



Wednesday, October 11<sup>th</sup>, 2023

## 2024 Translational Science Ensemble Awards Two Possible Awards, \$50,000 each

PLEASE NOTE: This RFA is significantly different than typical funding opportunities. Please read carefully.

### Funding Overview

In concordance with the National Center for Advancing Translational Sciences overall goal and mission, the Clinical and Translational Science Institute (CTSI) is embarking on developing the field of translational science and will support the performance of research in this field.

### *Translational Research*

Translation is defined as the process of turning observations in the laboratory, clinic, and community into interventions that improves the health of individuals and communities - from diagnostics, prevention, and treatments to medical procedures and behavioral changes. Translational research, as we are familiar with, is defined as the endeavor to traverse a particular step of the translational process for a particular target or disease.

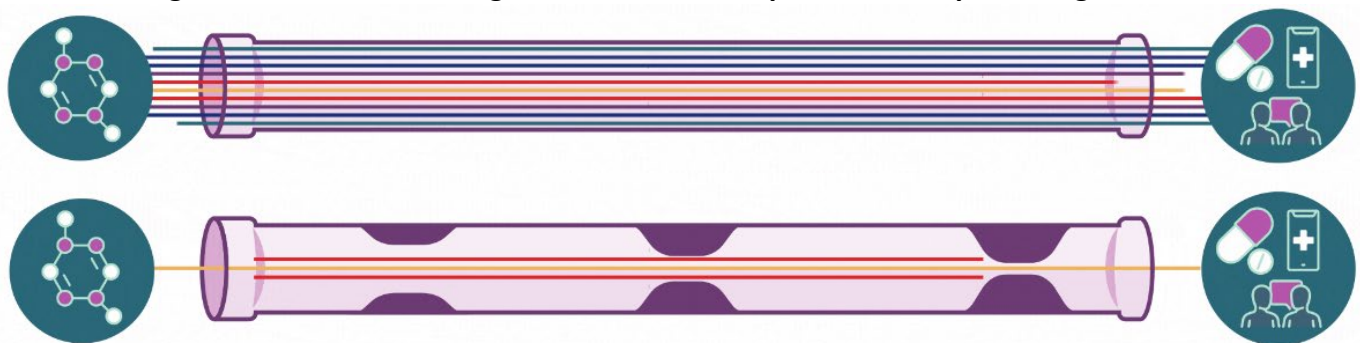
### *Translational Science is Different*

Translational science is defined as the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process.

Translational science research is defined as discovering the scientific, mechanistic, and operational principles of the intervention development and dissemination process, thereby providing the scientific foundation for improvement in translational efficiency that will accelerate the realization of interventions that improve human health.

To advance the field of translational science and its associated investigative expertise, CTSI will fund two **Translational Science Research Ensembles**. The product of these Ensembles should result in the identification and removal of obstacles and roadblocks that slow the performance and progress of translational research.

**Figure 1. Bottlenecks along the Translational Pipeline that Impede Progress.**



Credit: [How NCATS Tackles Persistent Problems in Translation](#)

Joni L. Rutter, PhD Director; National Center for Advancing Translational Sciences, Director

## ***Translational Science: “Sometimes the System or Process is Sick”***

For this award, Translational Science Research Ensembles will not conduct clinical and translational research to address an unmet patient medical need. Instead, funded Ensembles will focus their research activities and expertise exclusively on understanding the scientific and operational principles underlying a specific step(s) of a translational process, with the goal to improve translational efficiency. Teams will form around an identified translational barrier of their choice, and create solutions that accelerate the translational process. Because this award does not require focusing on a specific disease, the results of this research have the potential for broad impact that can benefit a greater number of patients, without regard to the specific disease or condition.

Ensemble teams may address any *underlying Translational Science barriers*.

Examples of Research Targets:

- Impediments that prevent:
  - translation of basic science discoveries into first-in-human investigation
  - collaboration between basic scientists and clinician scientists
  - meaningful participation and collaboration of community members in the research process
  - patient data de-identification
  - clinic uptake/adoption of new process
  - phase-out of outdated clinical processes
- Connecting parallel research activities/strategies to increase efficiency and innovation
- Increasing inpatient clinical trial recruitment
- Implementing efficiencies for recruitment, e.g., automatic opt-in, or E-consent process
- Standardizing education and training for clinical research
- Accelerating the patent or commercialization process

### **Team Composition**

The Translational Science Research Ensemble will integrate a variety of experts and stakeholders, as needed to address a specific translational process barrier. The traditional composition of a [CTSI Ensemble](#) is multidisciplinary and may include basic, clinical and translational investigators, clinicians, patients, patient advocacy groups, community stakeholders, and health system experts (Figure 2).

However, for Translational Science Research Ensembles, activities to identify and remove barriers may rely heavily on the expertise of **translational research accelerators**. These team members include any non-investigator expertise that help accelerate translational research, e.g., experts in clinical trial protocol development, patient recruitment and retention, budget development, grant management, clinical research coordination, project management, human subject research regulations and processes (IRB), advertising and communications, legal and risk management, intellectual property, etc. These are non-investigator experts who can help accelerate research through the various [stages of translational research](#).

Special Note: For this Translational Science Research Ensemble, **translational research accelerators** are eligible to lead these teams, because of their proximity to, and intimate knowledge of, the underlying translational processes.

Figure 2.

## Ensemble Team Composition is Inclusive



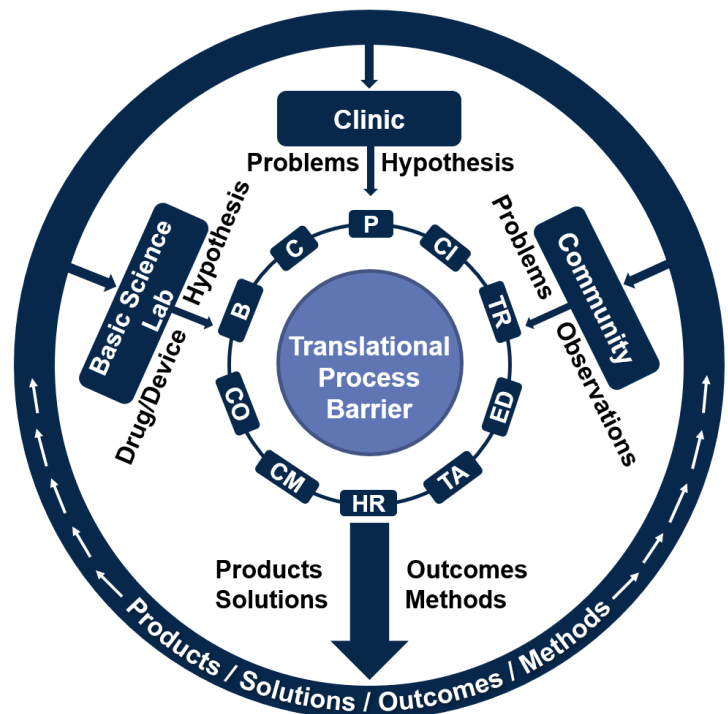
- P: Patient
- CI: Clinical Investigator
- CM: Community Member
- TA: Translational Research Accelerator
- ED: Enabling Discipline Researcher
- HR: Health System/Hospital Representative
- TR: Translational Investigator
- CO: Community/Population Health Researcher
- B: Basic Science Researcher
- C: Clinician

**Translational Research Accelerators.** Any non-investigator expertise that helps accelerate translational research, e.g., experts in clinical trial protocol development, patient recruitment and retention, budget development, grant management, clinical research coordination, project management, human subject research regulations and processes (IRB), advertising and communications, legal and risk management, intellectual property, etc.

### Functional Relationship of Ensemble and Translational Process Barrier

The composition of an Ensemble is important, because problems that may emanate from the research laboratory, clinic, or community, can be articulated by team members that work in these three sectors. As a result, the translational process barrier, shown in the center (Figure 3), is approached in the context of different perspectives and expertise, and thereby, leads to research approaches and solutions that are better informed by the participation of these team members. This intentional composition is also critical to bridging silos between the three sectors that impede collaboration and discovery. The addition of patients and community members to the team adds critical perspectives that help guide the direction of the team. Members of the team can also provide context-driven feedback after the Ensemble completes a research project.

Figure 3. Functional Relationship



## **Submission Details and Deadlines**

### **Letter of Intent (Required): Due by November 27, 2023**

Please submit a Letter of Intent (no more than one page) that indicates a team leader and the potential team members. **Describe the potential barrier(s) to traversing a specific stage(s) of translational research.** Letter of Intent and team details must be submitted through REDCap by 12 midnight, November 27th, 2023. A link to the REDCap LOI submission page will be released at the RFA Town Hall meetings (Oct 31/Nov 1) and posted afterwards to the CTSI RFA webpage. The Letter of Intent is only used to connect project managers with your team; not a limiting step.

### **Proposal Development**

A CTSI project manager will be assigned to each team that submits an LOI and will (1) provide further details on the Pre-Ensemble process, (2) assist in scheduling team meetings, and (3) provide guidance on the development of an Ensemble proposal. Teams should begin meeting ASAP with a goal of holding a minimum of 3-6 meetings to develop the Ensemble proposal. If your team wants to begin meeting earlier than December 15, 2023, contact Mike Anello ([manello@mcw.edu](mailto:manello@mcw.edu)) to begin scheduling.

*The proposal has 4 sections:*

1. Describe the potential barrier(s) to traversing a specific stage(s) of translational research.
2. Describe a robust team of expertise with diverse stakeholder composition.
  - Provide their title and a short description of their expertise.
  - Include the Ensemble role, e.g., Patient, Clinical Investigator, Community Member, Translational Research Accelerator, Enabling Discipline Researcher, Health System/Hospital Representative, Translational Investigator, Community/Population Health Researcher, Basic Science Researcher, Clinician. See Figure 2.
  - *Some expertise can be TBD at the time of proposal submission).*
3. Describe potential products (solutions) that you will develop, that will result from the Ensemble's research activities. You can choose any product pertinent to translational barriers.

Examples of translational science products that improve translational efficiency:

- Connecting parallel research activities/strategies to increase efficiency and innovation
- Increasing inpatient clinical trial recruitment
- Implementing efficiencies for recruitment, e.g., automatic opt-in, or E-consent process
- Standardizing education and training for clinical research
- Accelerating the patent or commercialization process

4. Reference List: No more than one page of the most critical references

Proposals should be 5-7 single-spaced pages, 0.5" margins. CTSI can provide recruitment assistance for teams that are seeking specific expertise. No budget details are required to accompany the proposal.

## **Proposal Deadline: March 11, 2024**

Teams submitting an LOI will be provided a link to submit the full proposal through REDCap after the initial meetings with Project Managers. eBridge is not required for submitting application or providing funds.

### **Project Period**

There are no end dates for this funding support. Once funding is approved, Ensembles will begin working on the delivery of potential products and provide brief quarterly progress reports. Funds are expended at a rate determined by the Ensemble's priorities. The Ensemble is required to make an annual presentation of their progress to the CTSI Executive Committee. Significant progress is expected within one year of funding.

### **Funded Ensembles**

Up to two Translational Science Research Ensembles will be funded through this mechanism. Funded Ensembles will receive a \$50,000 line of credit and the support of a CTSI Project Manager. Available CTSI supports will include: (1) Biostatistical assistance with project design; (2) Biomedical informatics; (3) Clinical trial protocol development & execution, (4) Community engagement expertise; (5) Medical writing expertise; (6) Team science training; and (7) Inter-Institutional and Interdisciplinary Connections.

Funds are not allowed for support of faculty effort. However, funds can support staff effort (including translational research accelerators), and other items e.g., supplies, stipends, services, or other items that support the goals of the research.

### **Testing Translational Science Solutions**

The ultimate goal of your Ensemble is to partner with a translational research project, pilot the translational science solutions, and publish the results of your translational science interventions. The Ensemble can partner with any translational research project, and if needed, CTSI will assist the Ensemble with partnering with a translational research project. The translational research project does not need to be identified at the time of proposal submission.

### **Eligibility**

All investigators and translational research accelerators at CTSI partner institutions are eligible to participate in this funding opportunity. Partner institutions include Medical College of Wisconsin, University of Wisconsin-Milwaukee, Marquette University, Milwaukee School of Engineering, Children's Wisconsin, Versiti Blood Center, Froedtert Hospital, and Zablocki Veterans Affairs Medical Center.

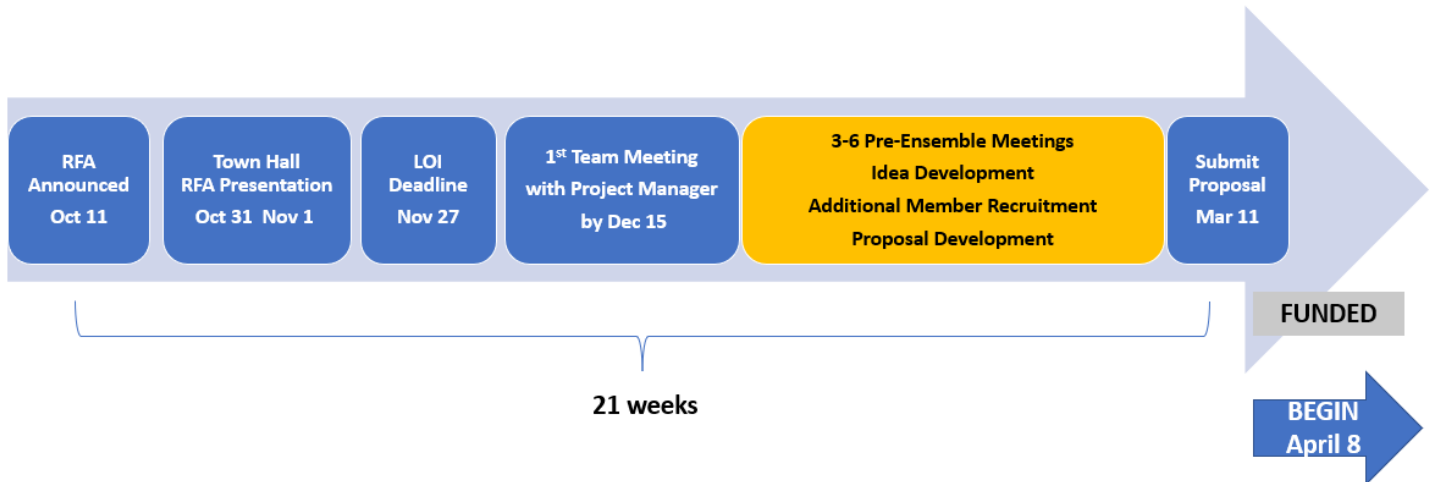
### **Important Dates**

- **October 11, 2023** – RFA Release
- **October 16, 2023** – Begin Consultation Sessions
- **October 31, 2023:** – Town Hall RFA Discussion (Virtual) at Noon.\* [Meeting Link](#)
- **November 1, 2023:** – Town Hall RFA Discussion (Virtual) at 5pm.\* [Meeting Link](#)
- **November 27, 2023:** – Letter of Intent (Required)
- **By December 15, 2023:** – Begin Pre-Ensemble meetings (Required) with CTSI Project Manager and applicant team for team building, development of shared goals, and proposal development.
- **March 11, 2024** – Proposal Deadline; Allows ~5 months for Pre-Ensemble meetings and proposal development

- **April 8, 2024** – Start Date

\*Video recording available for those that cannot attend.

## RFA Timeline



**HIGHLY RECOMMENDED:** Schedule a consultation session to review ideas and ask questions.

Contact Mike Anello ([manello@mcw.edu](mailto:manello@mcw.edu)).

**Questions:** Please contact Mike Anello ([manello@mcw.edu](mailto:manello@mcw.edu)) or David Zimmerman ([dzimmerman@mcw.edu](mailto:dzimmerman@mcw.edu)).

## References

### *Translational Science*

- [How NCATS Tackles Persistent Problems in Translation](#)  
Joni L. Rutter, PhD Director; National Center for Advancing Translational Sciences, Director
- [Divining the Venn Diagram of Translational Research versus Translational Science](#)  
Michael Kurilla, MD, PhD; National Center for Advancing Translational Sciences, Director of Clinical Innovation

### *Team Science*

- Bennett LM, Gadlin H. Collaboration and team science: from theory to practice. *J Investig Med*. 2012 Jun;60(5):768-75. doi: 10.2310/JIM.0b013e318250871d. PMID: 22525233; PMCID: PMC3652225. [Click to Download](#)
- National Research Council. 2015. Enhancing the Effectiveness of Team Science. Report Brief Washington, DC: The National Academies Press. [Click to Download](#)

### *Ensembles*

[CTSI Website](#)