REQUEST FOR PROPOSALS

Pilot and Feasibility Program

Health Delivery Systems – Center for Diabetes Translational Research

The Health Delivery Systems - Center for Diabetes Translational Research (HDS-CDTR) invites proposals for preliminary research that will provide pilot data essential for planning future diabetes translational research R01s, R21s, R34s, and R18s by Early Stage Investigators. All proposals must be aligned with the primary goals of diabetes translational research, which are to improve the effectiveness of diabetes care and prevention by making evidence-based practice more consistent and widespread, and to further our understanding of what works most efficiently to accomplish this translation.

Health Delivery Systems – Center for Diabetes Translational Research

Kaiser Permanente Northern California
HealthPartners Institute for Education and Research
University of California San Francisco
Harvard Pilgrim Health Care Institute

Support provided by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
[P30-DK092924]

UPDATED: January 2019

HDS-CDTR Pilot and Feasibility Program

Sponsoring organization: Health Delivery Systems – Center for Diabetes Translational Research (HDS-CDTR). The aim of this Center is to actively foster and support translational research in diabetes within health care delivery systems affiliated with the Health Care Systems Research Network (HCSRN), University of California San Francisco, and safety net health care organizations.

This Center addresses three core areas to improve diabetes care:

- health care disparities
- diabetes and obesity prevention
- health information technology interventions

Support is provided by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) [P30-DK092924]. More information is available at http://diabetestranslation.org/ .

The Pilot and Feasibility Program is one of the specific aims of the Health Delivery Systems – Center for Diabetes Translational Research (HDS-CDTR): "To create a Pilot and Feasibility Program to support and fund preliminary research that will provide pilot data essential for planning future diabetes translational research R01s, R21s, R34s, and R18s by Early Stage Investigators."

Eligible individuals/organizations: Applicants must be an Early Stage Investigator, with a doctoral degree (e.g. MD, PhD, DrPH) affiliated with one of the HDS-CDTR institutions (Kaiser Permanente Northern California, HealthPartners Research Foundation, University of California San Francisco, Harvard Pilgrim). Any individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for support. For definition of Early Stage Investigator, see http://grants.nih.gov/grants/new_investigators/.

Review and award process: The HDS-CDTR Program Committee members will review and score proposals. *Additional review may be provided by the HDS-CDTR External Advisory Board.* Selection of a proposal for award will be made within 8 weeks of submission date, with the caveat that a proposal may be selected provisionally with the award dependent on fulfilling any requirements or concerns of the Program Committee. Awards will be made to the awardee's institution on behalf of the awardee. The total amount to be awarded in this grant cycle shall not exceed $80,000. We expect to give out 2 awards this funding cycle.

Expectations: Awardee will be asked to provide quarterly progress reports to the HDS-CDTR Director, Julie Schmittdiel (send to Deanne Wiley (deanne.wiley@kp.org)) and expected to present at both an HDS-CDTR faculty meeting webinar and a national CDTR meeting webinar. Upon completion of the proposed project, there is an expectation that pilot data will have been collected for planning future diabetes translational research R01, R21, R34, or R18 by the applicant. In addition, it is expected that the investigators will use the results of the study to support the submission of a grant application within 6 months of completion of the study.

Questions: Please contact Deanne Wiley (deanne.wiley@kp.org) for assistance or questions.

Application

Applicants must complete the Pre-Application Clinical Trials Questionnaire. If a selected proposal is a clinical trial, additional materials may be requested including registering the project on ClinicalTrials.gov before award.

Pre-Application Clinical Trials Questionnaire (Required)

Before submitting an application, please complete the below Clinical Trials Questionnaire as appropriate.

Clinical Trials Questionnaire:

1. Does this study involve human participants? Yes/No
2. Are participants prospectively assigned to an intervention? Yes/No
3. Is the proposed project designed to evaluate the effect of the intervention on the participants? Yes/No
4. Is the effect that will be evaluated a health-related biomedical or behavioral outcome? Yes/No

If you answered Yes to all the NIH questions in the Clinical Trials Questionnaire, the proposed study meets the definition of a clinical trial. Please contact Deanne Wiley (deanne.wiley@kp.org) BEFORE completing an application.

If the proposed project does not meet the definition of a clinical trial, please proceed and complete the application per the instructions.

Application Process: Applicants must submit a written proposal in accordance with the following instructions:

- Applicants must have a sponsoring mentor who is Faculty or Affiliate Faculty of the HDS-CDTR. A letter of support from the sponsoring mentor must be included in the proposal application submission.
- Proposals should follow the designated format in MS Word (outline below). The proposal may be no more than 3 pages in length (excluding references, appendices, and letters of support) and strive to fulfill the four criteria listed below.
  1. A pilot project should be designed to be completed within one year.
  2. Proposals must be submitted electronically to the HDS-CDTR by the application deadline.
  3. Applications that do not comply with these instructions may be delayed or not accepted for review.
  4. Font type size no smaller than Arial font 11 point (10 characters per inch), margins at least 1 inch on all sides.
- Put proposal Lead PI(s) name (e.g., Smith) in the header of every page if the proposal, references, and appendices.
- NIH Biosketches can be bundled into one document (either MS Word or PDF). No more than 2 pages for each Key Personnel and Other Significant Contributor.
- Application should come directly from the applicant individual and must be submitted by email to deanne.wiley@kp.org
- Application deadline: **April 15, 2019, 5PM PST**

Budget Packet: Budget pages, Justification & Biosketches:

- The budget for this project is not to exceed $40,000 in total costs.
- Detailed Budget for Budget Period (Form PHS 398, Page 4).
- Budget Justification (using PHS 398 Continuation Page). Itemize and justify each expense. Include specific explanations of the roles of the principal investigator(s), co-investigator(s), and other project staff.
- Include biosketches for all Key Personnel and Other Significant Contributors. Once applications are selected, Other Support documents for Key Personnel may be necessary. Please do not submit Other Support documents.
- Institutional signatures are not due at this time.

Human Subjects Protection: Although proposals do not need to have been reviewed or approved by the appropriate institutional review boards at the time of submission, the pilot projects selected for an award must be reviewed and approved by the Institutional Review Boards (IRB) of the sponsoring Center site, and the KPNC 'lead' IRB, by August 1, 2019. A planned enrollment table will also be required by August 1, 2019 for proposals that are selected for award.

Review criteria

The project will be selected by the HDS-CDTR Program Committee using the following criteria.

1.Relevance to Diabetes Translational Research

The pilot project must be aligned with the primary goals of diabetes translational research, which are to improve the effectiveness of diabetes care and prevention by making evidence- based practice more consistent and widespread, and to further our understanding of what works most efficiently to accomplish this translation. Translational research for the purpose of these pilots is described as the translation of promising results from clinical studies into day-to-day medical practice, emphasizing using research to promote action and change in real-world healthcare settings

2.Promise for leading to an R-level Grant Submission to NIDDK

Candidate projects will be evaluated on whether the data and information gathered through the pilot could feasibly support a successful K or R-level grant submission for NIH funding. Preference will be given to a research project that is likely to lead to either R34 (Planning Grants for Translational Research for the Prevention and Control of Diabetes and Obesity) or R18 proposal (Translational Research for the Prevention and Control of Diabetes), but a pilot that will lead to an innovative R21 proposal or R01 with high potential impact in the field will also receive strong consideration.

Ideally, pilot completion will be followed by a full NIH grant proposal submission within 6 months. The likelihood of achieving that goal will be a selection criterion for a candidate project.

3.Connection to the Center's Translational Research Cores

The HDS-CDTR has significant depth of expertise in the key Translational Research Core areas of Health Disparities, Health IT, and Diabetes and Obesity Prevention; its Enrichment Program is designed to help investigators, operations leaders, and other stakeholders fully leverage this expertise. A pilot study that encompasses these areas will have the highest priority for selection, since it is most likely to benefit from the Center's Core research strengths. However, a very promising diabetes translational research pilot that falls outside of these areas will also be considered for funding.

4.Support of the Clinicians and Health Plan Leaders in the Delivery System

Successful translational research is developed and implemented in full partnership with the clinicians and operations leaders in the settings in which they take place. A pilot will be evaluated on whether it has the full support of delivery system partners, and whether the research goals align with the organizational goals of the health care system. For example, a pilot that takes advantage of strategic and potentially time- sensitive opportunities, such as the roll-out of a new diabetes prevention program within a Center-affiliated delivery system, would be given a high priority for selection.

HDS-CDTR PILOT PROPOSAL OUTLINE (three-page maximum)

Applicant include full name and contact information:

Applicant institution:

Title of project:

HDS-CDTR Mentor and Institution:

Other key personnel (if applicable):

Project description – provide a succinct and accurate description of the proposed work. State the application's broad objectives and describe concisely the research design and methods for achieving these goals.

Specific aims (for study and activities) including a statement of the major research question and/or hypothesis:

Background and significance, including how the project will fulfill the review criteria? (see RFP for details)

1. Relevance to Diabetes Translational Research
2. Promise for leading to an K or R-level Grant Submission to NIDDK
3. Connection to the Center's Translational Research Cores
4. Support of the Clinicians and Health Plan Leaders in the Delivery System

Data & Methods – This section should be sufficiently detailed to judge whether the methods are feasible, appropriate, and justified.

Timeline and Deliverables:

Plans for future research – Be very specific and include an anticipated timeline for development and submission of a future research proposal.

References: This should not be an exhaustive literature search. Include only citations of the publications referenced in the proposal. Main purpose is to demonstrate the contribution the project will make to the field.

Appendix materials: Use sparingly; limit appendix materials to those that are clearly relevant in evaluating the proposal.

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