Request for Applications:
Pilot Project Funding for Catalyzing Translational Research Opportunities

KEY DATES

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Letter of intent (LOI) deadline</td>
<td>April 22, 2013</td>
</tr>
<tr>
<td>LOI decision</td>
<td>May 10, 2013</td>
</tr>
<tr>
<td>Full application deadline (if invited)</td>
<td>June 14, 2013</td>
</tr>
<tr>
<td>Presentations to Scientific Review Committee (if invited)</td>
<td>July 10, 2013</td>
</tr>
<tr>
<td>Notification of award</td>
<td>July 15, 2013</td>
</tr>
<tr>
<td>Funding must start between</td>
<td>July, 2013 – June, 2014</td>
</tr>
</tbody>
</table>

PROGRAM OVERVIEW

The Oregon Clinical & Translational Research Institute (OCTRI) is now accepting letters of intent to apply for Pilot Project Funding for projects designed to enhance translational research at OHSU. This funding mechanism is offered in close collaboration with the SOM Research Roadmap, but is open to all OHSU faculty.

OCTRI will award up to 5 awardees ($400,000 total) to facilitate novel, collaborative, multidisciplinary studies that will lead to further research and funding in translational research. This funding is specifically intended to enable the development of compelling new grant applications that will sustain the proposed research activity.

Applications that are responsive to any one of the following three areas will be accepted:

1. Development of Large, Interdisciplinary Grants
2. Research Cohort Development
3. T1 Translational Research/First in Human Studies

Applicants may request budgets up to $100,000 for one year in direct costs; no indirect costs are available due to the structure of the OCTRI pilot fund. In addition to the request of direct cost funding, applications may also request up to $50,000 in infrastructure support from OCTRI programs such as the CTRC (nursing, study coordinator, core lab/sample processing, bionutrition/research kitchen), Informatics, Investigator Support and Integration Services (IRB applications and regulatory consultations), and Biostatistics. The OHSU Research Data Warehouse may also be instrumental in identifying patients for potential recruitment, and the OHSU Knight Biobank may be an essential core resource for specimen collection. Requests for support from these resources along with an estimated budget must be included in the project description. Visit
the OCTRI website (www.octri.org) for a listing of services. Before submitting an application involving these services, contact the OCTRI Research Navigator Program (503-418-9790, octri@ohsu.edu) for questions and help in estimating costs.

A portion of this funding is made available through NIH grant support via the CTSA mechanism and from institutional support of OCTRI from the Office of the VP Research. The School of Medicine Research Roadmap provides $200,000 for support of mechanism 1 (Development of Large, Interdisciplinary Grants).

FUNDING TYPES
1. Development of Large, Interdisciplinary Grants (e.g. Centers and Program Projects)
These awards, which directly support the recommendations of the SOM Research Roadmap, will catalyze outstanding multidisciplinary collaborations, further the development of strong foci of biomedical research and enhance the core resources available to OHSU investigators. The intent is to accelerate or launch a new scientific direction in clinical and translational research. This pilot award is to generate final preliminary data to enhance submission of a compelling application for larger collaborative grants such as PPGs and Center awards. It is expected that submission of a PPG or Center grant will occur within 12-18 months of the start of this pilot award. The purpose of the OCTRI award is not to support the development of individual grant proposals (e.g. R01). Strong preference will be given to applications that build on established collaborations/projects that are ready to launch into larger programs, that are likely to result in successful national funding applications, and that involve human research, including patients or human samples. OCTRI will consider requests for OCTRI Program services in addition to the monetary award; please visit the OCTRI website www.octri.org for a listing of services and contact the OCTRI Research Navigator Program (503-418-9790, octri@ohsu.edu) for questions and help in estimating the costs of services.

Letters of Intent must include:

- An explanation of how the application is responsive to Funding type 1.
- A brief summary of the scientific plan including aims.
- A list of anticipated personnel, roles and institutions that form a multidisciplinary team. It is expected that the interdisciplinary collaboration will substantively involve more than one OHSU department or division and will focus on collaboration across scientific disciplines. The submitting PI for this award must be from the School of Medicine.
- Specific plans (funding target, submission date and brief description of the proposed grant project) for submitting an application for a PPG or Center grant, for example the following: P01, P20, P30, P41, P42, P50 or equivalent. We are most interested in the development of large, impactful grant proposals.
- Estimated total direct costs and a description of any requested OCTRI services. Preference will be given to applications that use resources wisely to achieve the aim of a federal funding request.

2. Research Cohort Development
Large observational cohort studies provide essential research links between early pipeline research (bench research, biomarker discovery efforts and Phase I studies) and research in populations. They can provide an immense opportunity for translational research. It has been persuasively argued that basic discovery has outpaced the ability to test clinical relevance in part because of a lack of well-phenotyped human populations. Characterization of physiology and disease in well-
designed patient cohorts provides insights that fuel basic science research on the one hand and health services, delivery and economics research on the other.

OCTRI awards in this area may support initial cohort assembly, data system development, early biospecimen collection, initial phenotyping or other needs. It is expected that this OCTRI funding will be most useful for the final assembly, phenotyping, or specimen collection on an available cohort (for instance, a patient cohort already assembled as part of the clinical enterprise), rather than for the early stages of initial cohort recruitment. Moreover, the work done with OCTRI funding should be sufficient to provide compelling preliminary data regarding the feasibility and early productivity of the cohort, and that these data will be sufficient to enable submission of successful applications for larger grants to utilize and sustain the cohort. Applications for OCTRI funding should have a clear goal for submitting a follow up national funding request within 12-18 months of this pilot award. Ideally, the cohort assembled would be useful for multiple investigators, and could eventually serve as a platform for testing multiple scientific hypotheses.

Letters of Intent must include:
- An explanation of how the application is responsive to Funding type 2.
- A brief summary of the scientific plan and aims that includes a description of progress already in place toward establishing a compelling, well-phenotyped cohort for research purposes.
- A description of the breadth of impact this novel research cohort would have for other OHSU investigators. Applications that build on the work currently being done in OHSU’s large and active cohorts of existing clinical protocols are encouraged.
- A list of anticipated personnel, roles and institutions.
- Estimated total direct costs.
- A description of any requested OCTRI services. Preference will be given to applications that use resources wisely to achieve the aim of a federal funding request.
- Specific plans (funding target, submission date and brief description of the proposed grant project) for submitting a national grant application to sustain and utilize the cohort, and explain how this pilot award will enable the proposed application.

3. T1 Translational Research/First in Human Studies
The purpose of this funding mechanism is to help pre-clinical investigation cross over into human subjects research. While this does not necessarily preclude the use (or development) of non-human models, proposals should be clear about how the research is expected to lead quickly to a clinical phase. All proposed projects should have a clinical component. It is expected that OCTRI funding will lead to external grant applications for continued project support within 12-18 months. Such funding could be through typical investigator initiated funding sources (e.g. NIH) or via alternative sources (e.g. public private partnerships). Teams composed of basic and clinical investigators are encouraged to apply.

Letters of Intent must include:
- An explanation of how the application is responsive to Funding type 3.
- A brief summary of the scientific plan including aims that describes the translational pathway, timing and human health impact of the proposed research.
- A list of anticipated personnel, roles and institutions.
- Estimated total direct costs.
- A description of any requested OCTRI services. Preference will be given to applications that use resources wisely to achieve the aim of a federal funding request.
• Specific plans and timeline for submitting a national grant application (funding target, submission date and brief description of the proposed grant project) or prospects and plans for licensing to commercial partner as a translational pathway.

PROGRAM GUIDELINES
Principal Investigators must fit OHSU eligibility requirements. Budgets may include costs for study staff, laboratory tests, costs to generate preliminary data and other expenses, such as animal care costs, research assays, supplies, and study-specific travel. Investigator salary expense is allowed under special circumstances, but a clear justification should be provided. Large equipment expenditures are discouraged.

BUDGET CONSIDERATIONS
A well-considered, efficient, well justified budget proposal is expected. Proposals that appear to request $100,000 merely because it is the maximum allowable are not acceptable. Cost sharing or partnerships with other funding sources will be very favorably considered. After funding, any scope changes to the project must be approved in advance with OCTRI leadership.

LETTER OF INTENT INSTRUCTIONS (2-page maximum, 11-pt, single-spaced)
Please submit a letter that includes each of the bulleted sections listed under the opportunity description.

FULL APPLICATION (6-page maximum for sections 1-6)
Instructions and an application form will be provided to finalists. The research proposal will include the following elements:

1. Title and specific aims
2. Background and significance
3. Preliminary data
4. Project plan
5. Milestones and timeline
6. Plans for continuation
7. Summary budget and justification
8. References cited

REVIEW CRITERIA
An expert panel of senior research scientists appointed by OCTRI will review letters of intent and subsequent applications. The primary review criteria will be the responsiveness to the specific requirements laid out in the above instructions, scientific excellence and feasibility of the proposed research, and the likelihood of a resulting, successful grant or subsequent funding submission or licensing agreement. In addition, the Committee will look for applicability to clinical and translational research, innovation, and significance. Preference will not be given to applications that request OCTRI services.

LETTER OF INTENT SUBMISSION AND QUESTIONS
Submit your letter of intent to OCTRI via a redcap survey at: https://octri.ohsu.edu/redcap/surveys/?s=fhjSGF.
Please direct all questions to the OCTRI Research Navigator Program (503-418-9790, octri@ohsu.edu).