UH3 Transition Application Guidance

NIH SOBC Implementation Team

Updated November 16, 2017

Agenda

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2. Timeline
3. Required Application Contents
4. Administrative Review Considerations
5. January 2018 Steering Committee Meeting
6. Q&A

Purpose: UH2/UH3 Phased Award

- UH2 Phase Target Validation Steps
  1. Identify a set of putative targets (in the selected 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

Purpose: UH2/UH3 Phased Award

- UH3 Phase Target Validation Step
  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 targets identified and the behavior change outcomes measured should be selected based on their hypothesized relevance to at least two clinical endpoints or disease conditions

Timeline

- **March 1, 2018**: Notify your Program Official (PO) if you do not plan to submit a transition application
- **April 9, 2018**: UH3 transition application due to NIH. No exceptions
- **April-June, 2018**: NIH administrative review process
- **Mid-July, 2018**: Funding decisions made

Required Application Contents

- PHS 2590 Form
  - **https://grants.nih.gov/grants/funding/2590/2590.htm**
  - Pages 1-3: face page, detailed budget, justification, bio sketches
  - Page 5: **progress report summary** (up to 12 pages)
  - Pages 6-7: checklist and personnel report
  - **Human subjects information**
  - Inclusion enrollment form from UH2 phase (if applicable)
  - Appendix
    - Overview of **Data and Safety Monitoring Plan(s)**

Progress Report Summary (12 pages)

- NIH will provide you with a template for the 12-page Progress Report Summary that includes three sections:
  1. Section 1: UH2 milestone progress
  2. Section 2: SOBC Research Network participation
  3. Section 3: UH3 planned activities

Section 1: UH2 Milestones

- Describe how each milestone has been achieved
- Provide deliverables or metrics to demonstrate extent to which each milestone has been met
- Provide justification or explanation for any unmet milestones, or problems encountered

Section 2: Network Participation

- Describe how study team contributed to goals of the SOBC Program and Research Network
  - Examples include collaboration with other UH2 teams, participation in Network outreach and dissemination efforts, participation in Grand Rounds, participation in monthly Steering Committee calls and regular contact with NIH PO and Project Scientists, and contributing to developing Network processes
- Describe the extent to which the study team shared assays, measures, and/or intervention protocols with the RCC for inclusion in the SOBC Measures Repository

Section 3: UH3 Planned Activities

- Describe the planned activities for the UH3 phase
- Provide a justification for any proposed UH3 activity that is different than what was in the original application
- Provide evidence for feasibility and likelihood of successfully completing the UH3 planned activities

Human Subjects Information

- For each unique proposed UH3 study,
  - Identify whether it meets the NIH definition of a clinical trial
  - Provide a targeted enrollment form
- 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/

Data and Safety Monitoring Plan

- For any proposed clinical trial, NIH requires a data and safety monitoring plan (DSMP) that is commensurate with the risks of the trial, its size, and its complexity. Provide a brief description of the DSMP, including:
  - The overall framework for safety monitoring and what information will be monitored
  - The frequency of monitoring, including any plans for interim analysis and stopping rules (if applicable)
  - 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 Institute or Center, and other entities as appropriate
  - The individual(s) or group that will be responsible for trial monitoring and advising the appointing entity

NIH Administrative Review Considerations

1. Successful achievement of the UH2 milestones
2. Potential for successfully completing proposed UH3 activities
3. Demonstrated ability of the study team to contribute to the SOBC Research Network
4. Alignment of UH3 phase plans with SOBC Program priorities
5. Availability of funds

January 2018 In-person Meeting

- 30 minutes allotted to each UH2 team presentation plus 15 minutes of discussion and Q&A
- One or more of the named PIs should present
- NIH will solicit feedback from the External Scientific Panel (ESP) on each project based on these presentations
  - The ESP will be asked to consider how successfully each project is contributing to the larger goal of the SOBC Program to advance the experimental medicine approach to behavior change in the research community

January 2018: Project Presentations

Presentations should include:

1. Demonstrate how the UH2 project has contributed, and will contribute in the UH3 phase, to the larger SOBC Program goal of advancing the experimental medicine approach to behavior change research
2. UH2 milestone progress
3. Evidence of SOBC Research Network participation
4. Proposed UH3 planned activities

Q&A