Clinical & Translational Science Institute
of Southeast Wisconsin

CTSI Pilot Translational and Clinical Studies Program Start-up Awards

2018 Request for Applications

The CTSI of Southeast WI is pleased to open a new cycle of our Pilot Start-up Awards and requests applications for funding to support pilot preparatory work. Start-up projects are small, short-term feasibility studies for the purpose of developing a strong, highly competitive proposal for our Traditional Pilot Award. The duration of the award is 6 months, with projects ending March 31, 2019 - in time for the Traditional Pilot application due several months later.

Up to 6 awards are available for up to $12,500 each for a six-month project period.

KEY DATES

- **Request for Applications release date:** April 2, 2018
- **For projects with an MCW PI or Co-PI:**
    1. an eBridge Funding Proposal (FP) must be submitted to MCW Grants & Contracts Office (GCO) by: May 8, 2018 @ 11:59 a.m. CDT; *and*
    2. once the FP has been institutionally approved, the completed application must be submitted via REDCap to CTSI by: May 15, 2018 @ 5:00 p.m. CDT
- **For projects without an MCW PI or Co-PI**, the completed application must be submitted via REDCap to CTSI by: May 15, 2018 @ 5:00 p.m. CDT
- **Regulatory approvals, as applicable:** May 31, 2018*
- **Notifications of Award:** early July 2018
- **Project start date:** October 1, 2018
- **Project end date:** March 31, 2019 **

* Proposal will *not be considered for funding* if any required regulatory, safety, or other ancillary committee approvals are not in place by this date - this includes IRB; IACUC; OCRICC; IBC (biosafety); etc.

** No-cost extensions will *not* be allowed; all research expenses must be incurred by March 31, 2019.

The CTSI Pilot Translational and Clinical Studies Start-up Award Program is supported by the National Institutes of Health (NIH). These funds may be used to:

- Gather preliminary/feasibility research data
- Validate a research method or approach
- Conduct exploratory analysis
- Data mining to identify potential hypotheses
- Build community and/or academic partnerships (e.g. meeting costs, facility charges, and travel costs)
- Determine recruitment feasibility
- Develop or test survey instruments and other measures
- Explore methods for data collection
- On a case by case basis, funds may also be used for strategic training (e.g. specific methods or technical skills).

PROJECT EXAMPLES

- To administer a battery of instruments to a small test sample of subjects to determine subject burden: time for completing, problem items, and sequence of measures.
- To conduct complex cohort identification of cancer patients using the CTSI Clinical Data Warehouse.
- To conduct statistical power analysis to determine feasibility and assist in the development of a viable study.
- To conduct preliminary surveys in a community to gauge interest in engaging in Community-based Participatory Research (CBPR).
- To support meeting costs for convening community groups to explore partnering on a CBPR project.
- To establish reliability and/or validity of a research tool or measure in the population of interest.

REQUIREMENTS

PI and Study Team Requirements

- All PI(s) and Investigators must be CTSI Members. To become a member, please complete the CTSI Membership Form.
- There must be at least one PI from a CTSI partner institution: MCW, UWM, MU, MSOE, CHW, BCW, VA, Froedtert Hospital.
- Inter-institutional collaboration among CTSI academic/research partner institutions is *not* required for this award. However, it *is* a requirement for the CTSI Traditional Pilot Award. *Therefore, proposals for the Start-up which do not*

involve inter-institutional collaboration must include specific plans to establish these partnerships for the upcoming Traditional Pilot project. The inter-institutional collaboration requirement for the Traditional Pilot Award is explained at the bottom of this RFA for your reference.

- This award allows for, but does not mandate, a multiple PI model. In cases where a project has multiple PI(s) and one is from MCW, the MCW PI must submit the proposal through the MCW Grants and Contracts Office (GCO) eBridge system.
- All PI(s) must have full-time or full professional effort status at their primary academic institution to be eligible to serve as a Principal Investigator (PI). Adjunct and part-time faculty are not eligible to apply as a PI.
- There is no specific required minimum effort for PI(s) on Start-up projects; however, the proposed effort should be adequate and feasible for fulfilling project responsibilities including the development and execution of the project.
- PI(s) are responsible for all grant reporting and fiscal management and will be the main contact for budget and reporting management. PI(s) will be primarily responsible for ensuring compliance with the scientific, safety, and ethical responsibilities of the grant award.
- PI(s) will be expected to comply with reporting requirements as a condition of receipt and continuation of funds. Non-compliance of final and/or annual reporting could result in the rescinding of funds by CTSI.
- Community partners or investigators from other academic institutions would be welcome additions to study teams as Co-PI or Co-Investigator.
- All personnel must be identified prior to the start date to replace any “to be named” positions proposed in the application.

Regulatory Requirements

- Human Subjects Research projects need to have IRB approval **by May 31, 2018 - no exceptions**. If applicable, proof of any Exempt or Non-Human Subjects Research Status must be provided.
- Research conducted at Froedtert Hospital will need OCCRIC approval **by May 31, 2018 - no exceptions**.
- Animal Research projects need to have IACUC (or equivalent) approval **by May 31, 2018 - no exceptions**.

IMPORTANT NOTE: Proposals will not be considered for funding if any required regulatory, safety, or other ancillary committee approvals are not in place by May 31, 2018. This includes IRB; IACUC; OCRICC; IBC (biosafety); etc. Email all final approvals to Christine Zeller by 5:00 p.m. May 31, 2018.

Budget Requirements

- Projects will be funded at a level of up to $12,500. Institutional and departmental cost sharing to supplement these funds is highly encouraged.
- Projects must be completed within a maximum of 6 months.
- **No-cost extensions will *not* be allowed; all research expenses must be incurred by March 31, 2019.**
- No "indirect costs" may be charged for any CTSI funding. Because the source of these funds is the NIH, you will need to request an F&A override in eBridge (*please see specific eBridge instructions below*).
- No funds may be requested for general purchase of laboratory or clinical equipment greater than or equal to $3,000.
- Salaries are subject to the NIH parent award annual salary cap of $187,000.

Additional Requirements by Institution

All projects with an MCW PI must be routed through MCW eBridge and must be received by the MCW GCO at least 5 business days before the CTSI submission deadline (see key dates above). Different departments may have different deadlines for obtaining departmental approvals prior to receipt by the GCO. Once the eBridge Funding Proposal has been institutionally approved, the online application form must be completed and submitted via REDCap by the CTSI deadline.

For MU investigators, applications may need to be registered via the routine Proposal Registration process with the Office of Research and Sponsored Programs (ORSP) prior to submission. Please contact an ORSP staff member early in your application preparation process to ensure accurate compliance.

For UWM investigators, applications may need to be routed using the WISPER system and approved by the Office of Sponsored Programs (OSP) prior to submission. Please contact an OSP staff member early in your application preparation process to ensure accurate compliance.

For MSOE investigators, please contact Sheku Kamara, Dean of Applied Research, 414-277-7416, kamara@msoe.edu

HOW TO APPLY

The CTSI application process involves submitting an online REDCap application form where you will be required to upload the following documents:

REQUIRED DOCUMENTS

1. 2018 CTSI Pilot Start-up Award Proposal Form (DOCX)
2. Budget and Budget Justification Form (DOCX)
   Use one form per partnering institution/agency. NOTE: please indicate any cost-sharing within the budget justification and/or within a Letter of Support; cost-sharing commitment forms are *not* required at the time of application.
3. Current NIH Biosketch for each Investigator (PI; Co-PI: Co-I); limit 5 pages per individual.
4. Letter of Support from each Co-Investigator addressed (jointly) to the PI(s)
5. Letter of Support for project from the Department Chair(s) for each PI; Co-PI (if required by your institution)
6. Proof of any applicable regulatory submissions or approvals

ACCESS THE ONLINE REDCAP APPLICATION FORM HERE

All projects with an MCW PI or Co-PI must be routed through an eBridge Funding Proposal which must be received by the MCW GCO by noon on May 8, 2018.

eBridge Instructions for Funding Proposal SmartForm for CTSI Start-up Awards

- Investigator Information
  - Question 2.0 Title – please add "CTSI Start-up" at the beginning of your project title.
- General Proposal Information
  - Question 3.0 Type of Program – select "Research"
  - Question 5.0 Sponsor – select "NIH Advancing Translational Sciences"
  - Question 6.0 Type of Organization – select "Federal"
  - Question 6.1 Is the proposal being submitted to the NIH for one of the following funding mechanisms? – select "No"
  - Question 6.2 Select the Funding Mechanism… – select "UL1 – Linked Specialized Center Cooperative Agreement"
  - Question 10.0 Centers/Institutes – select "Clinical & Translational Science Institute (CTSI)"
- Proposal Attachments
  - Question 2.1 Sponsor Application – upload your completed CTSI Pilot proposal form and any additional required documents. Please create a single PDF of the full application to upload.
- Budget
  - Salaries are subject to the NIH parent award annual salary cap of $187,000.
  - Please request an F&A override within eBridge as no indirect costs are applicable to this award.

TERMS & CONDITIONS

NATIONAL INSTITUTES OF HEALTH (NIH) AND NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES (NCATS) PRIOR APPROVAL FOR STUDIES INVOLVING HUMAN SUBJECTS

For any project involving human subjects research, including human subjects data/specimens, the CTSI must collect and submit to NIH NCATS 30 days prior to funding approval the following documentation, much of which is available from an IRB submission:

- The complete clinical research protocol and consent document(s).
- If a clinical trial is proposed, product information, such as the clinical investigator brochure or package insert or description of the device shall be included. Documentation that an IND or IDE has been obtained or letter from FDA that the study is IND exempt or IDE has been waived.
- Description of risk, protections, benefits and importance of the knowledge to be gained by research involving human subjects.
- Inclusion Plans for Women, Minorities, and Children
- Targeted Enrollment Table or Inclusion Data Record (IDR)
- Data and Safety Monitoring Plan or Board (DSMB), as applicable.
- Certification that the pilot awardee and any key personnel directly involved in the study have taken appropriate education in protection of human subjects.

FUNDING ACKNOWLEDGMENT

Please help to ensure the future of clinical and translational research at the Medical College of Wisconsin and CTSI partner institutions. Cite the National Institutes of Health (NIH) CTSA award any time you use CTSI resources, services, and facilities, or refer to your CTSI-funded pilot study in a presentation or publication using the following language:

*The project described was supported by the National Center for Advancing Translational Sciences, National Institutes of Health, Award Number **UL1TR001436**. The content is solely the responsibility of the author(s) and does not necessarily represent the official views of the NIH.*

FOR YOUR REFERENCE: Traditional Pilot Award Eligibility Requirements

A Start-up project is *not* subject to the same requirements as the Traditional Pilot Award. However, since a Start-up project is expected to lead to a Traditional Pilot proposal, if your Start-up project does not meet one or more the requirements below, your application should address the specific steps you will take to meet the eligibility requirements for a Traditional Pilot Award proposal.

1. MCW PI
    a. Most Traditional Pilot awards are funded through the Advancing a Healthier Wisconsin Research and Education Program and according to AHW REP requirements, must have an MCW PI or Co-PI. In contrast, Start-up projects need not have an MCW PI.
    b. Projects with more than one PI are encouraged but not required.
2. Inter-institutional research collaboration
    a. The research team must include investigators (PI; Co-PI; Co-I) from at least two of the eight CTSI academic/research partner institutions (BCW, CHW, Froedtert Hospital, MCW, MSOE, MU, UWM, VA) *according to the investigator's primary employment platform*. For joint affiliations and appointments, the institution of primary employment will be the determining factor.
    b. The collaboration must be substantive and one of a genuine research team. So, for example, biostatistics support that is acquired as a service would not be considered research collaboration.
3. Translational T-level
    a. T-0 projects are allowed for Start-up projects but are *not* eligible for the Traditional Pilot Award
    b. The Traditional Pilot Award is limited to projects at the following T-levels of translational research (PDF):
        i. T-1 Translation to Humans
        ii. T-2 Translation to Patients
        iii. T-3 Translation to Practice
        iv. T-4 Translation to Communities/Population Health