

# Funding Opportunity Announcement: 2025 Clinical and Translational Science Research Program

The Clinical and Translational Science Institute (CTSI) at The Ohio State University is accepting applications for the 2025 Clinical and Translational Science Research Program Awards, funded by the National Institutes of Health's (NIH) National Center for Advancing Translational Sciences (NCATS) Clinical and Translational Science Awards (CTSA) Program.

The goal of the 2025 award is to fund a highly meritorious interdisciplinary clinical and translational science (CTS) project. We are seeking competitive proposals that develop equitable AI tools that address health disparities and advance health equity.

#### **FUNDING AND OTHER SUPPORT**

- Up to \$125,000 per year in direct costs can be budgeted for a two-year period, for a maximum amount of \$250,000.
  - Salary and fringe support for students, graduate students, clinical trainees, postdoctoral and clinical fellows are permitted.
  - Salary support for faculty may be requested under the following guidelines:
    - Assistant Professor 15% effort up to NIH CAP
    - Associate professor 10% effort up to NIH CAP
    - Full professor 5% effort up to NIH CAP
  - Research supplies, research participant travel and other expenses such as research beds, nursing or research nutrition staff, laboratory measures and generation of preliminary data are permitted.
    - Subcontracts for personnel or services outside Ohio State or Nationwide Children's Hospital are discouraged and must be approved by program leadership in advance of the application.
  - Travel funds needed to conduct the study (e.g., participant travel) are permitted if essential. No international travel is allowed.
  - Equipment that is essential for the study and not otherwise available may be requested, but equipment expenditures greater than \$3,000 are discouraged.
- A notice of intent to fund will be made by February 2025 and is subject to NCATS prior approval. Funds will be available beginning August 1, 2025, contingent on NCATS approval.
- Support for dissemination of validated methods across the regional and national CTSA networks for broader translational science impact will be provided to awardees.

#### **ELIGIBILITY REQUIREMENTS**

- Applicants must have Principal Investigator (PI) status as defined by The Ohio State University or Nationwide Children's Hospital.
- Applicants cannot have received a CTSI pilot grant award or Clinical and Translational Science Research Program Award within 24 months prior to the application deadline of Nov. 7, 2024.
- Prior to submitting a pre-application, all applicants must complete all necessary research training (Responsible Code of Research, Human Subject Protection and Good Clinical Practice) if the proposed project involves human subjects.
- Principal investigators are encouraged to be members of CTSI and affiliates of TDAI before submitting an application. Join the CTSI
- Proposed work must be innovative, equitable and generalizable.
- Proposals must develop new concepts, methods, technologies or research practices that drive translational science, and should clearly identify the translational science challenges or barriers that their proposal addresses.

 Proposed work must be completed within two years. NIH does not allow no cost extensions on these funds.

#### **TIMELINE**

- 1. Reguest for Applications Released: Sept. 6, 2024
- 2. Mandatory Pre-Applications Due: Oct. 22, 2024
- 3. Invitations to Submit Full Application: Nov. 7, 2024
- 4. Full Applications Due: Dec. 12, 2024
- 5. Notice of Intent to Fund: Feb. 3, 2025
- 6. Mandatory Regulatory Consult with April Green Due: Feb. 24, 2025
- 7. IRB Submission Due: March 17, 2025
- 8. NCATS Prior Approval Documents Due: June 15, 2025
- 9. Award Start Date (contingent upon NCATS Prior Approval): Aug. 1, 2025
- 10. Progress Report #1 Due: May 10, 2026
- 11. Release of Year 2 Funding: Aug. 1, 2026
- 12. Progress Report #2 Due: May 10, 2027
- 13. Progress Report #3 Due: May 10, 2028
- 14. Final Progress Report Due: May 10, 2030

#### **Information Session (VIRTUAL)**: October 1, 4:30 – 5 p.m.

An information session will be offered that features a short presentation on clinical and translational science, followed by a Q&A. It will be recorded and posted to the <u>Clinical and Translational Science Research Program Awards RFA webpage</u>.

# **Register for the Information Session**

# **Proposal Ideation Workshop (VIRTUAL)**: October 14, 1-3 p.m.

Prospective applicants are encouraged to participate in a virtual ideation workshop to present their initial ideas in a professional and friendly forum, as research shows that ideas that have gone through several iteration processes are stronger and have better potential of securing funding. The audience will include a mock review panel to provide expert comments, and general members of The Ohio State University and Nationwide Children's Hospital Community who have the opportunity to ask probing questions and offer comments on presented ideas.

Participation in this ideation workshop is not a prerequisite for application to the RFA, and feedback in this workshop is not indicative of application success. Up to 15 presentations will be accommodated in the workshop, on a first come, first served basis.

**To participate as a presenter**, choose the "presenter" option in the registration form and prepare a three-minute presentation that includes:

- 1. Translational science research question(s)
- 2. Research strategy, including data management plan and rigor of the study
- 3. Significance to clinical and translational science

### **Register for the Ideation Session**

# Reviews and Approvals

## **PRE-APPLICATIONS**

### Reviews

Directors of the Clinical and Translational Science Research Program review and evaluate the preapplications for significance, innovation and relevance to the current Clinical and Translational Science Research Program. Selected projects will be invited for full applications.

#### INVITED FULL APPLICATIONS

#### **Review Process**

- Invited full applications are scored by one to two external reviewers with relevant expertise using the NIH 9-point scale. Note: CTSI participates in a national CTSA External Reviewer Exchange Consortium to improve fairness in the scientific review process and better match applicants with feedback from experts in their specific fields. Trained patient and community reviewers are also included in the award review process. In submitting an application, you agree to allow reviewers external to Ohio State to access your application materials.
- Directors of the Clinical and Translational Science Research Program will assess full applications in an NIH-type study section that takes into consideration internal and external reviewer feedback, institutional context, and overall relevance to the mission of CTSI.
- With the recommendations made by Directors of Clinical and Translational Science Research Program, the final award and funding decision will be made in the CTSI Director's Council
- Important approvals: Full applications identified for funding are subject to NCATS prior approval before the release of funds, IRB approval (when relevant) is required before submitting for NCATS prior approval, and a regulatory consult with CTSI is required before submitting for IRB approval. The last day for regulatory consults is February 24, 2025, and it is strongly recommended that you contact April.Green2@osumc.edu as soon as possible to discuss your project.

#### **Evaluation Criteria**

Teams that receive invitations to submit full applications are encouraged to consider the following criteria when writing their proposal:

- I. Project Significance
  - a. The proposal's research question and the translational science challenges it addresses relate to primary themes of this RFA and are in the scope of health equity and health disparity.
  - b. The proposed project addresses a truly significant roadblock in CTS that if successful would have generalizable application.
  - c. The proposal includes a well-reasoned ethical consideration of the research and its broader implications.

#### II. Innovation

- a. The proposed project utilizes innovative approaches to accomplish its stated aims.
- b. The proposed approach is clear, reasonable and appropriate.
- c. The advantage of this approach over the next best alternative is well-justified.

#### III. Outcomes and Evaluation

- a. Proposed outcomes are new concepts, methods, technologies or research practices that drive translational science and are reasonable, justified and worthwhile.
- b. A definition of success and relevant metrics are included that are reasonable and appropriate.

# IV. Timeline and Budget

- a. A reasonable timeline and effective key milestones are included for completing the project within two years.
- b. The budget is reasonable and justified for the proposed activities and is within Clinical and Translational Science Research Program Award parameters.

#### V. Additional Considerations

#### The project:

- a. Includes one or more members of underrepresented groups in the team's composition.
- b. Includes student or trainee development opportunities.
- c. Uses and/or creates data assets that can be utilized by other Ohio State researchers.

# Required Formats and How to Submit MANDATORY PRE-APPLICATIONS

Mandatory pre-applications are required to be submitted via the online REDCap form that can be <u>accessed via the Clinical and Translational Science Research Program Awards webpage</u>, and they must include the following:

- Names and affiliations of:
  - Contact PI
  - Multiple-Pl(s)
  - Other Investigator(s)
  - Other Collaborator(s)

Note: Application teams that include both clinical faculty and research faculty at The Ohio State University or Nationwide Children's Hospital can indicate the co-PI relationship by using the designations Clinical co-PI and Research co-PI.

- One page description of the proposed work, including the questions and translational challenges it addresses, significance, specific aims and proposed methods
- PI Biosketch(es)
- Names and email addresses for five possible internal (Ohio State) reviewers with whom the team does not have a conflict of interest, which is defined as:
  - Co-authoring any publication, pending publication or proposal within the past three years
  - Collaborating on any project, including current and planned collaborations, within the past three years
  - Advisor/advisee or supervisor/supervisee status for thesis, dissertation or postdoctoral work
  - Any family relationship
  - Any business relationship within the last three years

#### **INVITED APPLICATIONS**

Full applications are <u>by invitation only</u>, must be submitted via the online REDCap form that can be <u>accessed via the Clinical and Translational Science Research Program Awards webpage</u>, and must include the following:

- I. **Abstract in lay language limit one page.** What problem does the proposed work solve, whom does it affect and why is solving the problem important, and how is your proposed approach advantageous over others?
- II. Research Strategy limit five pages. What does your proposed work consist of, and what will it produce?
- III. Data Management Plan limit one page
- IV. Project Timeline, Milestones, and Specific Deliverables less than one page
- V. **Team List less than one page.** Provide name, title/department and project contribution(s) for every team member, including faculty, postdocs, students and staff; include advisor or supervisor name for postdocs, students and staff.
- VI. NIH Biosketch for Every Faculty Team Member
- VII. **Budget.** If you are requesting personnel, include a line item and justification for each position.
- VIII. Budget Justification limit onesentence per budget line item
- IX. Letters of Collaboration. For collaborative arrangements of significance, include a signed letter that states the following: If the proposal submitted by Dr. [insert contact Pl's full name] entitled [insert proposal title] is selected for funding by CTSI, it is my intent to collaborate and/or commit resources as detailed in the Project Description.

# **Contact Information**

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