

2025 CTSI Translational Science Pilot Award Notice of Funding Opportunity

Request for Applications: Translational Science and Women's Health Across the Lifespan

The Clinical Translational Science Pilot Program (CTSP) at The Ohio State University's Clinical and Translational Science Institute (CTSI), formally the Center for Clinical and Translational Science (CCTS), is now accepting applications for the 2025 CTSI Translational Scient Pilot Award, funded through the NIH CTSA award. The goal of the Translational Science Pilot Award is to fund highly meritorious research for the development of preliminary data to enable researchers to be competitive in applying for extramural funding that advances clinical and translational science.

This request for applications (RFA) is designed to stimulate and support transformative, innovative, interdisciplinary studies that seek to advance team science, implementation science, interinstitutional partnerships and/or community partnerships through understanding and addressing the biological, behavioral, environmental, sociocultural and structural factors that influence women's health across the lifespan.

Successful <u>translational science</u> studies focus on a specific clinical and translational research area aimed to a develop or test a *translational science-directed hypothesis* that addresses a barrier to the progression of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public. Through employing one or more <u>translational science principals</u>, a *translational science-directed hypothesis* should generate a scientific, operational, financial or administrative innovation that addresses longstanding challenges along the translational research pipeline, transforming the way that research is done, making it faster, more efficient, and more impactful. For more information on translational science and the scientific and operational principles of translational science, please see <u>Faupel-Badger JM</u>, <u>Vogel AL</u>, <u>Austin CP</u>, <u>Rutter JL</u>. <u>Advancing translational science</u> education. Clin Transl Sci. 2022 Nov;15(11):2555-2566. PMID: 36045637.

In alignment with the historic Executive Order on Advancing Women's Health Research and Innovation signed early this year and the NIH Office of Research in Women's Health 2024-2028 Strategic Plan, the CTSI is seeking applications with a focus on women's health. Consistent with the NIH's Office of Research on Women's Health, we invite proposals that address research questions for diseases/health concerns that are distinctly female specific (e.g. menopause), disproportionately impact women (e.g. autoimmune disease), progress or present differently in women (e.g. cardiovascular disease) or that seek to integrate female subjects into ongoing research to advance our understanding of sex and gender as influences in health and disease. Proposals may encompass any of the life stages from childhood and adolescence through pregnancy, menopause and aging. Intersectional and/or multidimensional approaches that consider the health of women in context (e.g., projects accounting for social and structural



variables—including <u>race</u>, <u>ethnicity</u>, <u>socioeconomic status</u> and <u>State</u> and <u>Federal policies</u>— that affect women's health) are encouraged. For consideration under this RFA, projects are not required to exclusively focus on women. However, studies that include more than one sex or gender should be designed and powered to make generalizable conclusions about women and enable sex or gender difference comparisons.

CTSI Pilot funding is made available through the Clinical and Translational Science Awards (CTSA) program awarded to The Ohio State University by the National Center for Advancing Translational Sciences (NCATS). The NIH CTSA Funding Opportunity Announcement (PAR-21-293) stipulates that pilot studies funded through the CTSAs **must be focused on translational science** and understanding the <u>Scientific or Operational Principles</u> underlying a step of the translational process, with the goal of developing generalizable solutions to accelerate translational research.

The ultimate goal of this RFA is to strengthen efforts by The Ohio State University researchers in advancing clinical and translational science that aims to reduce health inequalities, promoting health for all.

NIH rules require that CTSA pilot funding recipients may not have more than one year of funding under this mechanism (i.e. no cost extensions are not allowed), and thus proposals should clearly be achievable within 12 months. As such, investigators are encouraged to consider how proposing more than one aim impacts the feasibility of completing their work in the allocated timeframe. Feasibility for the work to be completed within 12 months will be an important review criterion.

GENERAL GUIDELINES

Eligibility Criteria

- Applicants must have Principal Investigator (PI) status as defined by The Ohio State University or Nationwide Children's Hospital.
- Applicants have not received a CTSI pilot grant award or Data and AI Equity (Element E) award within 24 months prior to the application deadline September 16, 2024.
- Proposal for preliminary research that can be completed within one year with a high probability of obtaining future external funding.
- Development of new concepts, methods, technologies, or research practices that drive translational science. Such proposals should clearly identify translational science challenges or barriers that their proposal addresses.



Information and Ideation Sessions

Two information and ideation sessions will be held. Each session will include a short 30-minute presentation on Translational Science and question and answer session followed by a one-and-a-half-hour ideation workshop. Sign up for an information/ideation session on the CTSI website.

- 1. **Information and Ideation Session 1 (VIRTUAL)**: Monday, August 26, 2024, 2 3:30 p.m.
- 2. **Information and Ideation Session 2 (VIRTUAL)**: Friday, September 6, 2024, 9:30 11:00 a.m.

Ideation Session Details

- Prospective applicants are encouraged to attend for the virtual ideation workshop. This
 workshop is designed to elevate the strength and quality of proposals through early
 peer review and panel feedback. This workshop is a fantastic opportunity for applicants
 to present their initial ideas in a professional and friendly forum. Research shows that
 ideas that have gone through several iteration processes are stronger and have better
 potential of securing funding.
- If you plan to present your ideas, please choose the "presenter" option in the registration link, and prepare a five-slide, five-minute presentation that includes the following information:
 - 1. Translational science research question(s) of your project
 - 2. Overview of the research strategy
 - 3. Significance to the field of translational science
 - 4. How you are working as a team to do your proposed research
 - 5. How the research question addresses a critical scientific gap or unmet need in women's health
- Workshop audience will include a specially selected mock review panel, as well as general members of The Ohio State University and Nationwide Children's Hospital community. All audience participants will have the opportunity to ask probing questions and offer comments on your ideas. You will also receive expert comments from the review panel.
- We will accommodate up to eight presentations in the workshop, on a first come, first served basis. Participation in this ideation workshop is not prerequisite for application to the RFA and feedback in this workshop is not indicative of application success.
- Information slides and recordings can be requested at ctsi-pilots@osumc.edu.

Application Requirements

• <u>A pre-application</u> is required and must be submitted online through the REDCap form. The pre-application includes the following:



- o 2025 CTSI Translation Science Pilot Award REDCap Application Form
- o Research plan one page
- PI(s) Biosketch(es)
- A full application will be submitted through an online REDCap form by invitation only following successful completion of the pre-application.

Application Review Process

The Ohio State CTSI 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. Trained patient
and community reviewers are also included in the grant review process. In submitting
an application, you agree to allow reviewers external to The Ohio State University to
access to your application materials.

Funding

- \$25,000 \$35,000 in direct costs can be budgeted for the 12-month project. No cost extensions are not allowed with the mechanism, thus unspent funds by 12 months will not be available for further research. Salary support for faculty may be requested under the following guidelines:
 - Assistant Professor 10% effort up to NIH CAP
 - Associate professor 5% effort up to NIH CAP
 - o Full professor 2.5% effort up to NIH CAP
- Graduate student and technician support, as well as laboratory supplies, are permitted. Notification of awards will be made no later than January 31, 2025. Funds will be available for the next fiscal year, 08/01/2025 to 07/31/2026, to conduct the proposed research. Funds will not be available after 7/31/2026.
- Select awardees will also receive administrative support for a second year to facilitate validation of team science studies to enable advancement of the impactful and generalizable translational science approaches.
- Support for dissemination of validated methods across the regional and national CTSA networks for broader translational science impact will be provided to awardees.

2025 CTSI Translation Science Pilot Award Application Timeline

Release Date: August 12, 2024

Pre-Application Due Date: September 16, 2024

Invitation to Full Application: September 30, 2024



Full Application Due Date: November 1, 2024

Reviews: December 2024

Executive Committee Approval: January 23, 2025

Notice of Award Date: January 31, 2025

Mandatory Regulatory Consult with April Green Due Date: February 21, 2025

Last Possible IRB/IACUC Submission Date: March 15, 2025

NCATS Prior Approval Documents Due: June 15, 2025

Grant Start Date*: August 1, 2025

*Start date is contingent upon NCATS Prior Approval

Important Information

- If the study meets human subject research criteria, IRB approval documentation is required for NCATS Prior Approval Submission. IRB submission must be submitted by March 15, 2025, or the offer for funding will be withdrawn.
- Full applications will be sent to one-to-two external reviewers with expertise in the subject matter. All applications will be scored on each of the review criteria using NIH 9-point scale along with written reviews. Full proposals will be subject to a NIH-type study section assessment and interactive discussions based on the submitted written feedback from external reviewers, institutional context and the overall relevance to the mission of the CTSI.



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