A A A

Clinical & Translational Science Institute
of Southeast Wisconsin

2025 Pilot Award to Advance Translational Science

Please complete & submit this Grant Application form **by 5:00 p.m. on October 15, 2024**. You may use the 'Save & Return Later' button at the bottom of this page until this deadline.

Fields marked with a red asterisk (*) are required.

Questions? Please contact Renee McCoy, CTSI Pilot Award Program Director, at rmccoy@mcw.edu or Louann Sullivan, Project Coordinator, at lmsullivan@mcw.edu.

Instructions for Submitting an Application for the CTSI Pilot Award to Advance Translational Science

- Read all instructions and questions carefully.
- Provide complete and accurate information for each section.
- Upload all required documents. If needed, combine multiple files into a single PDF.
- Be sure to use the *Save & Return Later* button in order to come back to complete your application at a later time.
- For projects with any MCW investigators, a MCW eBridge funding proposal must be submitted by **October 8, 2024**.
- Be sure to select the SUBMIT button to submit your application by the **CTSI deadline of 5:00 p.m. October 15, 2024.**
- Contact Renee McCoy at rmccoy@mcw.edu if you have any questions.

Refer to the 2025 Pilot Award to Advance Translational Science RFA attached below.

To help you prepare a strong proposal, review criteria is available for your reference:

Reminder of eBridge Submission Requirement*

For applications that include **any MCW investigators:**

- **An eBridge funding proposal (FP) must be submitted by October 8, 2024, and**
- Once the FP has been institutionally approved, the completed application must be submitted via REDCap by **October 15, 2024, 5:00 p.m. CDT.**

Towards the end of this application you will be asked to attest that the FP was submitted by the deadline and provide the FP number.

Project Title

Project Title *

* must provide value

Lead Principal Investigator (PI)

Some fields below are pre-populated with information from your *Intent to Apply*. **Please ensure the information is correct. If changes are needed, type over the information that is provided. Please respond to any question for which a pre-populated response is not**

provided.

All PI/mPIs and co-investigators must have a minimum of 1% effort. The lead PI must be fully vested in the project in both spirit and practice and contribute actively on the project.
Please see RFA for further information.

Lead PI Demographics
As one of more than 50 NIH funded Clinical and Translational Science Awards (CTSA) Programs across the nation, our aim is not only to foster interdisciplinary and inter-institutional research, but to promote greater diversity in the clinical and translational research workforce as well. As such, this application includes questions related to diversity demographics including questions about race, ethnicity, gender and disability status.

PI First Name *
* must provide value

Please provide corrected information if needed.

PI Last Name *
* must provide value

Please provide corrected information if needed.

PI Credentials *
Example: MD, PhD, MPH
* must provide value

Please provide corrected information if needed.

PI Rank/Position *
* must provide value

PI Email *
* must provide value

Primary Institution
* must provide value

PI's Secondary inst
* must provide value

- [ ] Versiti [Formerly Blood Center of Wisconsin or BCW]
- [ ] Children's Wisconsin [Formerly Children's Hospital of Wisconsin or CHW]
- [ ] Froedtert Hospital
- [ ] Medical College of Wisconsin
- [ ] Milwaukee School of Engineering
- [ ] Marquette University
- [ ] University of Milwaukee - Wisconsin
- [ ] Zablocki VA Hospital
- [ ] Other inst/Agency
- [ ] Not Applicable

Please indicate inst of secondary affiliation or joint appointment, if applicable.

What race do you identify as?

Select all that apply

- [ ] American Indian or Alaskan Native
- [ ] Asian
- [ ] Black or African American

* *must provide value*

- [ ] Native Hawaiian or Pacific Islander
- [ ] White
- [ ] Other
- [ ] Prefer Not to Answer

What ethnicity to you identify as?

* must provide value

What gender do you identify as?

* must provide value

Do you have a disability?

Disability is defined as those with a physical or mental impairment that substantially limits one or more major life activities, as described in the Americans with Disabilities Act of 1990, as amended.

* must provide value

PI NIH eRA Commons Username

* must provide value

Please provide contact information for your coordinator or administrator who will assist with study preparation, budgets, reports, etc.

Please specify NAME, PHONE NUMBER, and EMAIL *

* must provide value

mPIs and/or Co-Investigators

Please specify all mPIs and/or Co-Investigators who will participate in the proposed project.
***Reminder*:**

- Proposals must be inter-institutional: the scientific team must include investigators (either mPI or co-I) from at least two different CTSI partner institutions: Versiti, Children's Wisconsin, Froedtert, MCW, MSOE, MU, UWM, Milwaukee VA (Zablocki). Please note, this condition is based on the investigator's institution of primary employment. Volunteer appointments do not qualify. The 'institution of primary employment' is the institution that pays greater than 50% of the investigator's salary.
- mPIs must have a primary affiliation with any of the eight CTSI partner institutions.
- Community partners or investigators from other academic institutions would be welcome additions to projects as co-investigators, but alone do not meet the inter-institutional requirement.
- Other study team members should be entered in the KEY PERSONNEL section as appropriate.

NOTE: Study personnel such as research assistants, study coordinator, or other staff needed for the conduct of the study may not serve as a co-investigator.
Please see RFA for further information.

Details on Investigator Demographics
As one of more than 50 NIH funded Clinical and Translational Science Awards (CTSA) Programs across the nation, our aim is not only to foster interdisciplinary and inter-institutional research, but to promote greater diversity in the clinical and translational research workforce as well. As such, this application includes questions related to diversity demographics including questions about race, ethnicity, gender and disability status.

Excluding the initial PI, how many additional mPIs and/or Co-Investigators will participate in the proposed project?

* must provide value

Key Personnel

Please specify all additional key personnel that will participate in the proposed project.

NOTE: Any key personnel listed on this application must be included in IRB/Regulatory submissions/approvals.

Excluding all investigators named above, how many additional Key Personnel will participate in the proposed project?

* must provide value

○0 ○1 ○2 ○3 ○4 ○5

Project Information

Please indicate whether your project involves the following (check all that apply):

* must provide value

- ☐ IRB-Defined Human subjects Research*
- ☐ Non-human subject research
- ☐ Animal subject research*
- ☐ Public Data Set
- ☐ Other**
- ☐ None of the above

* Select even if data or specimens are involved and not living subjects that may include HIPPA identifiers.
**For example, hazardous chemicals or substances.

Clinical Trials

Please refer to the NIH Definition of a Clinical Trial to determine whether or not your pilot project is subject to regulations governing clinical trials. For Clinical Trial related projects, all study team members must complete training in Good Clinical Practice (GCP)

Will your study involve FDA-regulated research?

* must provide value

○ Yes
○ No

Do you hold the IND or IDE?

* must provide value

○ Yes
○ No

Regulatory Requirements

Applicants must provide proof that all regulatory applications (IRB; IACUC; etc.) are in pre-submission, submitted, pending, or approved status. If applicable, proof of any non-human subjects designation or approved Public Data Set by the IRB must be provided. Please see MCW Designated Public Data Sets for more information, if needed. For regulatory approvals that are close to expiring, please upload proof of submitted CPR's/amendments/etc.

Applicants are encouraged to contact CTSI IRB Navigator, Charlotte Klis for assistance with any IRB-related questions/issues: cklis@mcw.edu. **Each pilot proposal that receives recommendation for funding will be asked to provide proof that all regulatory applications have been fully submitted by March 10, 2025.**

If required regulatory applications have not been submitted by March 10, 2025 the recommendation for funding may be rescinded. Submitted regulatory applications should be 100% complete and accurate to the best of your ability.

Reliance Request
Please reach out to your respective IRB Reliance office at the time of application if needed. Please be aware that IRB reliance is a process that can take some time as all sites must ensure that they understand the project, are willing to rely or accept IRB oversight, ensure their local requirements have been satisfied, and agree with the terms of the reliance. Each site may have their own unique reliance documentation system. Note: if you request that the MCW IRB serve as single IRB for a project, and if your project requires IRB oversight for sites outside of the Milwaukee area CTSI partner institutions, there may be a fee associated with this service.

I understand that if my project is recommended for funding, I will fully submit a Reliance Request form to the respective CTSI partner institution's IRB to help ensure that all inter-institutional research has the proper regulatory oversight.

○ Yes

Office of Clinical Research and Innovative Care Compliance (OCRICC)
Clinical research and clinical trials that utilize any Froedtert Hospital (FH) resources - medical records (PHI), staff, facilities, equipment, invoicing/billing, etc. - must be reviewed via the Office of Clinical Research and Innovative Care Compliance (OCRICC) to ensure that FH has the staff, equipment, and other resources to successfully support the study. The Froedtert Health OCRICC Administrative Approval process has been updated to streamline processes and improve approval timelines.

We highly suggest you visit the OCRICC website before beginning your project.

Will your project involve the use of Froedtert Hospital resources, clinical data, facilities and/or services?

* must provide value

○ Yes
○ No

Study Population Details

Select all age group(s) applicable to the study population

* must provide value

☐ Neonatal/Infants
☐ Children
☐ Adolescents
☐ Adults
☐ Geriatric
☐ Not Applicable/Unknown

Are any racial groups (based on NIH categories) represented in this research study population? (Select all that apply)

* must provide value

☐ American Indian or Alaska Native
☐ Asian
☐ Black or African American
☐ Native Hawaiian or Other Pacific Islander
☐ White
☐ Other
☐ There are no target racial groups as part of this project

Are any ethnic groups (based on NIH categories) represented in this research study population?

* must provide value

☐ Hispanic/Latino Populations
☐ Other Populations

- [ ] No ethnic groups are targeted for this research project

Does the study population include or focus on any of the following vulnerable or potentially vulnerable populations?

* must provide value

- [ ] Pregnant or Lactating Women
- [ ] Human Fetuses
- [ ] Prisoners
- [ ] Individuals with physical disabilities
- [ ] Individuals with mental disabilities or cognitive impairments
- [ ] Economically disadvantaged
- [ ] Socially disadvantaged
- [ ] Critically or Terminally Ill
- [ ] Institutionalized persons
- [ ] Other
- [ ] No Vulnerable populations are included or focused on within this research study

Does the study population include any Health Disparities Populations? (select all that apply)

* must provide value

- [ ] Underserved Rural Populations
- [ ] Sex and Gender Minorities
- [ ] Socio-Economically Disadvantaged Individuals
- [ ] Individuals from disadvantaged backgrounds (per NIH criteria)
- [ ] Other
- [ ] None of the above Health Disparities Populations are included in this study

Does the study population include any other Special Research Populations

* must provide value

- [ ] Veterans
- [ ] Individuals with Substance Use Disorders
- [ ] Survivors of previously lethal childhood diseases
- [ ] Adults with chronic health conditions that originated in childhood
- [ ] Individuals with an existing cancer diagnosis
- [ ] Other
- [ ] No Special Research Populations are included in this study

Research Project Keywords

The keywords and phrases you provide will help us to find a suitable scientific reviewer for your proposal. Please provide as many related keywords as you can that will assist us in this effort.

Would you like to provide additional keywords or phrases? Note that *more is better* for helping us find a suitable reviewer for your proposal.

* must provide value

- ○ Yes
- ○ No

Translational Science Project Uploads

Proposal Form
If needed, download a blank proposal form here.

Upload Completed Proposal Form
(in Word or PDF format)

* must provide value

Budget and Budget Justification Forms

- Download and complete the budget template provided below
- **One budget form is required for each partner institution providing personnel effort on the study that is not considered consultative or fee-for-service.** Consultant and/or service fees sourced from another institution or agency such as CW or Froedtert Hospital can be included on the MCW budget and need not be paid via a subcontract.
- **Effort must be specified for all personnel.**
- All salary support is subject to the current NIH salary cap **at time of award**. Current NIH salary cap is $221,900.
- No "indirect costs" may be charged.
- Budget tables must match information listed in budget Justification page.

Please download the budget form.

How many budget forms do you need to upload?

* must provide value

○2 ○3 ○4 ○5 ○6 ○7 ○8

NIH Biosketches
Please provide one biosketch for each investigator on your study team (limit 5 pages per individual), using an NIH template that is current per the *Approved Through…* date on the top right.
(OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 01/31/2026)

If needed, download a current template here: **NIH Biosketch Template**

Additional guidance from the MCW Grants and Contracts Office can be found **here**.

Lead PI Biosketch

* must provide value

Letters of Support / Acknowledgement / Intent to Establish Consortium

- **From Co-Investigators to PI/mPI(s)**
  - A Letter of Support is required from each co-investigator to the PI/mPI(s) explaining her/his intention and commitment to this project.
  - Letters of Support should be addressed to *all* mPIs.
  - A Letter of Support is *not required* from a mPI to other PIs.
- **From Division Chief or Department Chair to the project PI/mPI**
  - To acknowledge awareness and support of the project.
- **From other institutions - Letters of Intent to Establish Consortium**

- A Letter of Intent to Establish Consortium is required from any non-MCW institution indicating a willingness to negotiate a project-specific subaward and validation that the institution is on-board with the project and is aware of the effort commitments being made.

Letters of Support from the Principal Investigator's and each mPI's Division Chief or Department Chair.

Please combine all PI/mPI letters of support into a single PDF as applicable.

* must provide value

Please upload Letters of Intent to Establish Consortium.

Please combine multiple documents into a single PDF.

* must provide value

Additional supporting documentation
Use this area to upload any optional Letters of Support for your project that you wish to include.

Please combine multiple documents into a single PDF.

Attestation of Compliance

Inter-Institutional
The scientific team includes investigators (either mPI or co-I) from at least two different CTSI partner institutions: Versiti, Children's Wisconsin, Froedtert, MCW, MSOE, MU, UWM, Milwaukee VA (Zablocki).

I attest that my grant application fulfils the Inter-Institutional requirement and I understand that this condition is based on the investigator's institution of *primary employment*.

* must provide value

○ Yes

Submission

The CTSI of Southeast Wisconsin participates in a national CTSA External Reviewer Exchange Consortium (CEREC) to improve fairness in the scientific review process and better match applicants with feedback from experts in their respective fields.

Maintaining confidentiality throughout the peer review process is essential to allow for the candid exchange of scientific opinions and evaluations; and to protect trade secrets, commercial or financial information, and information that is privileged or confidential. Similar to the NIH peer review process, the CTSI is committed to protect the integrity of and to maintain confidentiality in peer review. See Guide Notice NOT-OD-22-044.

Please check the box below to acknowledge that your proposal may undergo external scientific peer review.
(CEREC is comprised of: Harvard Catalyst; Medical College of Wisconsin; Ohio State University; University of Alabama - Birmingham; University of Arkansas for Medical Sciences; University of California - Irvine; University of Southern California; University of Washington; Virginia Commonwealth University.)

* must provide value

○ I acknowledge that my proposal may undergo external scientific peer review.

PI's Full Name

* must provide value

Application Submission Date and Time
Once the application is fully complete, please select 'Now' to auto-fill the date and time, then click 'Submit'.

* must provide value

M-D-Y H:M:S

Please be sure to SUBMIT your application using the button below.
You will then receive an email confirmation with a PDF version of your submission.
Please contact Renee McCoy or Louann Sullivan if you have any questions or issues.

Thank you for applying for the CTSI Pilot Award to Advance Translational Science!

Submit

Save & Return Later