OREGON CLINICAL & TRANSLATIONAL
Research Institute
OHSU

Request for Applications:

Pilot Project Funding for Catalyzing Translational Research Opportunities

KEY DATES

Full application deadline	Noon on April 4, 2016
Presentations to Scientific Review Committee (if invited)	May 11, 2016
Notification of award	By May 20, 2016
Window of award availability	July 1, 2016 – June 30, 2017

OCTRI is funded by a grant from the NIH National Center for Advancing Translational Sciences (NCATS). NIH funding decisions may influence the disbursement of 2017 Catalyst Awards.

PROGRAM OVERVIEW

The Oregon Clinical & Translational Research Institute (OCTRI), in collaboration with the School of Medicine's Research Roadmap and the Office of the Senior Vice President for Research, is now accepting applications for pilot projects designed to **enhance translational research** at OHSU. This funding mechanism is open to all OHSU faculty who meet OHSU eligibility requirements, regardless of school or unit.

The Catalyst Awards are designed to support new clinical and translational research initiatives that will both lead to the dissemination of impactful **novel research methodology** and generate additional research funding. Project budgets should not exceed $75,000.

Due to the structure of the OCTRI Pilot Awards budget, indirect costs are not allowable. Projects that anticipate awarding subcontracts to non-OHSU entities will require prior OCTRI approval.

Development of Novel Research Methodologies

The development of new methodologies is a critical part of clinical and translational research. This program provides funding that can accelerate the work of OHSU investigators who are engaged in developing novel, consequential research methodologies. **The Catalyst Award is designed to facilitate development of state-of-the-art tools for translational research and to make these tools rapidly available to investigators.**

Examples of pilot projects that would be viewed as responsive include **but are not limited** to:

- Innovative mechanisms that increase the speed and reduce the cost of clinical trials
- New methods for phenotyping
- Predictive toxicology
- Novel and effective clinical subject recruitment techniques
- Ethics research that is specific to populations
- Clinical informatics for longitudinal studies
- Novel comparative effectiveness research methodologies
- Mass spectrometry-based techniques
- Innovative use of imaging and/or biomarkers to assess treatment prognosis
- Genomics research methodology
- Improved methods for community outreach
- Design or implementation of assays in medium throughput screening for drug discovery
- Innovative experimental design and/or development of statistical methodologies for clinical and translational research applications, including innovative clinical trial design
- Technologies for clinical decision support

Proposed methods should have wide applicability and should be ready for broad dissemination to the research community by the end of the one-year award period. Specifically, methods whose feasibility is questionable should not be developed via this award, since the emphasis in this mechanism is the development of tools that are applicable in a relatively short period of time.

<u>**APPLICATION INSTRUCTIONS**</u>

Fill out the online application at <u>https://octri.ohsu.edu/redcap/surveys/?s=9LFERXJ3MH</u>
Application components include:

1) Project title
2) Principal Investigator contact information
3) Project information
4) Abstract (see the description below)
5) Research plan (see the description below)
6) Biosketches for the project PI and key project personnel

Style Instructions

- **Font:** Arial, black, 11 points or larger
- **Page margins:** At least one-half inch margins for all pages.
- **Figures, graphs, diagrams, charts, tables, figure legends, and footnotes (included in page limit):** You may use a smaller font size but it must be legible and follow the other font requirements. Do not include figures or other materials that are not inserted directly into the body of the application. Any separate pages will be counted toward the page limit.
- **Documents and file names:**
   a. Documents can be in any of the following formats: *.doc, *.docx, *.pdf
   b. Turn off track changes and accept all changes.
   c. Follow the naming conventions below (with appropriate file extension):
      i. <u>Research Plan</u>: PI last name_plan.doc
      ii. <u>Biosketches</u>: PI last name_biosketch.doc (combine all biosketches into a single document with the PI biosketch first)

Detailed Overview of Application Components

- **Project abstract – limit of 250 words**
   o Write a paragraph that provides a clear and concise description of the project's objectives, proposed methodology, and anticipated results in layman's terms.
- **Research Plan – 6 page limit**
   o **Specific Aims**: Clearly articulate the hypotheses or objectives and specific aims of the study.
   o **Proposal Narrative** (Please adhere to the following outline, including headers for each section):
      ▪ **Background and Significance**: Describe the scientific context of the proposed work with reference to other relevant work in the field and, in that light, the significance of the project. What is the major opportunity that drives the proposal? Why is the project innovative? Describe how

the project could overcome existing barriers and open up new possibilities, or how it otherwise merits attention. Explain how the proposal is responsive to the call for novel research methodology projects. Highlight any proposed use of OHSU core facilities, unique aspects of the applicant's background or prior experience, and capabilities that will be brought to bear on the project. Explain why this project is a good opportunity for the people who are involved. Briefly describe the current status of related research at OHSU, including existing strengths and opportunities.

- **Preliminary Data**: Describe the work that supports the scientific worth and feasibility of the proposal, and thus enables the project. There must be sufficient preliminary data that establish feasibility in the approach.

- **Project Plan**: Against the background provided in the previous sections, describe the work you plan to undertake and its expected outcomes. Make a well-crafted plan clear to the reviewers and show how background information and preliminary data will support of the project. Include sufficient details of the science so reviewers can judge the feasibility of the plan. After reading this section, reviewers should appreciate how expected outcomes would address the critical opportunities and barriers identified in the previous sections.

- **Milestones and Timeline**: Provide a timeline for completion of the proposed work in a simple, readable form, such as a table or diagram. If the plan includes enrolling human subjects, one of the milestones must specify an enrollment period and recruitment goals. Include no fewer than 3 and no more than 10 project milestones. At six months post-project launch, milestone progress will be reviewed. Applications without measurable milestones will not be considered. Please direct any questions regarding this section to octrievaluation@ohsu.edu.

- **Plans for Continuation**: *This is a key section.* Explain how the science proposed will lead to the stated goals of the project. Priority will be given to those proposals that are likely to result in publication in high-impact peer reviewed journals or other far-reaching means of research dissemination (e.g., project website, conference presentations, workshops, etc.). A specific target journal or dissemination method must be clearly specified.

- **References and Letters of Support:** These documents *do not* count toward the page limit and should be added at the end of the proposal narrative.

BUDGET CONSIDERATIONS

Detailed budgets will be required once an applicant has been asked to present. Applicant budgets must meet the following award constraints:

- Not more than $75,000 in direct costs
- All funds must be spent by June 30, 2017

- The project will pass all regulatory requirements (such as IRB, IACUC, IBC) no later than mid-July 2016. To ensure that this process goes as quickly as possible, applications that include human subject research and are selected for presentation to the Scientific Review Committee will be required to have a full protocol by the time of their presentation.

REVIEW CRITERIA

An expert panel of senior research scientists appointed by OCTRI will review applications and subsequent presentations. The primary review criteria will be the responsiveness to the specific requirements laid out in the above instructions. Additionally, submissions will be scored on their strengths in the following categories:

1. **Likelihood of future funding or effective dissemination of new methodology.** Will this funding enable the development of compelling new grant applications or other investment that will sustain the proposed research activity? Will the proposed research activity provide impactful dissemination of an important new research methodology?

2. **Significance.** Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

3. **Investigators.** Are the PIs, collaborators, and other researchers well suited to the project? If the project includes early-stage investigators, new investigators, or individuals in the early stages of independent careers, do they have appropriate experience and training? If the project includes established researchers, have they demonstrated an ongoing record of accomplishments that have advanced their fields? If the project is collaborative or multi-PI, do the investigators have complementary and integrated expertise? Is their leadership approach, governance, and organizational structure appropriate for the project?

4. **Innovation.** Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research, or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

5. **Approach.** Are the overall strategy, methodology, and analyses well reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? If the project involves clinical research, are the plans for 1) protection of human

subjects from research risks, and 2) inclusion of minorities, members of both genders, and children justified in terms of the scientific goals and research strategy proposed?

6. **Environment.** Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment, and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

7. **Overall impact.** Reflects all scored criteria, plus additional criteria regarding the protection and inclusion of human subjects, vertebrate animal care and welfare, biohazards, and criteria specific to this funding opportunity.

Application SUBMISSION AND QUESTIONS

Submit your application to OCTRI via a redcap survey at:
https://octri.ohsu.edu/redcap/surveys/?s=9LFERXJ3MH
Please direct all questions to the OCTRI Research Navigator Program (503-418-9790, octri@ohsu.edu).