Washington University in St. Louis
Center for Diabetes Translation Research

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

2023-2024 Request for Applications

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**Purpose:** The purpose of this program is to promote innovative and transformative research, by investigators new to the field, to advance health equity in diabetes. The pilot and feasibility program focuses on T2-T4 translational research defined as 'translating interventions and approaches that have demonstrated efficacy into real-world healthcare settings, communities, and diverse populations with an emphasis on reach, sustainability, and potential for widespread implementation'.

**Two levels of funding are available for applicants**:

1) Pilot Grants: provide up to $50,000 direct costs for one year to facilitate the planning of a new clinical and/or translational research project. Pilot grants are typically used to fund developmental or early stage work, including collection of pilot data. Proposals should describe a concrete plan for further steps beyond the pilot grant.
2) Small Projects (accepted on a rolling basis): This $5,000 funding opportunity will support highly-focused data collection, secondary- or other analyses relevant to the WU-CDTR mission. *Small project application can be found here.*

## SUBMISSION AND REVIEW PROCESS

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| **Applications Open:** | September 1, 2023 |
| **Letter of Intent Due:** | November 1, 2023 |
| **Full Proposals Due:** | December 1, 2023 |
| **Earliest Project Start Date:** | March 1, 2024 |

**Step 1:** PI submit Letter of Intent (LOI) by **5:00 p.m. (CT)** on **November 1, 2023** to cdtr@wustl.edu. LOI requirements are shown below. *Early submission is encouraged so PIs have time to amend full proposal if needed.*

**Step 2:** WU-CDTR Pilot and Feasibility Program Director reviews LOIs and will respond to applicant regarding eligibility of the project for submission of full proposal.

**Step 3:** PIs submit full proposal applications (details below) by **5:00 p.m. (CT)** on **December 1, 2023.** This deadline will be strictly adhered to with no exceptions. An entire copy of the proposal must be e-mailed as a single PDF document to cdtr@wustl.edu.

**Step 4:** Proposals will be assigned to two experienced scientific reviewers and then evaluated in by the WU-CDTR Pilot and Feasibility Program Director and Executive Committee. Applicants will receive a

Summary Statement including comments from the, scientific peer reviewers and will be notified of funding decisions by **January 31, 2024.**

**Step 5:** Awardees must submit all JIT materials (e.g. IRB approval) and meet all compliance requirements prior to receiving funds for a **March 1, 2024** start date.

## REQUIREMENTS FOR PILOT & FEASIBILITY AWARD RECIPIENTS

- Acknowledge WU-CDTR support on all publications related to Pilot & Feasibility Award (P30 DK09250) and comply with NIH Public Access Policy: http://publicaccess.nih.gov/
- Assist the WU-CDTR in collecting program evaluation and follow-up data regarding their career progression and scientific output.
- Presentation of pilot results at a WU-CDTR works in progress meeting.
- Participation in at least one awardee meeting to promote scientific exchange among early stage investigators.

## APPLICANT ELIGIBILITY

- Principal Investigators must be members of the WU-CDTR (or eligible for membership). Membership criteria and application are available on our website. For assistance with applying, contact the WU-CDTR P&F Research Manager, Shelly Johnston, at shellyjohnston@wustl.edu or 314-935-7504.
- Applicants from Washington University or WU-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 WU-CDTR Pilot and Feasibility program are not eligible to apply except with prior approval.**

**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 diabetes/obesity research, but whose **proposed project is clearly different from their current or previous work**.
- Investigators collaborating with community-based organizations.
- Investigators from diverse backgrounds, including those from groups that have been shown to be underrepresented in health-related research

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*Application Guidelines*

## LETTER OF INTENT REQUIREMENTS (DUE NOV 1)

1) Descriptive title of proposed research
2) Overall aim/hypothesis of proposed research (4-5 sentences)
3) Description of how this project advances the investigator's overall research plan and career trajectory (2-3 sentences)
4) How health equity is being addressed in the proposed research (limit to 2-3 sentences)
5) Name, e-mail address, and telephone number of the Principal Investigator
6) Names of other key personnel
7) Participating institutions
8) Name, title and email address of 3 potential reviewers. Reviewers do not have to be WU-CDTR members but should not include Co-Is, direct supervisors, or department heads

## APPLICATION REQUIREMENTS (DUE DEC 1)

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, excluding references, 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 and/or how it addresses health equity in the prevention and treatment of diabetes and related conditions.
         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, clinical practice, or community-level intervention paradigms.

2. Explain how health equity issues will be addressed.
3. 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).
4. Explain any refinements, improvements, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

iii. Approach:

1. 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.
2. Describe ways in which your research methods inform and support health equity.
3. Describe how your approach will engage with relevant WU-CDTR research cores.
4. Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
5. 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.
6. 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 (Section 3.1). 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.
** Please note the new NIH Inclusion Across the Lifespan policy when completing enrollment tables*

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) **NIH Biographical Sketch**- 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

**1) Allowable Direct Cost Items:** Funding will be provided for items essential to the conduct of the project.

A. **Personnel**

i. 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.

ii. 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.

iii. 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.

B. **Consultant Costs**

i. 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.

C. **Equipment**

i. 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.
ii. 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.

D. **Travel**
i. 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.*

E. **Other Expenses**
i. Publication costs are limited to $1,000.

F. **Consortium/Contractual Costs**
i. Sub-agreements proposed to organizations other than WU-CDTR partners (includes associated community organizations) must be approved by the WU-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.

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

**2) Unallowable Direct Cost Items**

A. 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

B. 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 WUSTL. Any exceptions will be identified in the Notice of Award.

# APPENDIX A

## PROGRAM CONSIDERATIONS

**A. Translation spectrum:** All projects should fall under the umbrella of T2 - T4 translation research and address diabetes, prediabetes/metabolic syndrome, or obesity prevention or treatment. The following definitions for the stages of translational research will be used:

- **T2 Research: translation to patients:** Phase 2 and 3 clinical trials, and controlled studies leading to clinical application and evidence-based guidelines
- **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

**B. Address health equity:** To be responsive to this funding program, proposals must address a health equity issue or add to the evidence base about the issue with the ultimate goal of eliminating disparities in diabetes and related conditions.

The following definitions for health equity and related themes will be used:

- **Health equity:** Reducing and ultimately eliminating disparities in health and its determinants that adversely affect excluded or marginalized groups. Health equity can be viewed both as a process (the process of reducing disparities in health and its determinants) and as an outcome (the ultimate goal: the elimination of social disparities in health and its determinants).[1]
- **Health disparities:** Differences in health (or in key determinants of health such as education, safe housing, and freedom from discrimination) that adversely affect marginalized or excluded groups. Disparities in health and in the key determinants of health are how we measure progress toward health equity.[1]
- **Social determinants of health:** The conditions in which one lives, learns, works, plays, worships, and ages, and these conditions are shaped by historical and contemporary policies, law, governance, investments, culture, and norms. Addressing the root causes of health inequities, such as the social determinants of health, is important in part to help enable sustainable interventions by engaging multiple sectors and addressing multiple health outcomes simultaneously.[2]
- **Social needs**: unmet material needs experienced by individuals, such as food and housing insecurity.[3]

*Additional health equity related resources for applicants and reviewers can be found here.*

**C. Utilize WU-CDTR services:** Applicants are required to include use of WU-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 WU-CDTR tools and services. Information about available cores and services can be found on the Center website.

*If you're unsure if your project fits within the mission of this RFA, please contact cdtr@wustl.edu or 314-935-7504.*

# APPENDIX B

## SCORED REVIEW CRITERIA

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each, following standard NIH review guidelines. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

*Additional guidance related to health equity considerations for applicants and reviewers can be found here: Questions and Resources for Reviewing Research Proposals for Sensitivity to Health Equity Issues*

1) **Significance:** Does the project address an important problem or a critical barrier to progress in the field? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? Are the scientific rationale and need to test the proposed hypothesis or intervention well supported by preliminary data, clinical and/or preclinical studies, or information in the literature? Does the application have the potential to advance the PI's research career and lead to extramural funding? How strong is the intention to focus on health equity issues in the proposed research? How central are health equity issues to the study aims?

2) **Investigators:** Are the PI, collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? How appropriate is the team composition for achieving the equity-related goals of the study?

3) **Innovation:** Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed? Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice? Does the proposed research study have the potential to yield meaningful insights about an important health-equity issue?

4) **Approach:** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? Does the application include a description of the pathway(s) or mechanism(s) whereby intended impact on equity would be achieved? How strong are the proposed study design and methods for identifying equity impact of the intervention being evaluated? How appropriate is the dissemination plan for achieving the equity-related goals of the study?

5) **Environment:** Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?