## **Roybal P30 Introductory Conference Call – Meeting Minutes**

|  |  |  |  |
| --- | --- | --- | --- |
| **Date:** | Thursday, February 6, 2020 | **Call led by:** | Karina Davidson, RCC (Northwell) |

**Participants:** Janet Bettger, Partha Bhattacharyya, Niteesh Choudhry, Jason Doctor, Joe Doyle, Don Edmondson, Frank Keefe, Kathi Heffner, Ken Hepburn, Sue Hughes, Jeff Kaye, Honora Kelly, Ian Kronish, Margie Lachman, Vanessa Madden, Lisa Onken, Molly Perkins, Karl Pillemer, Kevin Volpp, Elaine Wethington

|  |
| --- |
| **Introduction/Executive Summary** |
| 1. **Conference call objectives**:    * Introduction of all the principal investigators from the Roybal consortium to each other as well as a welcome from the two NIA program officers    * Coverage of important announcements, updates, and the request for input 2. **Underlying mission of the Roybal Coordinating Center**    * We believe that the RCC can best support you by asking almost nothing of you, respecting your time as much as possible, and offering what you suggest to be useful resources    * We have a philosophy that all resources will be optional and available should they be useful to a given center or individual junior colleagues who are conducting pilot investigations |
| **Summary of Key Grant Related Announcements and Reminders**  **(Lisa Onken, Partha Bhattacharyya, Karina Davidson)** |
| 1. **Key differences between the new RFA and the old RFA:**  * The NIA wanted to ensure that Roybal pilot studies were maximally useful and potent. **The goal is therefore to provide the opportunity to conduct fully powered, meaningful pilots.** * The RFA for Roybal Centers has **increased its funding substantially** from a maximum of $300,000 to a new maximum of $500,000. In conjunction with an increase in funds, the NIA has **decreased the number of required pilots** from 6 pilots a year to 2 pilots a year. The intention was not for additional funds to go into the other infrastructure of the Roybals but rather to bolster those pilots. * In the previous RFA, sites would conduct pilots in which N could be as small as 5. Now, **clinical trial is required so that sites can create pilots with power.** The expectation with the above changes is that sites will be able to conduct fully fleshed-out **pilots with power that will eventually lead to an R01 grant.** Our goal is for some of the 80 **pilots that come through to migrate over to Stage IV and subsequently receive funding**; we have not seen much come out of these programs to date. * The new RFA is built around the **NIH Stage Model** so the expertise at every different level of intervention development can be supported; centers should not only develop the best most potent behavioral interventions but actually go back to Stage I as much as necessary in order to refine the interventions, come up with training procedures, test those procedures, and to make sure that the intervention can be implemented in the real world.  1. **Pilot Approval**    * **Even if you stated your pilots in your grant application, you still need to ascertain pilot approval from your program officer**.    * **Sites should be proposing pilots for the next year in their RPPRs. Guidance for essential content to be included is available on the website and RFA language is highlighted below:**   All awardee-selected **projects require prior approval by NIH prior to initiation** (with exceptions allowed as described below).     The awardee institution will provide NIH with written study protocols that address risks and protections for human subjects in accordance with [NIH's Instructions for Preparing the Human Subjects Section of the Research Plan](https://urldefense.proofpoint.com/v2/url?u=https-3A__grants.nih.gov_grants_guide_url-5Fredirect.htm-3Fid-3D12000&d=DwMFAg&c=vq5m7Kktb9l80A_wDJ5D-g&r=fTjH30IHZ_qlE_yoDry_kgZRXhl2-nddmrwhK_xJL0Y&m=3ZJ6NtwxPELRTSd4-UmwOCABBXrF_14FpK7xePnXeGQ&s=nIVmQXnbw7c6LVGFKhJHH7CyGDtfC0VNJo4cwKofUz4&e=). The awardee institution will provide NIH with specific **plans for data and safety monitoring** and will notify the IRB and NIH of serious adverse events and unanticipated problems, consistent with [NIH DSMP policies](https://urldefense.proofpoint.com/v2/url?u=https-3A__grants.nih.gov_grants_guide_url-5Fredirect.htm-3Fid-3D21600&d=DwMFAg&c=vq5m7Kktb9l80A_wDJ5D-g&r=fTjH30IHZ_qlE_yoDry_kgZRXhl2-nddmrwhK_xJL0Y&m=3ZJ6NtwxPELRTSd4-UmwOCABBXrF_14FpK7xePnXeGQ&s=mxVHC3_keMG35FCg1dbQNn93Yda6nbi1BJAVvNjdVoI&e=).   In the competing year, pilot projects (including those described in the competing application) must be submitted for approval by no more than 6 months after the start of the award.  **All pilot projects for subsequent award years should be described in the non-competing continuation progress report; descriptions should be a maximum of 2 pages in length.** The progress report should include detailed budgets for proposed pilots and the Curriculum Vitae of the proposed pilot project investigator. The progress report should also contain appropriate human subjects clearances for proposed pilot projects in accordance with NIH's Instructions for Preparing the Human Subjects Section of the Research Plan. Pilot projects with foreign components will require NIH and State Department foreign clearance prior to award. NIA will not accept pilot project proposals at other times during the year when there are unexpected opportunities or timeliness issues arise, if the institution wishes to redirect existing funds within the Center. If a pilot is proposed at another time, there must be a compelling justification citing the unexpected opportunity or timeliness issue. These pilot projects should be sent by email directly to the NIA Program Official and the NIA Grants Specialist along with an explanation of how funds would be redirected. |
| **P30 Sites** |
| Introductions of site PIs and/or representatives and discussion of major research focus **(see addendum)** |
| **Roybal Coordinating Center Resources** |
| * Externally facing **website** is live: <https://www.roybalniaresearchcenters.org/>. Shortly, we will release the internal website which will hold meeting notes, resource documents, announcements, and newsletters. * **AD Supplement for non-AD grants**: If you are a non-AD Roybal Center with an idea for a one-year supplement that would focus on Alzheimer’s or the related dementias, you are eligible to supplements for NOT-AG-20-008 to develop focus on ADRD in your interventions. (<https://grants.nih.gov/grants/guide/notice-files/NOT-AG-20-008.html>) * The RCC is in the process of finalizing development of a **Roybal data repositor**y through CTSA’s **WebCAMP software**. This will be a place to record pilot information for the RPPR and submit documents/info for pilot approval (to be reviewed by Program Officers). Training webinars will be available once finalized. * RCC proposed the creation of a **Single DSMB** for Roybal Center pilots requiring DSMB oversight (supplement pending). |
| **Roybal Annual Conference** |
| 1. **UPDATE**: Due to some key representatives at the NIA not being able to attend, **the annual conference is postponed until the fall.** Look out for another Doodle Poll. 2. **Please send along any suggestions for sessions at our annual conference**.   Dr. Keefe: So many projects involve interventions at different stages so treatment fidelity might be a particularly important issue to address. How treatment fidelity applies to the development of the interventions would be incredibly useful. We can discuss how to apply that stage of the science to these different projects that people are describing both through a formal presentation and an informal discussion. |