OCTRI Translational Science Pilot Project

REQUEST FOR APPLICATIONS

The Oregon Clinical & Translational Research Institute (OCTRI) is accepting applications for a translational science pilot project that can be developed with ~$30,000 in funding to collect preliminary data for inclusion as an R01-sized research project (up to $300,000) in OCTRI's next grant renewal submission due in May 2026.

PROGRAM OVERVIEW

OCTRI is primarily funded by the Clinical and Translational Science Award (CTSA) Program led by the NIH National Center for Advancing Translational Science (NCATS). We are one of 60+ funded CTSA programs around the country.

Our next NCATS grant renewal, due in May 2026, requires a series of R01-sized translational science research projects, up to $300,000. We are soliciting ideas for these projects from our research community. OCTRI will fund up to 2 pilot projects up to $30,000 each to start in August 2025 for inclusion in our May 2026 grant submission. Qualified awardees may have the opportunity to function as lead or co-lead of the section in the grant renewal that contains these projects.

Pilot funds will be awarded on a competitive basis. Each awardee will be assigned an OCTRI project manager and staff support to advise on translational science and help accelerate the project to completion in time for inclusion in the grant renewal. Awardees will have access to the full suite of OCTRI services to support their projects, including Informatics, Biostatistics and Research Design, Regulatory, Clinical and Translational Research Center, and others.

APPLICATION PROCESS OVERVIEW

STEP #1: LETTER OF INTENT

1. Complete a letter of intent using the template provided at the end of this document and send to octri@ohsu.edu by *11:59pm PST on February 15, 2025*.
2. Members of the review committee will review your letter of intent. They may reach out with questions or potentially request a brief meeting to discuss your proposed plans.

STEP #2: FULL APPLICATION

Once the letter of intent is approved, please submit your application using this online form. Components of the application include:

1. **Research Plan** that is no more than 3 pages long and that uses the same headings provided in the letter of intent template. References do not count toward page total.
2. NIH 398 budget **& budget justification.** Applicants will work with application reviewers and the OCTRI Navigator team to develop a Cooperative Agreement that details the budget up to $30,000, as well as any potential no-cost services provided by OCTRI.
3. NIH biosketches for project lead and key personnel.
4. *Optional* **Letters of Support** from mentors, collaborators, or resource providers (up to 3).

Projects selected to advance will be invited to participate in a Q&A with review committee members, after which, final funding decisions will be made. All application materials are treated as confidential documents. This application does NOT require a Proposed Project Questionnaire (PPQ).

REVIEW CRITERIA

- **Translational Science:** Does this project address a compelling translational science roadblock, barrier, or unmet need? See Translational Science section below for definitions and examples.
- **Project Design and Feasibility:** Is the proposed work feasible in the required timeframe? What types of expertise will be leveraged to move the project forward? What are the potential barriers, and what is the plan to overcome them?
- **Leverage Pilot Funding:** How will this funding position the project for inclusion in the CTSA UM1 submission in May 2026?
- **Impact to Human Health:** Does the proposed work aim to solve an important problem or remove a critical barrier to progress in the field?
- **Strength of Team:** Do the project leads have the requisite skills and experience to carry out the project successfully?

ELIGIBILITY

This funding opportunity is open to all faculty, employees and trainees of OHSU and OCTRI's research partner institutions (Portland State University, University of Oregon, Oregon State University, and OCHIN), with these important caveats:

- If either human subjects or animals are included in the project scope of work, the applicant MUST meet OHSU Principal Investigator requirements.
- Non-faculty applicants must submit written approval from their supervisor or department head authorizing "effort" on the grant – including the specific amount.

PROJECTS INVOLVING HUMAN SUBJECTS RESEARCH AND/OR LIVE VERTEBRATE ANIMAL STUDIES

In addition to IRB/IACUC approval, NCATS must approve human subjects research and/or live vertebrate animal projects before any funding can be released. Applicants will be strongly encouraged to complete the required components of the NCATS submission during the application phase to reduce the time to funding. If a letter of intent is chosen to move forward to a full application, then OCTRI will provide more information and support applicants through this process. *Applicants do NOT need to complete the NCATS components for letter of intent submission, only for full applications.*

POST-AWARD PROCESSES

All award recipients will be required to submit progress reports using guidelines that will be provided at a later date.

QUESTIONS?

If you have any questions about this request, please do not hesitate to reach out. OCTRI has flexibility in the projects we choose, and we want to hear your ideas. Please direct all questions to OCTRI Navigator at octri@ohsu.edu.

WHAT IS TRANSLATIONAL SCIENCE?

The goal of translational science is to identify and remove barriers, roadblocks, or bottlenecks in the translational research process. This approach solves problems that will benefit research across a range of diseases and conditions and accelerate health solutions to people. There are scientific and operational components to translational science. Scientific components focus on research (questions, methods, approaches), while operation components focus on organizational, financial, and administrative processes; leveraging partnerships and collaborations; and/or workforce development. Your proposed project may include either or both of these elements. Your project may also focus on a specific disease or field, as long as the methods or outcomes are generalizable. The overarching goal is to make research run more efficiently.

How to think about translational science for your proposed pilot project:

- What is the translational roadblock, barrier, or unmet need being addressed?
- What is the project that you propose to lessen or remove the roadblock?
- How will these findings increase translational efficiency and produce generalizable knowledge across therapeutic areas, contexts, etc.?

Examples of translational science

- Listen to examples described by Dr. Cindy Morris in the recording of the Dec 2, 2024 OHSU Research Town Hall, available here on O2 or in OCTRI's Accessing OCTRI Services YouTube playlist.
- Self-collection method for cervical cancer screening (Madding et al., 2024)
  - *Goal:* Reduce barriers to cervical cancer screening for women who have experienced intimate partner violence (IPV). This population has lower rates of screening and higher rates of cancer.
  - *Result:* Self-collection of samples for cervical cancer screening is accepted and feasible among women with a history of IPV.
  - *Translational Science:* Self-collection removes barriers to access for recommended health care screening and for participation in research studies for women who have experienced IPV. This community-engaged, self-collection method can be applied to other types of health care that women may need but are not getting due to discomfort with the process.
- Pragmatic trial for testing treatment of atopic dermatitis in infants (Eichner et al., 2020)
  - *Goal:* Measure the effectiveness of lipid-rich emollients to reduce the risk of developing atopic dermatitis (AD) in infants using a pragmatic trial design with practice-based research networks in four states, including the Oregon Rural Practice-based Research Network.
  - *Result:* Successful collection of real-world data with minimal additional burden on patients, to include patients in rural areas.
  - *Translational Science:* This study design reduced barriers to participation in research for families with infants and for those living in rural areas. This approach can be replicated for other health issues affecting infants and for other populations, who may not be able to travel long distances to participate in research studies.
- Pragmatic trial for testing impact of IV fluids on outcomes for ICU patients (Semlor et al., 2018)
  - *Goal:* Use rigorous research methods to measure adverse kidney outcomes for critically ill ICU patients who receive saline vs. balanced crystalloids, which have been used interchangeably for decades, although saline has been associated with worse kidney outcomes.
  - *Result:* ICU patients who received balanced crystalloids had a lower rate of major adverse kidney events than those who received saline.
  - *Translational Science:* This trial design answers questions about outcomes for critically ill patients without disrupting their care and reduces the barrier for conducting research with critically ill patient populations. This design can be replicated to answer questions about other types of

outcomes in this population and can also be leveraged to answer questions about non-critically ill adults (see Self et al., 2018).

- NIH ACTIV trials - Nationwide decentralized, platform clinical trials to accelerate the evaluation of COVID-19 treatments
    - o *Goal:* For the ACTIV-6 trial, accelerate evaluation of promising, re-purposeable drugs to provide evidence-based treatment options for adult patients with COVID-19 who have mild-to-moderate symptoms and are not sick enough to be hospitalized (details on NCATS website).
    - o *Result:* The drugs tested in the ACTIV-6 trials were not found to improve symptoms or reduce recovery time in adults with mild to moderate COVID-19 (NIH ACTIV-6 trial results). This result was achieved in less than half the standard time for a phase 3 clinical trial (NCATS 2021-2022 Biennial Report).
    - o *Translational Science:* This trial design tested new methodologies for decentralized clinical trials and demonstrated reduced time to draw meaningful clinical conclusions. This design can be replicated for rapidly testing treatments for other diseases/health conditions and can be leveraged in other future global health crises.
- Other examples from NCATS (videos): 1) Tool kit to align efforts across various rare disease patient advocacy groups; 2) Solution for cancer metastasis that can be applied to all types of cancer; 3) Tissue chips for developing and testing drug treatments.
- Examples on alleviating research bottle necks from the Montefiore-Einstein CTSA hub in New York, including clinical and preclinical examples.

LETTER OF INTENT (LOI) TEMPLATE FOR TRANSLATIONAL SCIENCE PROJECT

Please use the template below to complete your LOI. LOI should be ~1 page in length. Please include an NIH Biosketch for the project lead with the LOI. References do not count toward the page limit.

PROJECT LEAD (NAME AND TITLE; PLEASE ATTACH BIOSKETCH):

PROJECT TITLE:

BACKGROUND: Briefly describe the significant problem, barrier, or unmet need to be addressed. (~100 words)

PROPOSED PROJECT/SOLUTION: Please include a description of the translational science aspect of your proposed project (i.e. the problem/roadblock/barrier/unmet need and the solution). The project may focus on a specific disease or field (translational research), as long as the methods or outcomes are generalizable (translational science). (~200 words)

PRELIMINARY DATA: Preliminary data (if any) that support the feasibility and relevance of the proposed project and outcomes. (~100 words)

R&D TIMELINE: Outline 12-month project timeline and milestones. Project must result in a significant amount of data by February 2026 for inclusion in the May 2026 CTSA UM1 submission. OCTRI will schedule quarterly progress meetings and monthly check-ins. Do not include a detailed budget at this time. We will discuss budget with you, if your project moves forward to the application phase. (~200 words)

TEAM MEMBERS: List team members, their expertise, and project role.