CTSI Pilot Translational and Clinical Studies Program (PTCS)  
Integrated Clinical and Research Ensembles (ICRE) Awards  
2021 Request for Applications

The CTSI of Southeast WI is pleased to open a new cycle of the Pilot Translational and Clinical Studies (PTCS) Program Awards, in support of novel CTSI 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.

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 Awards will support small, short-term feasibility studies addressing the identified unmet clinical need for the purpose of developing a strong, highly competitive proposal for our Translational and Clinical Pilot (TCP) Award or other comparable proposal.

The duration of the Pilot/ICRE Award is 12 months; this includes time for team development and for the conduct of research projects. 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. A total of 4 to 5 awards are available for up to $35,000 each (funded using NIH dollars) and are intended to develop effective, integrated and interdependent teams with long-term collaborations.
KEY DATES
• Request for Applications release date: October 31, 2020
• Application Due date: the completed application must be submitted to CTSI via REDCap by: February 1, 2021 @ 5:00 p.m. CDT*
• Notifications of recommendation for award: May 2021
• Pilot/ICRE start date: June 1, 2021**
• Pilot/ICRE end date: May 31, 2022***

* 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 Core Team member (see below Eligibility section for description) will be required to provide the appropriate eBridge funding proposal number and meet the MCW respective deadlines.

** 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 award 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, 2022.

ELIGIBILITY
• Inter-institutional collaboration among CTSI academic/research partner institutions is required. This requirement includes:
  o A Core Team made up of CoPIs from at least two different CTSI partner institutions: Children’s Wisconsin, Froedtert Hospital, Marquette University, Medical College of Wisconsin, Milwaukee School of Engineering, UW-Milwaukee, Versiti, and Zablocki VA Medical Center.
  o CoPIs must have a primary affiliation with any of these eight CTSI partner institutions. For joint affiliations and appointments, the institution of primary employment will be the determining factor.
• Pilot/ICREs require that an Ensemble designate one CoPI per Ensemble as the Contact CoPI/Team Lead. This individual will be responsible for all grant and fiscal compliance and management, as well as related reporting requirements ensuring compliance with the scientific, safety, and ethical responsibilities of the grant award.
• All CoPIs must meet all eligibility requirements for PI status at their respective institution.
• All Ensemble CoPIs must be CTSI Members. To become a member, please complete the CTSI Membership Form.
• Coinvestigators from CTSI partner institution, the community, or from academic institutions outside the CTSI would be welcome additions.
APPLICATION

- Applications will be accepted only via the REDCap application link provided at https://ctsi.mcw.edu/investigator/funding/
- 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 a 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
    - Utilizing a novel apparatus, anal sphincter resistance exerciser, combined with Kegel exercises to increase the workload of the muscles involved in anal resting and squeeze pressure to improve incontinence
    - Improving outcomes of amyloid patients through early diagnosis and treatment
- 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).

IMPORTANT INFORMATION

- If applicable, researchers must obtain full regulatory approvals for the identified research projects.
- In the absence of progress (research plan/project and approvals; Pilot Interim Progress Report at three and six months), 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 Translational and Clinical Studies Program (PTCS)/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 PTCS/ICRE Team to review progress, discuss challenges, and receive feedback.

REQUIRED TRAINING

- Awardees 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/