The National Institutes of Health (NIH)
Science of Behavior Change (SOBC) Common Fund Program

SOBC Research Network
UH3 Transition Application
Guidance for Investigators

All UH3 transition application materials are due to NIH by April 9, 2018.

Revised December 12, 2017

National Institutes of Health
Office of Strategic Coordination - The Common Fund

SOBC Science Of Behavior Change

Contents

Overview

The objective of the UH3 phase is to complete Step 4 of the target validation activities described below. The original Requests for Applications (RFAs) instructed applicants to propose UH3 phase activities designed to evaluate the validity of putative targets by integrating the assays tested in the UH2 phase into controlled experimental or early stage intervention studies. The goal of activities in the UH3 phase is to produce short-term health behavior change in a controlled environment via target engagement in two or more health behaviors, one of which must be medical regimen adherence.

UH2 Phase

1. Identify a set of putative targets within the self-regulation domain that are implicated in medical regimen adherence and at least one other health behavior;
2. Leverage existing or develop new experimental or intervention approaches to engage identified targets;
3. Identify or develop appropriate assays (measures) to permit verification of target engagement;

UH3 Phase

4. Test the degree to which engaging identified targets produces a desired change in medical regimen adherence and at least one other health behavior. While testing target engagement in specific clinical samples is permitted, the identified targets and the behavior change outcomes measured should be selected based on their hypothesized relevance to at least two clinical endpoints or disease conditions.

This guidance provides an overview of required UH3 transition application contents and the administrative review considerations NIH will use when evaluating applications. The request for transition to the UH3 phase must be completed using the application forms required at the time of submission. The PHS 2590 application forms (Type 4 noncompeting continuation application) are the currently required forms. This UH3 transition application serves as a Type 4 application. **Please submit a PDF of the entire application package to your Program Official (PO) and copy chandra.keller-allen@nih.gov by April 9, 2018.**

You will also submit the same, or similar, information for the regularly required Type 5 Research Performance Progress Report (RPPR) via the eRA Commons on the normal timeline. Talk to your PO if you have any questions.

The SOBC Program awards are *funded* by the NIH Common Fund, which is part of the Office of the NIH Director, and *administered* by individual Institutes and Centers (IC). The Common Fund will make final funding decisions no later than early August 2018. Projects that move to the UH3 phase will need to work with their POs to supply additional information and materials (e.g., Just-in-time (JIT) information). In particular, the IC administering your reward will request materials relating to the new clinical trials requirements such as protocol synopses for each proposed study that meets the NIH definition of a clinical trial, Institutional Review Board application(s), informed consent waiver(s), and data and safety monitoring plan(s) in the format required by the IC. You may wish to discuss these JIT requirements with your PO ahead of time and prepare in advance.

Resources

PHS 2590 Application Forms: http://grants.nih.gov/grants/funding/2590/2590.htm

General Instructions for PHS 2590 forms: https://grants.nih.gov/grants/funding/2590/phs2590.pdf

RFA-RM-14-020 (self-regulation) https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-14-020.html

RFA-RM-14-019 (stress) https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-14-019.html

Clinical trials guidance: https://osp.od.nih.gov/clinical-research/clinical-trials/

DSMP guidance: https://humansubjects.nih.gov/data_safety

Required UH3 Application Contents

1. PHS 2590 Form pages 1-3
    a. Face page, detailed budget pages for all proposed UH3 years, and budget justification
    b. Biographical sketches for all key personnel
2. *SOBC-specific progress report summary form
    a. Use up to 12 pages for the progress report summary. Ignore the 2-page limit.
    b. Use the SOBC-specific template provided for the progress report summary (NOT the Form Page 5 downloadable from the PHS 2590 site)
    c. The progress report summary includes three sections:
        i. UH2 milestones
        ii. Participation in the SOBC Research Network
        iii. UH3 planned activities
    d. We advise that you discuss with your PO/PS team any broad deviations from the UH3 planned activities outlined in your original application prior to submitting the application.
3. PHS 2590 Form pages 6-7
    a. Checklist
    b. All personnel report
4. Human Subjects Information: Talk to your Program Official if you are unsure whether a study meets the NIH definition of a clinical trial. For more information, visit https://osp.od.nih.gov/clinical-research/clinical-trials/. For each unique proposed UH3 study,
    a. Identify whether it meets the NIH definition of a clinical trial
    b. Provide a targeted enrollment form
5. Inclusion enrollment form for UH2 phase (if applicable)
6. *Initial Data and Safety Monitoring Plan (DSMP): Research grant applications that involve clinical trials must include a general description of the DSMP. Upon award, a detailed DSMP will be requested by the administering IC. For the initial DMSP in this application, include the following:
    a. The overall framework for safety monitoring and what information will be monitored
    b. The frequency of monitoring, including any plans for interim analysis and stopping rules (if applicable)
    c. The process by which Adverse Events, including Serious Adverse Events (SAEs) such as deaths, hospitalizations, and life-threatening events and Unanticipated Problems (UPs), will be managed and reported, as required, to the IRB, the person or group responsible for monitoring, the awarding IC, and other entities as appropriate

d. The individual(s) or group that will be responsible for trial monitoring and advising the appointing entity

*An SOBC-specific template will be provided for this item.

NIH Administrative Review Considerations

1. **UH2 Milestones**: Successful achievement of the UH2 study-specific milestones
    a. Has a set of putative targets been identified?
        i. Do these putative targets have relevance to multiple health behaviors, at least one of which is medical regimen adherence?
        ii. Have these putative targets been shown to be promising drivers of behavior change?
        iii. Are these putative targets likely to be measurable in multiple ways and at multiple levels (e.g., biological, behavioral, social)?
        iv. Are these putative targets likely to be malleable?
    b. Have existing or new experimental manipulations or intervention approaches been developed to engage putative targets?
        i. Have experimental manipulations or intervention approaches been developed or identified?
        ii. Have these experimental manipulations or intervention approaches demonstrated a high likelihood of engaging one or more putative target(s)?
    c. Have assays (measures) been identified or developed to assess target engagement?
        i. Have assays (measures) been identified or developed?
        ii. Have these assays (measures) demonstrated a high likelihood of assessing engagement of one or more putative target(s)?
        iii. Do these assays (measures) capture target engagement at different levels (e.g., biological, behavioral, social)?

2. **Proposed UH3 Activities**: Potential for successfully completing the UH3 planned activities
    a. Are the planned projects for the UH3 phase feasible and likely to be successfully achieved based on UH2 phase progress?
    b. Is the initial DSMP adequate and consistent with NIH and SOBC Research Network guidelines?
    c. If UH2 phase activities resulted in changes to the plans for the UH3 phase, are these clearly explained and adequately justified?

3. **SOBC Research Network Activities**: Demonstrated ability of the UH2 team to work within and contribute to the Network structure
    a. In conducting the UH2 phase work, has the study team facilitated the goals of the Network in working with the Resource and Coordinating Center (RCC), Steering Committee, and applicable sub-committees?
    b. To what extent have assays, measures, and/or intervention protocols been shared with the RCC for the benefit of the Network and the public SOBC Measures Repository?

4. **Program Priorities for the Project**
    a. As UH2 activities have been completed, do the UH3 aims and planned activities remain a priority for the SOBC Research Network and for the administering NIH Institute or Center?

b. Is there a high potential for the study to develop useful resources (e.g., tools, methods, best practices) that will be generalizable for behavior change research, advance the overall goals of the SOBC Research Network to identify promising targets for behavior change, and develop measures to be used in subsequent studies testing causal mechanisms of behavior change?

5. **Availability of Funds**
   a. Per the RFA language: "for the UH3 phase, application budgets are limited to $1.25M in total costs [per year] for FY18 and FY19. All application budgets should reflect the actual needs of the proposed project."
   b. Is the detailed annual budget for the UH3 phase project appropriate for the intended scope of work and funding of the Network effort?
   c. Are any changes in the proposed budget anticipated because of the UH2 phase? Is the budget realistic and feasible?

NIH Implementation Team Contacts

Each UH2 cooperative agreement award is assigned a PO from the IC that administers the award funded by the Common Fund, and one or more Project Scientists. A "lead" Project Scientist is designated in cases where the UH2 award has more than one Project Scientist. Some individuals have roles on more than one UH2 award.

Last Name	First Name	IC	Email	Role
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PO: Program Official
PS: Project Scientist