Mechanisms of Behavior Change and Improve Mood and Weight Outcomes
Jun Ma, University of Illinois at Chicago, and Leanne Williams, Stanford University

Although many behavioral and lifestyle interventions are efficacious, they do not all work for every patient. A lack of understanding of self-regulation mechanisms underlying evidence-based behavioral therapies hampers efforts to optimize treatment in diverse settings and

subgroups. This project leverages the ongoing and independently funded Research Aimed at Improving Both Health and Weight (RAINBOW, R01HL119453) trial—the first randomized controlled trial of an integrated model of two proven behavioral therapies to treat adults with comorbid obesity and depression. The goal is to establish self-regulation targets and assays to facilitate mechanism-driven tailoring in behavioral therapies across a range of comorbidities.

The RAINBOW trial administers an integrative lifestyle intervention focusing on problem solving, goal setting, self-monitoring, action planning, social support, and anti-depressant medication as needed. The primary outcome measures are depressive symptoms and body mass index. Secondary outcomes include depression remission, cardiovascular risk factors, anxiety, quality of life, disability, and sleep quality. Leveraging a trial with clear outcomes, the investigators will identify aspects of self-regulation that may predict outcomes, mechanisms of self-regulation, and approaches to personalizing interventions. Based on known brain circuits related to self-regulation, the investigators will assess targets of the regulation of emotion, cognition, and self-reflection using fMRI, physiological, behavioral, and self-report assays.

Hypotheses
The investigators expect to observe engagement of the three neural circuits through imaging and virtual reality simulations. These laboratory and virtual reality assays are further expected to correlate with passive sampling of actual life behaviors in each of the three self-regulation constructs. The investigators predict longitudinal changes from baseline to within weeks and months of treatment across all assay platforms. Finally, the investigators hypothesize that these changes in self-regulation assays will predict changes in problem solving and adherence to physical activity and healthy eating recommendations.

Possible Roadblocks to Success
Possible challenges include target measure identification and validation, particularly in virtual reality settings. Participant recruitment and retention may also pose a challenge, although drawing from the RAINBOW trial should help to mitigate this.

Mindfulness Influences on Self-regulation: Mental and Physical Health Implications
Eric Loucks and Willoughby Britton, Brown University

There are early indications that mindfulness-based interventions might impact self-regulation targets and improve health behaviors and outcomes. Existing studies, however, are of small sample sizes and brief duration. It remains unclear which aspects of mindfulness interventions produce the observed effects and which targets of self-regulation are engaged. A better understanding of the mechanisms will allow more targeted mindfulness interventions.

Hypotheses
The investigators hypothesize that targets in the self-regulation domains of cognitive processes, emotional regulation, and self-referential processing are influenced by mindfulness-based interventions, and that targeting these domains with customized interventions will increase effectiveness.

Study Design

The project comprises four concurrent studies: (1) the Dismantling Mindfulness Study, a three-arm randomized controlled trial of mindfulness-based cognitive therapy, focused attention, and open monitoring; (2) dietary health behavior studies, including a randomized controlled trial of yoga at different doses and a randomized trial of mindfulness-based stress reduction and healthy living classes; (3) the MINDFUL-PC study, a randomized comparison of mindfulness training for primary care and referral to standard community mindfulness resources; and (4) the Mindfulness-Based Hypertension Therapy study, which includes treatment development and evaluation phases of mindfulness-based hypertension therapy compared to standard care. These studies are in various stages of completion; late-stage studies will be used to identify targets whereas early-stage studies will be modified to include identified targets of self-regulation.

Health behaviors to be examined include diet, physical activity, alcohol consumption, medication use, and initiation and maintenance of self-management behavior change action plans. Proposed targets comprise cognitive processes, self-referential processing, and emotion regulation domains.

Possible Roadblocks to Success

There is currently a human subjects hold on the study protocol that is improving the quality of the study but impacting recruitment. The investigators are working to resolve this as soon as possible.

Group Discussion

Participants discussed areas of overlap and potential synergies between the different projects. It was noted that several of the projects focus on the same domains of self-regulation. Although the RAINBOW trial does not focus on mindfulness, mindfulness research from other projects could inform the design of interventions during the UH3 phase. Several projects also share common interests in the tasks used to probe different targets. These tasks could be shared across the groups. Sharing laboratory assays, imaging protocols, and virtual reality methods is also of interest.

One participant noted that the concept of temporal discounting challenges the notion that mindfulness improves self-regulation. This is because the discounting theory is that present-biased individuals have poorer self-regulation, yet mindfulness interventions may work in part by focusing attention on the present. The studies in the SOBC Research Network have the potential to elucidate the mechanisms and clarify the constructs of mindfulness and temporal horizons.

Nielsen acknowledged that there may be a tension between the milestone structure, which provides fixed goals to promote success, and the flexibility needed to work with the RCC and respond to information from other projects in the Network. The ultimate goal is to disseminate high-performing assays to the entire community, which requires communication between projects. The NIH seeks feedback from investigators on balancing milestone activities and the flexibility to communicate freely and respond to new opportunities.

Davidson suggested brainstorming ways to encourage future researchers to use the resources generated by the SOBC Research Network. Ideas include mechanisms to actively disseminate resources instead of passively hosting them on a website to be found. One goal is to become the go-to resource among researchers in the field when searching for help writing grants and for methods to include in their laboratory and field work.

Stress Reactivity and Stress Resilience and Interpersonal and Social Processes Projects

Everyday Stress Response Targets in the Science of Behavior Change
David Almeida, Joshua Smyth, and Martin Sliwinski, Pennsylvania State University

Evidence suggests that prolonged and frequent responses to everyday stress can influence health outcomes. The cumulative impact arises from the proximal influence of stress on health behaviors, such as physical activity and sleep. Existing tools to measure stress provide broad, relatively static, person-level indicators that may not account for temporal response components and contextual influences critical to shaping health behaviors. This project aims to develop a within-person approach to measuring everyday stress and intervening to help individuals meet recommended levels of physical activity and sleep.

The project focuses on the temporal component of stress by distinguishing the magnitude, duration, and frequency of stress responses. Leveraging existing data on repeated within-person stress measurements, the investigators will conduct coordinated analyses and cross-validation, an easy-to-use theory- and evidence-based ambulatory stress assay, and provide a platform that enables a range of interventions.

Specific Aims
In Aim 1, the investigators will examine three stress response components (stressor reactivity, stress recovery, and pile-up) hypothesized to exert short-term effects on physical activity and sleep. The second aim is to examine the unique and collective impacts of stress components to on achieving recommended amounts of physical activity and sleep. Aim 3 is to examine between-person moderators of stress components and their prediction of physical activity and sleep. Finally, Aim 4 is to deliver a final version of the ambulatory stress assay, and Aim 5 is to apply the assay and implement adaptive, real-time interventions in daily life.

Possible Roadblocks to Success
Implementation challenges include coordinating analyses across multiple datasets, addressing the inconsistent measurement of health behaviors across existing datasets, and balancing the density of measurement with the feasibility of assay deployment.

How Does Stress Affect Health Behaviors: Preferences, Beliefs, or Constraints?
Johannes Haushofer, Princeton University

Behavior change interventions tend to produce small and inconsistent effects. Cross-sectional data suggest that stress is associated with low adherence, and some studies show that reducing stress improves adherence. How stress affects adherence, however, is unknown. This study examines three possible mediators of the impact of stress on adherence to health behaviors: temporal discounting, self-efficacy, and cognitive function.

The hypotheses are that (1) stress increases temporal discounting, focusing individuals on immediate outcomes at the expense of more distant and possibly greater rewards; (2) stress leads to low self-efficacy, reducing self-perceptions of control and self-worth; and (3) stress impairs executive control, hampering goal setting and planning, cognitive flexibility, and working memory.

Study Design
The study targets a population in Kenya with high infant and maternal mortality and diarrheal disease caused by low rates of completion of perinatal care visits and chlorination of drinking water respectively. Behavioral outcomes will include clinical service utilization rates and chlorination rates. Clinical outcomes will include infant morbidity and mortality, postpartum depression, and infant diarrhea. The first study phase will consist of a primary literature review, adaptation of methods to the sociocultural context, and field and laboratory surveys of approximately 500 individuals. In the second phase, the investigators will conduct a series of laboratory investigations (N=1750) evaluating the effects of induced acute and chronic stress on the three behavioral targets. Finally, the third study (N=3370) will comprise a series of combined laboratory and field experiments to engage the three targets through videos, exercises, and in-person training.

Possible Roadblocks to Success
Anticipated challenges include the ambitious number of subjects and studies, participant refusal rates, particularly for the physiological measures, cross-cultural validation of measures and stressors, and developing and implementing interventions to effectively engage targets. It is also unclear how well the investigators will be able to mimic chronic stress in a laboratory or field setting.

Targeting Corrosive Couple Conflict and Parent-Child Coercion to Impact Health Behaviors and Regimen Adherence
Amy Slep and Richard Heyman, New York University

Coercive conflicts are common in interpersonal relationships and negatively affect health behaviors. These relationships involve the escalation of hostile behaviors and hostile effects. Individual instances tend to end abruptly and reinforce the cycle; the winner is positively reinforced for the escalation, and the loser is negatively reinforced for ending the winner's aversion. Typically both partners experience both the winning and losing roles during different instances of conflict.

Study Design

This study will administer behavioral and cognitive interventions to reduce coercive processes in two types of dyads, parent/child dyads and romantic partners. A reduction in coercive processes is expected to improve health behaviors, namely healthy eating and drinking and, in children, tooth brushing time and quality. In each study, approximately 100 dyads will be randomized to receive either behavioral or cognitive interventions. Each dyad will be randomly assigned to receive initially an intervention or control treatment. Crossover will occur halfway through the study, so all participants will receive both the intervention and control.

Repeated measures will include observed behavior, physiological measures, and self-reported behavior. Because the gold standard for collecting this type of observational data takes several months, the research team will develop and test new measurement methods.

Possible Roadblocks to Success

The investigators anticipate some potential difficulties recruiting participants for the study. Measuring coercion via self-report has few precedents, and measuring coercion physiologically may be technically challenging with young children. Adapting traditional observational methods to be shorter in duration will be challenging. Distinguishing self-reports of coercion from self-reports of general conflict may also present a challenge.

Group Discussion

Participants noted synergies between the projects in this section, including exploring the relationship between stress and health outcomes. There may be opportunities for the groups to share expertise about specific measurement techniques and interventions. For example, laboratory developed assays from one study could be used in another study's field component. For example, Haushofer commented that measuring time preferences takes his group 30 minutes; his project would benefit from Epstein and Bickel's much faster assessment. Several other investigators expressed interested in the brief delay discounting assessment as well.

One participant noted that these studies collectively cover the lifespan. There may be age-related differences in stress response and emotional regulation. Similarly, mood impacts self-regulation and stress and might influence study results.

Bickel noted that it is important to define what is meant by change in stress levels. Change can be absolute or proportional to a baseline. In some fields, the goal of change is to increase the level of variability. There is a need to determine whether this is true for behaviors.

Several projects in the SOBC Network focus on interventions; however, the interventions are not sufficiently granular to target specifically identified components. In other words, it may be difficult to know whether the intervention causes change in the identified target. Instead, it may be that contextual circumstances affect the utility of interventions in different settings. Continued discussion and collaboration across projects will be useful in informing the interventions as work is done to measure and validate the targets.

Opportunities to Share across Projects

Karina Davidson and Donald Edmondson, Columbia University

Davidson and Edmondson presented a summary of items discussed by project teams during the speed dating session and described opportunities to swap methods and/or expertise. Examples include sharing expertise in ecological momentary assessment of stress, reactivity, and recovery; the brief assessment of delay discounting; an EFT intervention protocol; information about the Kenyan population; the brief mindfulness measure; measurement expertise, neuroimaging results; and the ontology of self-regulation processes. The specific ideas for swapping tools and expertise will be shared with the PIs of each team and available on the online Rapid Science collaboration platform for further internal discussion and follow-up.

Appendix 1:
Meeting Agenda

Revised 11-30-15

Thursday, December 3, 2015   **Room 6C10**

9:00 am	**Introductions**	Facilitated by RCC
9:30	**SOBC Program Overview**	Jonathan W. King Melissa Riddle
10:00	**Resource and Coordinating Center (RCC) Overview**	Karina Davidson
10:15	**Break**	

Self-regulation Projects—Part I

10:30	Delay Discounting as a Target for Self-regulation in Prediabetes	Leonard Epstein Warren Bickel
10:45	Applying Novel Technologies and Methods to Inform the Ontology of Self-regulation	Lisa Marsch
11:00	**Group Discussion** Identify commonalities and differences in targets, health behaviors, populations, measures, and approach	Facilitated by RCC

Self-regulation Projects—Part II

11:15	Targeting Self-regulation to Promote Adherence and Health Behaviors in Children	Alison Miller
11:30	Engaging Self-regulation Targets to Understand the Mechanisms of Behavior Change and Improve Mood and Weight Outcomes	Jun Ma Leanne Williams
11:45	Mindfulness Influences on Self-regulation: Mental and Physical Health Implications	Eric Loucks Willoughby Britton
12:00	**Group Discussion** Identify commonalities and differences in targets, health behaviors, populations, measures, and approach	Facilitated by RCC

12:15	**Lunch**	

**Stress Reactivity and Stress Resilience & Interpersonal
    and Social Processes Projects**

1:30	Everyday Stress Response Targets in the Science of Behavior Change	David Almeida Joshua Smyth
1:45	How Does Stress Affect Health Behaviors: Preferences, Beliefs, or Constraints?	Johannes Haushofer
2:00	Targeting Corrosive Couple Conflict and Parent-Child Coercion to Impact Health Behaviors and Regimen Adherence	Amy Slep Richard Heyman
2:15	**Group Discussion** Identify commonalities and differences in targets, health behaviors, populations, measures, and approach	Facilitated by RCC
2:30	**Break**	

2:45	**RCC Detailed Presentation—The Big Picture**
	  ■ Subcommittee plans and structure
	  ■ Annual Steering Committee meetings
	  ■ Oversight of clinical research and protocol development
	  ■ Data sharing and Rapid Science platform
	  ■ Outreach, dissemination, and publications
		Karina Davidson
		Donald Edmondson
		Sarah Greene

4:00	**Target Validation Project Speed Dating** Each team identifies 3 skills or resources it has and 3 skills or resources it needs. Teams meet with each other and swap skills/resources.	Room 6C10 Room 6C5
5:15	**Closing Remarks**	Melissa Riddle
5:20	**Adjourn**	

Friday, December 4, 2015   **Room 6C10**

9:00 am   **Action Items and Timeline**   Karina Davidson

9:30   **Subcommittee Break-out Sessions with the RCC**
               ▪ Protocol Development and Methods   Room 6C10
               ▪ Technical Guideline Development   Room 6C10
               ▪ Outreach, Dissemination, and Publications   Room 6C9
               ▪ Systematic Review   Room 6C5
               ▪ Data Sharing and Replication   Room 6C7

11:10   **Break**
               Projects and NIH Program Officers and Project Scientists Room 6C10
               Mingle and Connect   Room 6C7

11:30   **Procedures to Apply for Transition to UH3 Phase**   Wendy Weber
               Q&A and Discussion   Jonathan W. King

12:00   **SOBC Outreach**   Lisbeth Nielsen
                                                                        Melissa Riddle
                                                                        Karina Davidson

12:30   **Adjourn**

Appendix 2:
List of Participants

Revised 12-3-15

PRINCIPAL INVESTIGATORS AND KEY PERSONNEL

Carmela Alcantara, Columbia University
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Ian Eisenberg, Stanford University
Zeynep Enkavi, Stanford University
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Louise Falzon, Columbia University Medical Center
Carl Fulwiler, University of Massachusetts Medical School
Ashley Gearhardt, University of Michigan
Lisa Goldman Rosas, Palo Alto Medical Foundation Research Institute
Oscar Gonzalez, Arizona State University
Sarah Greene, Rapid Science
Johannes Haushofer, Princeton University
Richard Heyman, New York University
Elizabeth Hoge, Georgetown University Medical Center
Chaning Jang, Princeton University
Sunny Jung Kim, Dartmouth College
Jean King, University of Massachusetts Medical School
Ian Kronish, Columbia University
Eric Loucks, Brown University
Jun Ma, University of Illinois at Chicago
Lisa Marsch, Geisel School of Medicine at Dartmouth
Laura Meli, Columbia University
Alison Miller, University of Michigan School of Public Health
Stephanie Navarrete, Columbia University
Russell Poldrack, Stanford University (December 4 only, via phone)
Zev Schuman-Olivier, Cambridge Health Alliance and Harvard Medical School
Joseph Schwartz, Columbia University
Amy Slep, New York University
Marty Sliwinski, Pennsylvania State University

Joshua Smyth, Pennsylvania State University
Mark Snowden, University of Washington
Jennifer Sumner, Columbia University
Catherine Thomas, Princeton University
Leanne Williams, Stanford University
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