

Monday, October 30th, 2023

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

2024 Translational Research <u>and</u> Translational Science "Dual Focus" Ensemble Awards Two Possible Awards, \$50,000 each

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 improve 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 <u>underlying each step of the translational process</u>.

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 <u>translational efficiency</u> that will accelerate the realization of interventions that improve human health.



Figure 1: Bottlenecks along the Translational Pipeline that impede progress

Credit: <u>How NCATS Tackles Persistent Problems in Translation</u> Joni L. Rutter, PhD Director; National Center for Advancing Translational Sciences, Director To advance the field of translational science and its associated investigative expertise, CTSI will fund two **Translational Research AND Translational Science "Dual-Focus" Research Ensembles**.

The research activities and products of these Ensembles must be two-fold:

- 1. <u>Translational Research</u> Use clinical and translational research and appropriate expertise to create solutions that address an important unmet patient medical need.
- 2. <u>Translational Science</u> Identify underlying obstacles and roadblocks that slow the translational process and use appropriate research activities and expertise to develop and implement solutions that remove these roadblocks and improve translational efficiency.

Ensembles may focus their clinical and translational research on <u>any disease</u> and may address any underlying translational science barriers.

Translational Science: "Sometimes the System or Process is Sick"

Examples of translational science research targets:

- Impediments that prevent:
 - o translation of basic science discoveries into first-in-human investigation
 - o collaboration between basic scientists and clinician scientists
 - o meaningful participation and collaboration of community members in the research process
 - o patient data de-identification
 - o clinic uptake/adoption of new process
 - o phase-out of outdated clinical processes
- Implementation of novel research methods such as decentralized trials, platform trials or n-of-1 trials
- Connecting parallel research activities/strategies to increase efficiency and innovation
- Increasing inpatient clinical trial recruitment
- Implementing efficiencies for patient recruitment, e.g., automatic opt-in, or E-consent process
- Standardizing education and training for clinical research
- Accelerating the patent or commercialization process

Team Members

The Translational Research AND Translational Science Research Ensemble will integrate various experts and stakeholders to address a specific <u>unmet patient medical need(s)</u> and <u>translational science barrier(s)</u>. The composition of a <u>CTSI Ensemble</u> is multidisciplinary, and may include basic, clinical, translational, and community health investigators, as well as clinicians, patient representatives, advocacy groups, community stakeholders, and health system experts (Figure 2).

Important: The addition of patients and community members adds critical perspectives that help guide the team's direction. Members of the team can also provide context-driven feedback after the Ensemble completes a research project.

Ensemble Team Forms Around Two Translational Problems



Cl: 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
Basic Science Researcher
C: Clinician

Translational Research Accelerators

Translational science research activities may rely heavily on the expertise of translational research accelerators, because of their proximity to, and intimate knowledge of, the underlying translational processes. These team members may include any <u>non-investigator expertise</u> 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. These are non-investigator experts who can help accelerate research through the various <u>stages of translational research</u>. The addition of these experts to your Ensemble team may prove critical for developing and implementing solutions.

Research Example

An example of a translational research AND translational science "Dual-Focus" research project might be a project to develop an intervention for diabetes that is tailored towards members of African American or Hispanic communities, with an additional focus on identifying and overcoming barriers in community focused participant recruitment and retention, or barriers to awareness, dissemination, and adoption in the broader community.

Functional Relationship of Ensemble and Dual Research Focus

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 dual research focus unmet patient medical need and translational process barrier, (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 domains that may impede collaboration and discovery.

Submission Details and Deadlines

Letter of Intent (Required) Due by December 11, 2023



Please submit a Letter of Intent (no more than one

page) that identifies a team leader along with potential team members. Describe the (A) unmet patient medical need AND (B) potential barrier(s) to traversing a specific stage(s) of translational research. The Letter of Intent and team details must be submitted through REDCap by 12 midnight, December 11th, 2023. A link to the REDCap LOI submission page will be released at the RFA Town Hall meetings (Nov 14/Nov 15) 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. These "Pre-Ensemble" meetings should begin no later than January 12th, 2024, 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 January 12th, 2024, please contact David Zimmerman (dzimmerman@mcw.edu) to begin scheduling.

The proposal has 3 sections:

- 1. Describe the (A) unmet patient medical need and (B) 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 concise 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, but Translational Research Accelerators must be identified in the proposal.

- 3. Describe potential products (solutions) that you will develop, that will result from the Ensemble's research activities. Your products must include solutions to the unmet patient medical need and products pertinent to translational barriers.
- 4. Reference List: No more than one page of the most critical references

Proposals should be 6-8 single-spaced pages, 0.5" margins in Arial 11 pt font. CTSI can provide recruitment assistance for teams that are seeking specific expertise. No budget details are required to accompany the proposal.

Proposal Deadline: March 25, 2024

Teams submitting an LOI will be provided with a link to submit the full proposal through REDCap following the initial meetings with Project Managers. eBridge is not required for submitting applications or providing funds. Proposals are due by midnight, March 25th, 2024.

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 must 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 Ensembles will be funded through this mechanism. Funded Ensembles will receive a \$50,000 <u>line of credit</u> 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 dual goals of the research. All such support must be pre-approved by the CTSI.

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 30, 2023 RFA Release
- November 6, 2023 Begin Consultation Sessions
- November 14, 2023: Town Hall RFA Discussion (Virtual) at Noon.* Meeting Link
- November 15, 2023: Town Hall RFA Discussion (Virtual) at 5pm.* Meeting Link
- December 11, 2023: Letter of Intent (Required)
- **By January 12, 2024:** Begin Pre-Ensemble meetings (Required) with CTSI Project Manager and applicant team for team building, development of shared goals, and proposal development.
- March 25, 2024 Proposal Deadline; Allows ~5 months for Pre-Ensemble meetings and proposal development
- April 22, 2024 Start Date

*Video recording for those that cannot attend

RFA Timeline



<u>HIGHLY RECOMMENDED</u>: Schedule a consultation session to review ideas and ask questions. Contact David Zimmerman (dzimmerman@mcw.edu).

Questions: Please contact David Zimmerman (dzimermman@mcw.edu).

References

Translational Science

- <u>How NCATS Tackles Persistent Problems in Translation</u> Joni L. Rutter, PhD Director; National Center for Advancing Translational Sciences, Director
- <u>Divining the Venn Diagram of Translational Research versus Translational Science</u> Michael Kurilla, MD, PhD; National Center for Advancing Translational Sciences, Director of Clinical Innovation
- Nakao K. <u>Translational science: Newly emerging science in biology and medicine lessons from</u> <u>translational research on the natriuretic peptide family and leptin.</u> *Proc Jpn Acad Ser B Phys Biol Sci.* 2019;95(9):538-567. doi: 10.2183/pjab.95.037.
- Kim YH, Levine AD, Nehl EJ, Walsh JP. <u>A bibliometric measure of translational science</u>. *Scientometrics*. 2020;125(3):2349-2382. doi: 10.1007/s11192-020-03668-2.
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- Ke Q. <u>Identifying translational science through embeddings of controlled vocabularies</u>. *J Am Med Inform Assoc.* 2019;26(6):516-523. doi: 10.1093/jamia/ocy177.
- Tsevat J, Smyth SS. <u>Training the translational workforce: Expanding beyond translational research to</u> include translational science. J Clin Transl Sci. 2020;4(4):360-362. doi: 10.1017/cts.2020.31.
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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. <u>Click</u> to Download
- National Research Council. 2015. Enhancing the Effectiveness of Team Science. Report Brief Washington, DC: The National Academies Press. <u>Click to Download</u>

Ensembles CTSI Website