



CTSI Pilot Translational and Clinical Studies Program (PTCS) Integrated Clinical and Research Ensembles (ICRE) Awards 2022 Request for Applications

The CTSI of Southeast WI is pleased to announce our second cycle of support for the CTSI Pilot - Integrated Clinical and Research Ensembles (ICRE), and requests applications for funding to support pilot team development and preparatory work.

The vision is to organize and leverage clinical/translational research to improve patient health and health care. The mission of an **ICRE** is to integrate clinical and research faculty, community stakeholders and health system representatives in highly innovative and efficient units/Ensembles to get more treatments and interventions more quickly to more patients and our community.

Ensembles are groups that may be comprised of appropriate basic/clinical and translational investigators, clinicians, patients, patient advocacy groups, community stakeholders and health system experts to provide solutions to unmet health needs emanating from clinic, community and the laboratory. This design allows for identification of real unsolved patient care problems and provides the opportunity for the Ensemble members to develop a solution to these unmet shortcomings.



P – Patient
CI – Clinical Investigator
TR – Translational Researcher
ED – Enabling Discipline Researcher
HR – Health System / Hospital Representative
CM – Community Member
CO – Community / Population Health Researcher
B – Basic Science Researcher
C – Clinician

The goal of this Pilot-ICRE funding path is to foster the development of these Ensembles to collaboratively focus on advancing the health of our patients and community through clinical and translational research; thus, it is not required that all potential ICRE participants be present at the time of application. Once the appropriate Ensemble is formed, the research portion of the Pilot-ICRE funding will support small, short-term feasibility studies addressing the identified unmet clinical need for the purpose of developing a strong, highly competitive proposal. The expected outcome of these research Ensembles should demonstrate a clear path leading to a CTSI Translational and Clinical Pilot (TCP) Award, clinical and translational research proposal submission to CTSI partner institutions, or for extramural funding.

The duration of the Pilot-ICRE funding is 12 months; this includes time for team development and for the conduct of research projects. **Up to 2 Ensembles will be funded through this mechanism. Funded Ensembles will receive \$50,000 in funding** and are intended to develop effective, integrated and interdependent ICRE teams with long-term collaborations.



KEY DATES

- **Letter of Intent submission due date:** January 12, 2022
- **Meeting/orientation with Ensemble Project Managers:** by January 27, 2022*
- **eBridge funding proposal deadline:** February 21, 2022 (for ensembles with *any* MCW investigators)
- **Application Due date:** March 1, 2022 @ 5:00 p.m. CDT**
- **Orientation:** May 2022
- **Pilot-ICRE start date:** June 1, 2022***
- **Pilot-ICRE end date:** May 31, 2023****

* Since the Pilot-ICRE team research method is still very new, meeting with the Ensemble Project Managers prior to application submission will ensure that investigators fully understand the ICRE team design in their application development.

** Applications must meet the respective institution's grant/research office notification requirements, this includes eBridge (i.e. MCW research submission/management system) funding proposal deadlines. Any team which includes an MCW PI/mPI/Co-investigator will be required to provide the appropriate eBridge funding proposal number and meet the MCW respective deadlines. Appropriate documentation from partner institutions may also be required.

*** CTSI is supported by the National Institutes of Health, National Center for Advancing Translational Sciences. As such, CTSI is required to submit documentation based on IRB and/or IACUC approval for each applicable project. NCATS requires at least 30-days to review approval requests. To accommodate this requirement, Pilot-ICRE teams must allow time within the first few months of the funding period for any required regulatory, safety, or other ancillary committee approvals to be obtained and for the NCATS Prior-Approval request to be received. **Timeliness is important to avoid delays that could affect the project timeline.**

**** No-cost extensions will *NOT* be allowed; all research expenses must be incurred by May 31, 2023.

ELIGIBILITY

PRINCIPAL INVESTIGATOR & STUDY TEAM ROLES

- **Proposals must be inter-institutional:** the scientific team must include investigators 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 and must be identified and confirmed on the Intent to Apply**.
 - For faculty from the MU/MCW joint department of biomedical engineering as well as for faculty from other CTSI partner institutions with joint appointments, faculty should use their primary employment platform to determine institutional affiliation.
- Note that for the purposes of the Pilot-ICREs and in the language of this RFA, the roles of Principal Investigator (PI) and multiple-Principal Investigator (mPI) are equivalent. PI/mPI are distinct from the roles and requirements of the Co-Investigator (Co-I).
- For the inter-institutional requirement, the Lead investigator must be a PI and the investigator from the second partner institution may be an mPI or Co-I.
- For these Pilot-ICREs, only CTSI partner institution faculty meeting their institution's requirements to serve as PI can be listed as PIs or mPIs.



- Community partners or investigators from other academic institutions would be welcome additions to projects as co-investigators, but do not meet the inter-institutional requirement.
- All PIs/mPIs must have full-time or full professional effort status. Adjunct and part-time faculty are not eligible to apply as a PI. ([Principal Investigator Eligibility](#))
- A minimum of 5% effort is required for the primary contact PI/Team Lead and mPIs and is to appropriately reflect effort.
- A minimum of 1% effort is required for co-investigators and is to appropriately reflect effort.
 - All salary support is subject to the current NIH salary cap at time of the funding notice. Current NIH salary cap is \$199,300.
 - Investigators will be required to attest to effort and cost-sharing intent on the application budget.
- The primary contact PI will be responsible for all fiscal compliance and management, as well as the related reporting requirements ensuring compliance with the scientific, safety, and ethical responsibilities.
- A co-investigator must have the requisite research training/credentials/expertise to make a substantive contribution to the science of the study and must have a minimum of 1% effort on the project. Note: Investigators will be required to attest to effort and cost-sharing intent.
 - Study personnel such as research assistant, study coordinator or other staff needed for the conduct of the study may not serve as a co-investigator
- All Ensemble PIs/mPIs must be CTSI Members. To become a member, please complete the [CTSI Membership Form](#).

LETTER OF INTENT SUBMISSION

THE ONLINE INTENT TO APPLY FORM MUST BE COMPLETED AND SUBMITTED BY January 12, 2022, 5:00 P.M. CDT.

APPLICATION

- Once the Intent to Apply Form is reviewed and approved, applicants will be contacted to attend a pre-application orientation. Attendees that complete this orientation will be sent a link to an online application form which must be submitted along with the following documents (templates will be available within the application form).
 - **Proposal narratives** need to provide specific team development activities to build the Ensembles and a clear research plan related to the unmet clinical need outlining the scope of work.
 - The Pilot/ICREs are not designed to support groups that form on an ad-hoc basis for expertise needed on single-investigator projects.
 - The Pilot/ICREs are intended to primarily support the development of a research team. This includes preliminary research activity such as:
 - A pilot study to demonstrate the feasibility of transcranial direct current stimulation and cognitive training as a viable intervention to improve cognitive function
 - Developing an evidence-based treatment research program to maximize interest and engagement of patients with traumatic brain injury
 - A pilot study to test the effects of a lifestyle intervention supporting diet and physical activity changes to improve body composition on quality of life and biomarkers of disease progression in multiple myeloma patients after therapeutic interventions
 - Improving outcomes of amyloid patients through early diagnosis and treatment



- **Budget and Budget Justification Forms**, one form is required for each partner institution providing personnel effort on the project that is not considered consultative or fee-for-service.
 - Funds are limited to Allowable NIH Costs
- **NIH Biosketch** in the most current NIH format is required for all PIs/mPIs, Co-Investigators, and Other Significant Contributors.
- **Letters of Support / Letters of Intent to Establish Consortium**
 - From Co-Investigators to PI(s)
 - From Division Chief (or Department Chair) to PI/mPI(s).
 - From other institutions – Letters of Intent to Establish Consortium
- As aforementioned, the expected outcome of these research Ensembles should demonstrate a clear path leading to a clinical and translational research proposal submission to CTSI partner institutions or for extramural funding.
- Applications will undergo a scientific review by a committee comprised of the ICRE Review Committee and Pilot Award Committee (i.e. basic and clinical scientists, experts in team science, community members and stakeholders as determined by the content of proposals).
- **Team Science:** The Pilot-ICREs are intended to stimulate inter-institutional and interdisciplinary / multidisciplinary clinical and translational research among the CTSI partner institutions. In supporting such collaboration, these Pilot-ICREs promote and support best practices in team science research.¹

¹ For more information on team science, see: [Collaboration and team science: From theory to practice](#); [Making virtual teams work: Ten basic principles](#); [Team science learning module from Northwestern University](#)

IMPORTANT INFORMATION

- If applicable, researchers must obtain full regulatory approvals for the identified research projects. Because the funding period for these CTSI Pilot - Integrated Clinical and Research Ensembles (ICRE) is capped at 12-months, early regulatory approval of protocols is essential, this includes inter-institutional IRB reliance agreements.
- In the absence of progress (research plan/project and approvals, and Pilot-ICRE Interim Progress Reports), funds may be frozen and/or rescinded per the recommendation of the Pilot Award Committee and the Executive Committee of CTSI. Non-compliance of final and/or annual reporting could result in the rescinding of current or future funds by CTSI.
- Working with the CTSI Pilot/ICRE Team
 - Each Ensemble that has been recommended for funding will be scheduled for an orientation to start working on a collaboration plan. All team members must attend.
 - During the funding period, teams will also routinely meet with the Pilot/ICRE Team to review progress, discuss challenges, and receive feedback.

REQUIRED TRAINING

- Funding recipients will be required to attend at least one Team Science educational session/workshop that provide(s) an introduction and overview to Team Science principles and practice.

Please see HOW TO APPLY and REQUIREMENTS as outlined at
<https://ctsi.mcw.edu/investigator/funding/>