National Institutes of Health Science of Behavior Change Common Fund
PA-16-334 Administrative Supplement
Pre-application Technical Assistance Webinar Summary

September 8, 2016
2 – 3 p.m. Eastern Time

Purpose of the Webinar

On Thursday, September 8, 2016, the National Institutes of Health (NIH) Science of Behavior Change (SOBC) Common Fund Program hosted a pre-application technical assistance webinar for a new SOBC funding opportunity announcement (FOA). The receipt date for PA-16-334 *Science of Behavior Change: Use-inspired Basic Research to Optimize Behavior Change Interventions and Outcomes (Admin Supp)* applications is November 10, 2016. The earliest submission date is October 10, 2016, and the awards are expected to be made by September 1, 2017. Webinar speakers provided an overview of the SOBC Common Fund Program, described the experimental medicine approach to behavior change research, and reviewed details of the Program Announcement.

Webinar Speakers

Anita McRae-Williams, M.A., Outreach Program Manager, National Center for Complementary and Integrative Health (NCCIH), webinar moderator

Jonathan W. King, Ph.D., Program Director for Cognitive Aging, Division of Behavioral and Social Research, National Institute on Aging (NIA), and co-coordinator of the SOBC Common Fund Program

Will M. Aklin, Ph.D., Director of the Behavioral Therapy Development Program, Division of Therapeutics and Medical Consequences, at the National Institute on Drug Abuse (NIDA)

Melissa Riddle, Ph.D., Chief of the Behavioral and Social Sciences Research Branch, Behavioral Research Program, National Institute of Dental and Craniofacial Research (NIDCR), and co-coordinator of the SOBC Common Fund Program

SOBC Common Fund Overview

The SOBC Program is funded by the NIH Common Fund in the Office of Strategic Coordination at NIH. NIH Common Fund programs are intended to be transformative, cross-cutting, unique, synergistic, and catalytic. The goal of the SOBC Program is to fundamentally transform the way behavior change research is conducted by supporting research to infuse the study of mechanisms of behavior change throughout the basic-to-applied research pipeline.

The SOBC Program is a trans-NIH effort because we see the potential for making a transformative contribution to the field by working together—harnessing synergies and implementing unique initiatives—to accomplish goals that would be difficult for an individual Institute, Center, or Office (ICO) to tackle. More than 17 ICOs across NIH participate in the SOBC Program because there are common challenges that cut across the diverse behavior change programs, including:

- Breaking down siloes between parallel programs of research (across diseases, disciplines, developmental stages)
- Formalizing and rationalizing the concepts and methods used to study causal pathways of behavior
- Translating basic science on causal pathways leading to poor health behaviors into effective interventions
- Tailoring interventions to be relevant and acceptable (and therefore more efficacious) to different communities or populations
- Focusing on making interventions more efficient so that they are sustainable in different settings

Common Fund programs are intended to achieve high impact goals within a period of time not to exceed 10 years. The SOBC Program, which is in its second 5 years of funding will therefore need to find ways to sustain its transformative influence on behavior change to continue even after the end of support by the Common Fund. The SOBC Program aims to infuse the study of mechanisms of behavior change across ICOs, behaviors, diseases, and translational stages on a large scale that lives on after the SOBC Program.

Introduction

Behaviors are among the most important factors that determine whether people will live long, healthy lives, but most people find it difficult to make positive, lasting behavior changes. Researchers need a way to better identify the mechanisms that make behavior change efforts successful, so that we can quickly find out what works—and what doesn't. In the SOBC Program, researchers are developing new scientific methods that will reveal how and why people start and sustain healthy behaviors. This new approach will benefit scientists and the public by providing blueprints for effective and efficient behavior interactions that will reliably improve health outcomes.

The Experimental Medicine Approach to Behavior Change Research

An experimental medicine approach to behavior change seeks to answer the question, *What are the processes or mechanisms that drive behavior change?* This approach requires:

- Hypotheses about targets (processes/mechanisms) that drive behavior change
- Experimental methods for engaging the target
- Valid measures of target engagement

As a parallel, in the experimental medicine approach to medication testing, drugs are used as clinical manipulations of specific molecular targets believed to play a causal role in the disease process, and the immediate goal is therefore not to develop a treatment but to identify targets and show that you can measure their levels of activity. Once you have identified targets and can measure them, drug development then turns to testing whether a drug actually does act on the target (whether it "engages" the target) and whether the result of his target engagement is an effect on a biological process or endpoint related to a clinical disorder.

For example, once we know that we can measure the activity of (say) a glutamate receptor in a neuron, we can test whether a drug can block or enhance the activity of that receptor, starting at synaptic level, but eventually verifying that it alters the behavior of specific neural circuits or the behavior of the individual. Applying the experimental medicine approach to behavior change research focuses on developing probes to identify or verify that a specific process that is a putative target for changing behavior can be engaged and manipulated. Once viewed this way, it becomes apparent that an intervention could fail to work *either* because it just does not engage the putative target, *or* that the putative target just does not have the intended effect on behavior. The experimental medicine approach therefore also allows you to figure out why an intervention does not work, or, if it does work, how to optimize its effect. Because the experimental approach can be used to develop completely new interventions or to test and optimize existing interventions, it can be fruitfully used at many different stages of intervention development, providing an even stronger rationale for introducing the concept into ongoing NIH-funded studies.

Looked upon from a different angle, rarely, if ever, does an interesting intervention directly cause a behavior or a behavior change; there are intermediate stages, and therefore a *causal change* that connects the intervention with the outcome. Similarly, we rarely, if ever, develop an intervention without having one or more putative intervention targets in mind (we have a theory) that we are hoping to manipulate; and our intervention is therefore at some level a test of the hypothesis that this target is causally connected to the behavior we wish to change. But even though we can do a randomized trial that will tell us that an intervention has *some* positive effect on a targeted behavior, we really cannot meaningfully test whether the intervention engages these putative targets, or whether engaging those targets really does lead to behavior change unless we have a way of knowing whether we can engage the target. And

for this we need assays that validly measure changes in target "activity"—that is, a change in the target will cause a change in the assay. These assays could take the form of behavioral tests, neuroimaging data, an endocrine assay such as cortisol or alpha amylase, or gene expression (even in the case of a behavioral intervention). Once assays are in place, we can verify whether or not the manipulation we have in mind engages the target, and whether engaging that target leads to the hoped-for change in behavior. If it does, we might be able to answer the question of whether the target was valid in the first place.

Purpose of the Program Announcement

The funding opportunity for administrative supplements, PA-16-344, will support the use of a mechanisms-focused, experimental medicine approach to behavior change research and the development of tools required for implementation beyond the SOBC Research Network. The SOBC Program invites applications to study putative targets/mechanisms of action critical to the efficacy and effectiveness of behavior and social interventions to produce and sustain desired change(s) in health behavior(s), including medical regimen adherence, when applied in experimental, clinical, community, or population-level settings.

For the purposes of this announcement, putative intervention targets are synonymous with mechanisms of action and with processes that are hypothesized to be malleable and to play a causal role in producing behavior change. Behavior change, as defined here, includes the initiation, cessation, modification, and maintenance of behaviors, and medical regimen adherence (e.g., diet, exercise, abstinence from substance use, behavioral regimens, treatment regimens) that have broad health implications across a wide range of clinical endpoints.

The SOBC Program and this FOA is focused on supporting research on target validation, assay development, and target engagement activities in one of three specified domains: self-regulation, stress reactivity and stress resilience, and interpersonal and social processes. These three domains are hypothesized to be relevant to multiple health behaviors and implicated in multiple clinical endpoints. Clearly, these are broad and overlapping domains, and some constructs may reasonably be argued to fit into multiple domains. For the purpose of simplicity in supplemental applications, however, we recommend identifying one domain into which a putative mechanism or target fits best, and specify the selected target domain in your application. Speak with one of the scientific contacts about your proposed project if you are unsure which target domain fits best with your activities.

Examples of appropriate supplement activities include, but are not limited to, projects that will:

- Involve experimental manipulation of putative targets/mechanisms of action
- Add one or more measures/assays of a hypothesized target/mechanism
- Adapt an experimental manipulation of putative targets/mechanisms of action for a new health behavior or condition

- Develop or adapt measures/assays of a hypothesized target/mechanism for use in other settings

PA-16-334 solicits applications for administrative supplements to existing NIH awards with eligible activity codes. Eligible activity codes include:

- P01 Research Program Projects
- P20 Exploratory Grants
- P30 Center Core Grants
- P50 Specialized Center
- RF1 Multi-Year Funded Research Project Grant
- R56 High Priority, Short-Term Project Award
- U54 Specialized Center – Cooperative Agreements
- UL1 Linked Specialized Center Cooperative Agreement
- R00 Research Transition Award
- R01 Research Project Grant
- R15 Academic Research Enhancement Award (AREA)
- R21 Exploratory/Developmental Research Grant Award
- R21/R33 Phased Innovation Award
- R34 Clinical Trial Planning Grant Program
- R37 Method to Extend Research in Time (MERIT) Award
- U01 Research Project – Cooperative Agreements
- UH2 Exploratory/Developmental Cooperative Agreement Phase I
- UH2/UH3 Phase Innovation Awards – Cooperative Agreements

Application Details

Applicants are highly encouraged to consult with their Program Officials before submitting an application to be sure the proposed supplemental work is within scope and within the project period as defined by the awarding ICO. Determination of whether a supplemental project is within the original scope of the parent project is made by the Program Official administering the parent grant. Other key details include:

- The parent award must be active and the supplemental research proposed must be accomplished within the competitive segment.
- The supplemental activities must be within the original scope of the parent award.
- There must be sufficient time remaining in the parent project period to allow for completion of the supplemental work.
- The project and budget periods for the supplemental activities must be within the currently approved project period for the existing parent award.
- The research strategy portion of the application is limited to six pages.

Budget Details

Typically, supplement funding can be used to cover cost increases that are associated with achieving certain new research objectives within the scope of the parent award, including the cost of making modifications to the parent project that would increase or preserve the overall impact of the project consistent with its originally approved objectives and purposes. Again, policies and procedures of allowable supplemental activities that are considered within scope of the parent award vary by ICO, and therefore, it is important that prospective applications discuss their ideas with the Program Official of their parent award. Other key budget details include:

- The administrative supplement award will be for 1 year of funding only.
- The budget should be commensurate with proposed activities and is limited to no more than the amount of the parent award.
- The NIH Common Fund intends to commit a *total* of $2 million for these awards in fiscal year 2017, pending availability of funds and meritorious applications. It is estimated that 12–14 awards could be made with this budget.

Review of Applications

Applications to PA-16-334 will not be peer-reviewed. The SOBC Program will conduct a 2-stage administrative review of applications.

1. The Program Official of the parent award will review the application in accordance with ICO-specific policies and procedures concerning administrative supplements. If the application does not meet ICO requirements at this stage, it will not proceed to the next level of review.
2. Members of the NIH SOBC Working Group will convene as a review committee to administratively review each application for scientific merit and responsiveness to the Program Announcement.

Once both stages of the administrative review are complete, the SOBC Working Group will make recommendations to the NIH Common Fund Program. The NIH Common Fund Program will make all final funding decisions.

Scientific Contacts for PA-16-334

- Dr. Will M. Aklin, NIDA, aklinwm@nida.nih.gov
- Dr. Paige Green, NCI, paige.green@nih.gov
- Jonathan W. King, NIA, kingjo@nia.nih.gov
- Melissa Riddle, NIDCR, riddleme@nidcr.nih.gov

Resources for Prospective Applicants

- Funding Opportunity Announcement PA-16-334: http://grants.nih.gov/grants/guide/pa-files/PA-16-334.html
- NIH Science of Behavior Change Common Fund Web site: https://commonfund.nih.gov/behaviorchange/index
- Frequently Asked Questions: https://commonfund.nih.gov/behaviorchange/faq
- Resources resulting from the September 8, 2016 Webinar: https://events-support.com/events/NIH_SOBC_Program_PA-16-334

Summary of Questions and Answers

Can you explain the experimental medicine approach again and how it applies to behavioral change research?

The experimental medicine approach, as applied to behavior change research, involves identifying an intervention target, developing assays (i.e., measures) to permit verification of target engagement, engaging the target through experimentation or intervention, and testing the degree to which target engagement produces the desired behavior change.

What is the difference between a target and a mechanism or process, do they all mean the same thing in this context?

Putative intervention targets represent mechanisms or processes that are hypothesized to be measurable, malleable, and to play a causal role in producing behavior change. It has been hypothesized that self-regulatory functions, processes involved in stress reactivity and stress resilience, and a range of interpersonal and social processes play causal roles in behavior change, including adherence to medical regimens. If this is the case, then intervening to alter these processes could result in behavior change. But overall, we use the word *target* when we are emphasizing the fact that something (a process or mechanism) is what we are intervening on.

Would probing the targets using pharmacological probes be acceptable?

The Program Announcement does not restrict the types of experimental or interventional methods used to engage and verify the engagement of putative targets. If using a pharmacological probe will provide insights on whether you are engaging particular putative target(s) that can lead to health behavior change, then this is the case you are trying to make in your application.

Does a supplemental project have to show change in a clinical end point?

No, not necessarily. For many clinical endpoints, it might not be reasonable to expect change within a 1-year timeframe coinciding with the supplement period. It is acceptable to focus on engaging the putative mechanism/target in the study itself, but the application should make a clear case for why the putative mechanism is important (e.g., it is related to one or more clinical endpoints).

Do we need to show not only that the treatment moves target, but also whether engaging the target impacts clinical endpoints? Also, will we need to measure the putative mechanism at more than one time point? Is that feasible in the time frame and budget?

There is no requirement specifically in this Program Announcement that your supplemental activity would measure the effect of your intervention on the putative mechanism and also the putative mechanism on the clinical endpoint. It would be responsive to measure one piece of that causal chain. It might not be feasible to measure the impact on clinical endpoints within the specified time frame. However, some projects might be farther along than others in the causal chain, which might facilitate study of impact on clinical end points.

Measuring at multiple time points could be a strong strategy, but, in some cases, an appropriate design could be to measure targets at just one time point. For example, if you are introducing measures of a target following the beginning of an intervention in a randomized trial, randomization in theory should mean there is no expected difference between treatment arms in the target you are measuring before the intervention, so seeing a difference after the intervention implies the possibility of target engagement. Overall, the idea is to show that whatever you are attempting to do is having an effect on some putative target. Your proposed activities should represent the best science you can do that are appropriate to your parent project.

Another point of consideration for multiple time points is that the frequency with which you measure target engagement should be connected to the changeability of that process. For example, if you think the process changes moment to moment, it would be appropriate to measure much more frequently. In contrast, if you are examining a more stable process, then it would be appropriate to measure at less frequent time points. Justify your proposed design in the application.

Should the primary outcome be a behavior versus clinical outcomes, such as body composition?

In some cases, you can imagine that a clinical outcome such as body composition is a good primary outcome for the supplemental activity—change in muscle mass for an obesity study, for example. In other projects, it might be that you would not get to an outcome as quickly as that. For example, in a substance use study, you would not have time to demonstrate participants are abstinent for 18+ months if the administrative supplement lasts only a year.

However, you could show that more participants are successfully initiating a quit date and abstaining for an initial period of time.

Are Principal Investigators able to select broad clinical targets such as the gut microbiome?

Yes, this could be possible. For example, it could be appropriate if the application was for a project on healthy eating where you have a predicted effect on the gut microbiome and later outcomes. The Program Announcement does not specify the clinical targets or particular health behaviors, but the target itself **does** need to be identified as being in one of the three domains (self-regulation, stress reactivity and stress resilience, and interpersonal and social processes), **and** clearly connected to one or more health behaviors and/or medical regimen adherence.

Can I apply for support to recruit additional participants for an experimental medicine sub-study so I don't compromise the parent study population?

Yes, this could be an acceptable activity for the supplement project, as would adding existing measures to an ongoing trial. However, you might need to consider the views of your Data Safety Monitoring Board (DSMB), if applicable. Depending on the trial, the DSMB might be concerned about additional subject burden, for example, and might not approve the proposed supplemental activities. Obtain necessary approvals from within your study structure for the proposed supplemental activities before submitting an application.

My study involves animal models of human health behavior. Can I apply for this supplement?

Current NIH-funded research that involves animals as a critical component of a health behavior change intervention may be appropriate. However, research focused exclusively on animal models of human health behavior and social processes are not appropriate for this administrative supplement Program Announcement.

How will these applications be reviewed?

Applications received for PA-16-334 will be reviewed first by the Program Officer of the parent award in accordance with ICO-specific policies and procedures concerning administrative supplements. In the second stage of review, members of the NIH SOBC Working Group will review each application for scientific merit and responsiveness to the FOA.

I understand that the SOBC Research Network already has projects funded; is this FOA for supplements only for them?

This funding opportunity is open to any project with an eligible activity code listed in the FOA, whether or not that project is part of the SOBC Research Network. We encourage new applicants because a main goal of the SOBC Program is to diffuse the experimental medicine approach to behavior change research beyond the currently funded SOBC projects.

What does the six-page research strategy need to include? Is there a list of required elements?

The six-page limit is for the research strategy portion of the supplement, which in any NIH application is supposed to address the review criteria listed in the FOA: significance, innovation, quality of investigators, environment, and approach. Applicants are free to organize the research strategy portion in a way that makes the most sense for the project and presents the best case. Because these are supplements to existing awards, it might be reasonable to show preliminary results from the parent award project, but this is not required.

Is the $2 million dollars of funding available as indicated in the FOA the *total* amount for all the awards, or for *each* award?

The $2 million in available funding is the total amount spread across all the awards. There have been occasions, however, where ICOs have funded additional meritorious supplement awards in their areas of interest, which is yet another reason to be in touch with the Program Official of your award in advance.

You've said that these are 1-year awards. What if the design requires retesting and a longer time frame to collect the data? Can the supplemental project use a no-cost extension?

Administrative supplements are added to current parent award, so whatever the current award is allowed to do, the supplement funding can be used for that too. In other words, if the parent award receives a no-cost extension, the supplemental funds and activities could also be part of that extension.

The SOBC Program will only make one award in fiscal year 2017; additional money will not be awarded in subsequent years.

If a parent study has more than 1 year remaining, can the supplement funds be used across the remaining years?

Administrative supplements are added to current parent award, so whatever the current award is allowed to do, the supplement funding can be used for that too. Discuss the project period with your Program Official because the specifics of this question might depend on ICO-specific policies and procedures for administrative supplement awards.

Is a subcontractor to an R01 award allowed to apply?

Only the named Principal Investigator(s) on the parent award can submit an application. However, it could be appropriate for the Principal Investigator(s) to apply for supplemental funds for activities that the subcontractor is intended to perform as part of the overall project.

Can one Principal Investigator submit two applications for two different R01 parent awards?

Yes, an individual who serves as a Principal Investigator on more than one current award could submit more than one application to PA-16-334, as long as there is only one application per parent award. The FOA states in Section III, 3, that "Only one administrative supplement application per parent award will be considered for this FOA."

Can a Principal Investigator apply for and receive this supplement award if he/she is also applying separately for a diversity supplement?

Yes, if you have an application pending for a diversity supplement, you can still apply to PA-16-334.

My project will be in a no-cost extension by the time these are awarded. Can I still apply?

Projects must have sufficient time remaining to allow for completion of the supplemental work. The project and budget periods must be within the currently approved project period for the existing parent award. ICOs handle supplementing projects in no-cost extensions differently, so it is best to discuss this with your Program Official first. Also, you might want to think carefully if your project is in a no-cost extension whether you really have time to do the proposed supplemental work.

How long should my application be?

The research strategy portion, which is the most critical component of your application, is limited to six pages.

When do you think I need to talk to my Program Official and one of the scientific contacts?

Early and often. More seriously, engaging your Program Official early in the process to find out if you are even eligible, or whether the ICO would be comfortable supporting your application, is just the very least you can do. Similarly, engaging one of the scientific contacts early on might make the difference between proposing something that would not be competitive for this FOA and something else that would be extremely competitive. You should talk to us often because as your idea changes and evolves, we may have different opinions on how best to improve it, or make the strongest case for your projects.

If there is approximately $2 million available and there will be 10–12 awards, would this imply budgets of approximately $150-$200K for most supplements?

Supplement budgets are limited to no more than the amount of the parent award. The actual number of applications funded will depend on the size, responsiveness, and merit of the applications. In many cases, ICOs have limits or recommendations on *direct* costs of administrative supplements (e.g., in some cases, a request for more than $100,000 in direct

costs could trigger an additional level of review, and could make your application difficult to fully evaluate or fund).

Does this opportunity apply to provider behavior?

Yes, a supplemental application can propose to examine provider behavior, as long as the applicant can make a compelling case that provider behavior is important to one or more health behaviors, that provider behavior figures into an experimental medicine approach to behavior change, and that the project focuses on a target or process that falls into one of the three broad target domains (self-regulation, stress reactivity and stress resilience, or interpersonal and social processes). Including or focusing on provider behavior may add complexity to a test of mechanisms of behavior change, so it may be especially important in such cases to clearly specify the intervention or manipulation meant to engage a target, what the target or process is, how target engagement will be measured, and the effect(s) expected on some proximal health behavior or distal clinical endpoint.

Are international consultants allowed on the budget?

Yes, international consultants are allowed on the study budget. As with all consultants on NIH-funded projects, their role must relate directly to the project.

Are reviewers able to view the parent grant or do submissions need to include enough details about the parent grant and explain how this submission is synergistic or different?

No. Reviewers will be instructed to evaluate the content of the supplement application alone without referring to the parent grant. It is imperative to first ensure the supplement is within the scope of the parent grant (confirm with the Program Official), and provide enough detail about the parent grant and indicate how the proposed supplement aligns with or enhances the goals of the parent grant.

I have a study supported by the Clinical and Translational Science Award (CTSA) pilot program at my institution. Can I apply for a supplement under this FOA?

Please check with the Principal Investigator of your CTSA grant. Note that the currently funded project supported by the CTSA program must have ongoing funding for the expected duration of the planned administrative supplement. Awards for successful applications in response to this FOA are not expected to be issued until the summer of 2017. Thus, the underlying project must have ongoing support at least through summer of 2018. Additionally, the proposed supplement activity must be within the scope of the ongoing project supported by the CTSA award. Requests for funding for new projects unrelated to an ongoing CTSA-supported project are not allowed under this FOA.

I have a project supported by a CTSA KL2 grant. Can I apply for a supplement?
No. The KL2 is not an eligible activity code for this FOA.

Is it expected to use mediation analysis to analyze the data?

This announcement defines a mediator as a variable that is hypothesized to be part of a causal chain between an intervention and an outcome, but for which causation has not yet been established. Until a mediator is shown to cause an outcome, it cannot be considered a mechanism of action, but can be considered a putative (or hypothesized) mechanism of action. In contrast, a mechanism of action is a demonstrated part of a causal chain between an intervention and its effect. Following from these definitions, mediators may be tested as possible causal mechanisms of an intervention's effect, and such tests must be designed to allow for causal conclusions. Also for the purposes of this announcement, the term "target" refers to the putative mechanism an intervention is meant to engage in order to cause behavior change. The expectation is to develop a design and subsequent analyses to ensure the study is properly conducted and will yield statistically valid answers to the study questions.

Should one use the Research Domain Criteria (RDoC) approach recommended by the National Institute of Mental Health?

In line with the goals of the SOBC Program, your application should address one of the three behavior change target domains specified in the FOA (self-regulation, stress reactivity and stress resilience, or interpersonal and social processes). Applications should identify candidate targets of interest that fit into one of the three SOBC domains, which could also be included in the RDoC framework.

Can this be a multiple Principal Investigator (PI) supplement with the original PI and a new PI together? Can the supplement include a Co-PI who was not included on the parent grant?

As noted in the FOA, this administrative supplement application may not be used to add, delete, or change the PIs listed on the parent award. Visit the Multiple Program Director/Principal Investigator Policy in the SF424 (R&R) Application Guide for more information.

Can one apply for this supplement for a project that has not begun recruiting but will be recruiting by the time the supplement is awarded?

Yes, it is acceptable to apply for a supplement award before a parent project has begun recruitment. However, it is important to include a detailed timeline that corresponds with the 1-year award period, as awards are expected to be made by September 1, 2017.

Can one request a delay in the supplement if awarded until a substantial number of participants have been enrolled?

Because only funds from fiscal year 2017 are being used for this FOA, no delayed awards will be issued. But do see the answers to previous questions concerning whether supplemental funds

could be used to support activities after the one year we are making the award for is over; in most cases, funds would still be available in future fiscal years.

Does the intervention need to be an already validated procedure?

Not necessarily. A newly developed intervention can be used as long as the supplement is designed to test how and why the intervention produces and sustains desired outcomes.

Is there a one-page specific aims in addition to the six pages?

All aspects of the research strategy, including the description of the specific aims, must fit within six pages. The application does not allow for an additional page to describe the specific aims.

Is there a minimum percent effort that PIs need to include in the budget to demonstrate adequate time/commitment?

There is no minimum percent effort required for PIs on supplemental projects. As with most grant projects, the percent effort should be sufficient to demonstrate scientific leadership of the project, although as noted in the answer to one of the above questions, the greatest portion of an award could be made to investigators working on a subcontract.