

OCTRI Today and Tomorrow: How you can contribute

DATE: December 2, 2024 Dr. Cynthia Morris OREGON CLINICAL & TRANSLATIONAL RESEARCH INSTITUTE

We are part of a national network of NIH-funded institutions called hubs – working together to improve the translational research process to get more treatments to more patients more quickly. CTSA=Clinical and Translational Science Award



OCTRI is infrastructure

OCTRI builds research



Workforce Development Clinical Research Development Team: Recruitment, regulatory, CTRC Entrepreneurship. Pilot award, program evaluation

OCTRI is a team

1. Investigator with grant idea or protocol to implement

3. Written output to guide investigator to next steps

2. Meet with CRDT for coordinated advice and guidance

Note: CRDT is the biggest version of this type of quality input we provide, but there are other variations

OCTRI is in the community

OCTRI develops the workforce

OCTRI innovates

Intellectual Property Protection and Transactions

Collaboration Management

Technology Funding

New Ventures

Entrepreneurial Education

OCTRI is data

- Solutions to store clinical research data
- To obtain and use real world data
- To develop custom solutions to collect data
- To display and analyze data

How to get started

Contact an OCTRI Navigator to connect with research resources

503-418-9790 octri@ohsu.edu

Where are we going?

- OCTRI was funded in 2006, renewed competitively in 5-year cycles
- Next renewal is 2027, application due May 2026
- A suite of 7 applications: UM1, K12, T32 (predoc, postdoc), R25, RC2 (x2)
- New emphasis on translational science

How you can participate in our renewal

- We are looking to identify impactful research barriers, work on solutions. We are releasing an RFA today for a pilot study
- Consider research barriers, a research challenge that needs an innovative solution, what is holding research back?
- Element E: A R01/R21 sized project that is *included* in our UM1 application, funded for 2-3 years
 - Must address a research barrier, pose a generalizable solution
 - Pilot funding to be released in 2025 to provide prelim data, feasibility
- RC2: A separate application that proposes a high impact, interdisciplinary project that accompanies the main UM1
- Future pilot studies funded by the UM1 will be oriented to TS

Translational Research vs. Translational Science

Translational science focuses on innovations that overcome longstanding challenges in the translational research pipeline

- *Scientific, operational, and administrative roadblocks* or barriers
- *Innovations transform the way research is done*, making it faster, more efficient, more impactful

Many illnesses without effective treatment, lack of appropriate models

Paradigm-changing goals, innovations that broaden impact

Accelerate the pace, milestone driven, form teams more rapidly

> Be ambitious, use rigorous approaches to generate reproducible data

What types of projects would we expect?

- Informatics, data management, integrating data from multiple sources
- Regulatory such as obtaining consent, IRB approval
- Drug and device research design
- Improving the process of early translation to humans
- Improvements in research design (adaptive, decentralized, platform)
- Community engagement research
- Collecting specimens and outcome data from remote populations
- Recruitment and retention
- Biostatistical analysis
- Team science
- And many more

Examples of translational science studies

- Can we develop research procedures to enroll and follow participants from community practices that minimize impact on these overburdened practices?
- Using social media can increase accessibility to broad geographic areas and diversify participants. Can a process or algorithm reliably improve the ability for timely and efficient recruiting to increase diversity?

Examples of translational research vs science

TRANSLATIONAL RESEARCH	TRANSLATIONAL SCIENCE
Phase 1 trial of a new compound that has proven effective in reducing damage from ischemia in an animal model	Developing models/assays that can be better predictors of efficacy in humans than current cell/animal models
Identifying early biomarkers of MS	Development of a reliable framework/model to identify how biomarkers that change early in intervention predict intervention efficacy
Creating a registry to study the impact of type 2 diabetes in Oregon communities	Developing a system to merge data from multiple data sources to efficiently create a representative population data set, including multiple resources
Improve the diversity of recruitment into a trial of Alzheimer's disease prevention	Systematically study the barriers that prevent enrollment of participants into a clinical trial, including geography, trust, motivation, outreach, health and digital literacy, using Alzheimer's disease as a focus

Examples – Hub 1 - Community recruiting, engagement

Theme: Enhancing engagement in translational science using innovative strategies and techniques

Project 1. Enhancing integration of patient-generated data into electronic health records in a study of patients recovering from sepsis

Project 2. Recruiting a diverse population into clinical trials of chronic disease is difficult and often not accomplished. Using patient-driven recruitment can enhance the speed and diversity of recruitment in a common condition like administration of flu vaccine.

Project 3. Incorporating future dissemination into clinical trials

Example – Hub 2 – Mobile technology

Widespread access to smart phones allow access to health data collected in patient's homes. Yet collecting data can be difficult w/ custom apps that are difficult to use; poor bandwidth in this rural state; and a lack of widespread use of devices like BP monitors.

Aim 1. Develop a reliable, flexible, and scalable platform to collect remote data from study participants, including a platform for sharing images, video and audio files, and health-related data such as FitBits, BP monitors, indoor environment monitors.

Aim 2. Test the efficiency by recruiting and observing a cohort such as women in pregnancy monitored for weight and BP for early detection of preeclampsia.

Example – Hub 3 - Informatics

Theme: Improvement in measuring social determinants of health can improve collection and use of real world data (RWD)

- **Project 1.** Develop, implement, and evaluate a hands-on course and data support structures to increase use of data from large national RWD sets.
- **Project 2.** RWD often uses area-based social deprivation indices. This project uses machine learning approaches to apply US Census tract data to test for bias in social deprivation indices.
- Project 3. Using the PRIDE study, apply lessons learned in data collection, curation and harmonization to renovate the architecture of PRIDE to incorporate new types of data to improve understanding of underrepresented and vulnerable communities.

Example – Hub 4 – Community engagement

Theme: To set priorities for research, translational researchers and communities need to collaborate to identify health inequities and potential underlying causes, to identify solutions and track progress.

Aim 1. Engage a range of community partners to co-create a statewide system of health measures and analyses (map).

Aim 2. Disseminate and support researchers, care teams, policymakers, and learners to use this statewide system to develop strategies to reduce inequities.

Aim 3. Demonstrate that this system increases research, changes care, and affects policy to address equity statewide, and that these interventions extend "bright spot assets" to communities in need.

What is the process to contribute in OCTRI?

• Step 1: Letter of intent that describes the barrier or challenge and proposed solution, due Feb 15.

This will be considered as a collaborative agreement with OCTRI

- Step 2: An internal committee in OCTRI will assess all letters to narrow the pool to those with the most promise as Element E
- Step 3: Propose a feasibility study, may award up to 2 at \$30K in 2025
- Step 4: Final selection submitted as Element E in 2026

Who is eligible?

Anyone can propose a research barrier, will need an eligible PI for funding

What can the pilot study do?

- Explore a barrier and possible innovation or new direction for an established investigator
- Stimulate investigators from other areas to provide expertise
- Provide initial support for proof of concept

How will this be reviewed?

Each proposal should have:

- A translational science question or hypothesis (focus)
- A translational research question or hypothesis (case or setting)

Key concepts in review:

- Does this pose a generalizable problem?
- Will this improve the efficiency or speed of translation?
- Is this a disruptive innovation?
- Does this make use of team science? Multiple disciplines? Multiple partners?

Wrapping Up

- Staff often has the best insight into research barriers
- We are open to the broad range of research challenges, particularly those well-aligned with OCTRI strengths
- We do not expect a "shovel ready" project; we expect to collaborate
- Feel free to reach out to OCTRI navigator for advice
- This is only the first outreach for translational science; if successful in our application, opportunities for participation will increase

https://bit.ly/OCTRI-TS-RFP

