Washington University Center for Diabetes Translation Research: Pilot and Feasibility Program

Program Overview and Budget Guidelines

The purpose of the Washington University Center for Diabetes Translation Research (CDTR) pilot and feasibility program is to advance translation research, preferably T3 or T4, in the areas of diabetes, prediabetes/metabolic syndrome, or obesity prevention or treatment. T3 research is translating clinical findings into everyday practice in real world settings; T4 research explores testing and implementing solutions at a population level.

PROGRAM CONSIDERATIONS

All projects should be T3 or T4 and address diabetes, prediabetes/metabolic syndrome, or obesity prevention or treatment. The following definitions for the stages of translational research will be used:

- **T3 Research – Translation to Practice:** Effectiveness, cost effectiveness, and comparative effectiveness studies conducted in practice sites, ensuring the translation of results from clinical studies into clinical practice settings
- **T4 Research – Translation to Population:** Dissemination and implementation research, which identifies and resolves barriers to implementation of evidence-based guidelines into community practice

If you're unsure if your project fits within the mission of this RFA, please contact Allison Phad at allisonphad@wustl.edu, 314-935-3005.

Applicants are encouraged but not required to include use of CDTR cores & services to support their proposed research and to consult with core personnel during the development of their proposal to discuss application of available CDTR tools and services. Information about available cores and services can be found on the CDTR website.

- Dissemination and Implementation Diabetes Research Core (DIDR) provides expertise in advancing the study of implementing, disseminating, and sustaining evidence-based approaches to eliminate disparities and translate diabetes prevention and control practices through integration in real-world settings.
- Health Communication and Health Literacy Core (HCHL) supports investigators in advancing the study of health communication science to test strategies for addressing health disparities in diabetes prevention and control.
- Health Informatics in Diabetes Research Core (HIDR) works to expand the use of state-of-the-art health informatics methods; advance the means of managing, analyzing, and extracting information from large, heterogeneous data sets to accelerate the progress of translational diabetes research, discovery and informatics; and increase the capacity for use of health informatics in diabetes research.

- Policy and Systems Science Analysis Core (PASSA) advances the study of policy and system level interventions in translation research. The core addresses the large gap that exists between the ability of researchers to link policy and systems interventions to the outcomes and prevention of diabetes by providing services to assist in this process.
- Research Partnership with American Indian/Alaska Natives Core (AIANC) addresses the unique challenges of indigenous peoples-focused research and increases the capacity of CDTR investigators to address the root causes of diabetes disparities through a partnership with the Policy Research Center at the National Congress of American Indians and our AI/AN members across the country.
- Solution to Diabetes in Black Americans (SDBA) provides methodological and content expertise to advance the field of diabetes research in Black Americans through a partnership with the Council on Black Health

APPLICANT ELIGIBILITY

- Principal Investigators must be members of the CDTR (or eligible for membership). Membership criteria and application are available on our website. For assistance with applying, contact the CDTR Research Coordinator, Allison Phad, at allisonphad@wustl.edu or 314-935-3005.
- Applicants from Washington University or CDTR partner academic institutions must hold a faculty level appointment. Fellows in the final year of training with a letter of commitment from their department head for a faculty position effective by the time of award are also eligible.
- Applicants may be the Principal Investigator on **only one LOI and one proposal**. There can be only ONE Principal Investigator on an application.
- PIs previously funded by the CDTR Pilot and Feasibility program are not eligible to apply.

Investigators in the following categories are encouraged to apply.

- New investigators in either translational research who do not yet have their own peer-reviewed research support. NIH 'New Investigator' definition: The individual has not competed successfully for a substantial, competing NIH research grant. In terms of NIH awards, the PI still fits into the New Investigator category if the PI only received such awards as a Mentored Career Award (K08, K12, K23, etc.) or small or early stage research awards, including R03, R15, R21, etc. This same logic would also apply to funding from other agencies.
- Established investigators who are working in other fields, but are interested in exploring new directions in diabetes translational research.
- Established investigators already active in the field of diabetes/obesity research, but whose proposed project is different from their previous work.
- Investigators collaborating with community-based organizations.

REQUIREMENTS FOR PILOT & FEASIBILITY AWARD RECIPIENTS

- Acknowledge CDTR support on all publications related to Pilot & Feasibility Award (P30 DK09250).
- Comply with NIH Public Policy: http://publicaccess.nih.gov/
- Recipients will assist the CDTR in collecting follow-up data regarding their career progression.

LETTER OF INTENT REQUIREMENTS

1) Descriptive title of proposed research
2) Overall aim/hypothesis of proposed research and how this project fits with the investigator's overall research plan (4-5 sentences)

3) Name, e-mail address, and telephone number of the Principal Investigator
4) Names of other key personnel
5) Participating institutions
6) Name, title and email address of 3 potential reviewers. Reviewers do not have to be CDTR members but should not include Co-Is, direct supervisors, or department heads.

APPLICATION REQUIREMENTS

1) **PHS 398 facepage** – including department grants administrator contact information
    a. "Official Signing for Applicant Organization" is not required

2) **Research Plan** - maximum of **5 single-spaced pages for sections A - C** (described below) including tables and/or figures; use Arial 11 point font size or larger; minimum 0.5 inch for all margins for all pages. The following headings should be used noting "N/A" for non-applicable sections:

   If this is a Resubmission application: An Introduction must be included that summarizes the substantial additions, deletions and changes to the application. The Introduction should also include a response to the issues and criticism raised in the previous review, be no longer than one page in length, and is not part of the 5-page limit for the Research Plan.

   A. **Specific Aims:** State concisely the hypothesis to be tested and the specific aim(s) to be achieved during the pilot award. The aims must be reasonable to achieve during the one-year budget period of the grant.

   B. **Research Strategy:**
      i. Significance:
         1. Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
         2. Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
         3. Describe how the concepts, methods, technologies, treatments, services, or preventive interventions that drive this field will be changed if the proposed aims are achieved.
      ii. Innovation:
         1. Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
         2. Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation or intervention(s).
         3. Explain any refinements, improvements, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions. iii) Approach:
         4. Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately, include how the data will be collected, analyzed, and interpreted as well as any resource sharing plan as appropriate.
         5. Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
         6. If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work.

7. Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.

If an applicant has multiple Specific Aims, then the applicant may address Significance, Innovation, and Approach for each Specific Aim individually, or may address Significance, Innovation, and Approach for all of the Specific Aims collectively.

Preliminary Studies. If applicable, include relevant information on Preliminary Studies. Discuss the PI's preliminary studies, data, and/or experience pertinent to this application as part of the Research Strategy, keeping within the sections listed above: Significance, Innovation, and Approach.

C. **Next Stage Funding:** Identify potential funding sources for the next stage of this project. If known, include all four of the following: name of PI for external grant submission; 2) funding agency; 3) funding mechanism; and 4) anticipated date of submission.

D. **Bibliography and References Cited:** Provide a bibliography of any references cited in the Research Plan. Each reference must include names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Follow scholarly practices in providing citations for source materials relied upon in preparing any section of the application.

The references should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research.

E. **Protection of Human Subjects (follow NIH guidelines):** Go to the Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan. Do not use the protection of human subjects section to circumvent the page limits of the Research Strategy. Include a **Planned Enrollment Report** and a **Data and Safety Monitoring Plan,** if applicable to your project.

3) **List of key personnel/other significant contributors**

A. Key Personnel are individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries are requested. (These individuals will have effort included on the budget or will be a paid consultant.)

If PI is an Established Investigator: Describe how this project will lead to a new direction in your research or is different from your previous work.

B. Other Significant Contributors are individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort to the project. Unpaid consultants/collaborators should be included if they meet this definition.

4) **Detailed Budget Pages** – see below for allowable costs

5) **Budget Justification -** provide a short justification for all costs (both personnel and non-personnel). Describe the role of each individual listed on the project. Do NOT include any salary figures in the justification. For non-personnel costs, itemize the expenses and describe how they will be used to conduct this project.

6) **Biosketches** - Submit biosketches in the new NIH format for Key Personnel and Other Significant Contributors. The biosketch is limited to five (5) pages and includes 4 sections: Personal Statement, Positions and Honors, Contribution to Science, and Research Support.

7) **Letters of Support** – from any collaborators not listed as key personnel

BUDGET GUIDELINES

Allowable Direct Cost Items

Funding will be provided for items essential to the conduct of the project.

Personnel

- Allowable personnel expenses include salary and applicable fringe benefits for: the principal investigator, co-investigator(s), postdocs and graduate students if employees receiving a salary, and other professional and technical staff.
- The current NIH salary cap must be used if applicable. Cost sharing of salary is necessary when using the salary cap or in other situations where the effort exceeds the amount of salary being requested.
- Current KL2/K12 scholars may not request support for effort already supported by their K award. This effort should be shown as cost shared on the budget form pages (show effort, no dollars) and described in the budget justification.

Consultant Costs

- Provide the names and organizational affiliations of all consultants other than those involved in consortium/contractual costs and provide any expected compensation, travel and other related expenses. When applicable, signed agreements which meet all compliance requirements of the individual grantee organization must be in place prior to any project-related consultant work being performed.

Equipment

- Only equipment essential to the conduct of this project is allowed. A detailed description must be provided with an explanation as to how it directly relates to this project and is not otherwise available.
- For budget submission purposes, equipment should be defined as items ≥ $5,000 and having a useful life of more than 2 years. Upon award, a grantee institution may re-categorize items to meet internal definitions. *Items costing less than $5,000 should be included in the Supply category.*

Travel

Travel must adhere to the grantee's established travel policy and is only allowable if needed to conduct the project. ***Travel to general scientific meetings is not allowable.***

Other Expenses

Publication costs are limited to $1,000.

Consortium/Contractual Costs

Sub-agreements proposed to organizations other than CDTR partners (includes associated community organizations) **must be approved by the CDTR Administration prior to submission of the application**. The participating consortium organization must submit a separate face page, detailed budget page(s), and budget justification to the PI who will include it as part of the overall application submission.

Other allowable budget categories include: Supplies and Patient Care Costs.

Unallowable Direct Cost Items

Funding will not be provided for the following:

- Administrative personnel
- Stipends for students/trainees
- Dependent Tuition Fringe Benefit
- Administrative supplies/services normally considered indirect costs (i.e. office supplies, phone, fax and modem line charges, etc.)
- Office equipment and furniture
- Tuition
- Purchasing and binding of periodicals and books
- Dues and membership fees
- Honoraria or travel expense for lectures
- Maintenance/Service Contracts
- Construction, alteration, maintenance or rental of buildings or building space
- Faculty/Staff recruiting /relocation expenses
- Entertainment/Social Expenses
- Pre-award costs
- Any expense contrary to applicant's institutional reimbursement policies

Facilities & Administrative Costs (F&A)

Do not include F&A Costs in the applicant or consortium organization budgets. F&A costs are expected to be a contribution to the program by institutions outside of WU. Any exceptions will be identified in the Notice of Award.