Request for Applications:

Project Funding for Translational Research Leading to Biomedical Commercialization

This funding is intended to support research & development efforts that will lead to the introduction of new products in the healthcare field.

KEY DATES

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<td>Innovation Panel Discussion</td>
<td>11/11/2013</td>
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<td>Letter of intent (LOI) deadline</td>
<td>11/28/2013</td>
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<td>LOI decision</td>
<td>12/18/2013</td>
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<td>Full application deadline (if invited)</td>
<td>2/13/2014</td>
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<td>Application presentation (if invited)</td>
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<td>Scientific/administrative review of full applications completed</td>
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<td>Funding must start between</td>
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PROGRAM OVERVIEW

The Oregon Clinical & Translational Research Institute (OCTRI) is now accepting letters of intent to apply for Biomedical Innovation Program funding. The intent of this funding mechanism is to accelerate the delivery of healthcare technologies from academia to the marketplace and thereby to improve health care. This funding mechanism is offered in close collaboration with the SOM Research Roadmap, but is open to all OHSU faculty and qualified employees as outlined in the eligibility guidelines.

The Biomedical Innovation Program is designed to identify and foster creative solutions for important health care problems. Critical elements of successful proposals will be a well developed idea or vision for the end product and a collaboration between clinician scientists and bioengineers; that collaboration will make possible the identification of a significant clinical problem, an innovative idea for a device or diagnostic to address the problem, bioengineering approaches for device or diagnostic development, and early clinical validation of effectiveness.

This funding opportunity is not intended to support basic biomedical research. Rather, it is to enable innovative bioengineering solutions to be applied to solve important clinical problems, and to yield clinically useful products in a relatively short period. An overarching goal of the program is to foster collaborative translational research that will lead to technology commercialization within a 3-5 year horizon.

Applications will be judged not only on the scientific feasibility but also on the clear articulation of a potential product, the importance of the clinical problem, the clinical need for the new technology, the patentability of the solution, and the meaningful impact this funding will have for promoting further investment or commercialization.

The Program will support the early stages of concept development. Because the focus is on early phase experiments intended to yield clear proof of concept results, Biomedical Innovation funding can be likened to an R21 grant. Specifically, funding is intended to allow the bioengineering necessary to create
a prototype device or diagnostic and the initial clinical validation of its effectiveness (proof of concept). A final phase of the Program’s support will be to prepare the technology for licensing to either a) an existing company or b) as the basis for a start-up company. Thus, a successful end point for the Program’s projects will be independent funding for subsequent commercialization.

Projects will typically be for an initial one-year period with specific pre-defined milestones and quantitative metrics of success evaluated on a quarterly basis. Continuation and renewal applications will be evaluated on a competitive basis; particular attention will be paid to milestones achieved vs. those planned in the original award. Awardees should expect to have interactions/support from Program staff and members of the Scientific Review Committee over the course of the award period.

Inventorship of any IP will be determined in accordance with United States patent law. IP ownership will follow OHSU’s IP and Royalty Distribution Policy (OHSU Policy No. 04-50-001). Non-OHSU employees who serve on the Scientific Review Committee have assigned their inventorship rights in any IP under the OHSU Biomedical Innovation Program to OHSU. Such non-OHSU employees will be treated as OHSU employees for the purposes of royalty distribution per OHSU Policy No. 04-50-001. Any IP generated by parties being funded by OHSU out of the OHSU Biomedical Innovation Program will be subject to the contractual terms of such funding, and the contractual terms of such funding will override any other terms herein if language conflicts.

**PROGRAM GUIDELINES**

Principal Investigators must fit [OHSU eligibility requirements](#). Budgets may include costs for outside engineering and prototype development, study staff, laboratory tests, costs to generate preliminary data and other expenses, such as animal care costs, research assays, supplies, and study-specific travel. A limited pool of funds is available annually, so we are looking for compelling opportunities with the potential for high impact. Funding requests that involve partnering with other sources (e.g. departmental sources) are strongly favored. Because the funds are so limited, it is expected that investigator salary expense will be provided by the department or with another cost sharing mechanism.

**Proposal Review:**
A Scientific Review Committee will review Letters of Intent and make recommendations on funding priority. Committee expertise includes clinical science, bioengineering, business development, and technology transfer. After an initial review, a small number of final candidate proposals will be asked to give a brief presentation to the Scientific Review Committee.

*Funding preference will be given to those projects in which follow-on funding from other sources and follow-on commercialization activity (i.e., licensing) is promising.*

**Submission Guidelines:**
Proposal submission is a three-stage process. Step 1 is to submit a 1-2 page “Letter of Intent” (LOI) proposal. Selected projects will then be invited to submit a “Full Proposal” in step 2. Based on the strength of the applications, in step 3 projects will be invited to present to the Scientific Review Committee before selection of final proposals that will receive funding.

**Step 1: LOI Submission Guidelines:**
*Letters of Intent:* The LOI is a 1-2 page narrative that provides a description of the intended product and the unmet or poorly met clinical need. This should include some metrics, such as the number of patients affected annually, health care expenditures for treatment and/or diagnosis, likely future trend
of the problem, etc. How would the proposed devise/solution solve the problem and how/why it is better than everything else on the market?

1. The proposed solution. This section should be focused on the idea for the planned technology. The details of the technology need not be described, but sufficient information should be provided to allow a determination of the feasibility of the approach. Please note that all letters of intent and applications are treated as confidential documents and terms of non-disclosure and confidentiality are in place with all members of the Scientific Review Committee.

2. Preliminary data, such as published articles, if any, which support that the proposed technology would actually work and that there would be a future clinical demand for it.

3. A likely total R&D / product development timeline (i.e., “bench to bedside” time). Is this a 1-2 year project expected to yield proof of concept? Strategy for potential licensees or providers of 2nd phase funding including sponsored research agreements, and other grant mechanisms to further commercial development after the funded project concludes.

4. A gross estimate of the one-year direct R&D costs for study personnel, minor equipment and supplies (do not add in the university overhead). For PI salary, please work with your department administrator to include a cost share letter signed by the department chair or a letter explaining how PI effort will be subsumed.

5. Identification of the most closely related commercial products, if any.

6. The Intellectual Property status including existing invention disclosures, patent applications filed, shared IP ownership with others, patents awarded and/or technologies licensed, related to your proposed technology, including third party IP.

Submit your letter of intent to OCTRI via a redcap survey at:

https://octri.ohsu.edu/redcap/surveys/?s=LXobritQRx.

Please direct all questions to the Program Manager, Colleen Lay at lay@ohsu.edu.

The Scientific Review Committee will evaluate the LOI proposals. Proposals with the highest ranking will be invited to submit a Full Proposal. Investigators will be notified with the result of the LOI proposal on or before December 18, 2013.

Innovation Panel Discussion

All applicants are strongly encouraged to take advantage of the Innovation Panel Discussion being held November 11th from 3:00 – 4:00 in CHH 3171. Representatives from the Scientific Review Committee, Technology Transfer & Business Development (TTBD), and Biomedical Engineers (both internal and external to OHSU) will be on hand to answer questions and assist applicants work through those aspects of the application that they may need help with. After the panel discussion there will be an opportunity for private discussions with the experts. Please visit the OCTRI Biomedical Innovation Website to RSVP and for information and how to sign up for a 1:1 session with experts from the panel from 4:00 – 5:00 following the panel discussion.

Step 2: Full Proposal Submission (5-page maximum for sections 1-8) Instructions and an application form will be provided to finalists. The Full Year funded translational research grant proposal should be modeled from the LOI proposal and must include a complete discussion of:

1. The unmet or poorly met clinical need or disease, including the current approaches for assessment or treatment of your chosen clinical problem and the known shortcomings of those approaches.

2. The clinical relevancy and market need for the proposed research, including the market metrics for your proposed product, such as the number of patients likely affected, expected savings in health care/societal expenditures, etc.
3. The envisioned future health care industry product, which includes a description of the technological solution, and the advantages it would have compared to the current approaches.
4. The expected R&D timeline to create the proposed technology product.
5. Specific quarterly and yearly milestones and the research plan for their achievement.
6. Intellectual property status, strategy and future plan including invention disclosures, patent applications filed, shared IP ownership with others, patents awarded and/or technologies licensed and third party existing IP related to your proposed technology. All projects selected for a full proposal must submit an invention disclosure with TTBD as part of the application process.
7. Estimated R&D costs to achieve the complete envisioned future clinical product.
8. A plan for possible sources of funding after OCTRI funding expires.

**Step 3: Proposal Presentation** Instructions and a presentation format will be provided to finalists.

Each applicant will have 10 minutes to present the main points of the application or market case with the assumption that everyone present has read their application. The brief presentation will be followed by a 15 minute Q&A session with the committee members.

**Post Award:**

All award recipients will be required to submit progress reports using the following guidelines:

Reports should not exceed 3 pages and need to cover the following topics:

1. Project Progress:
   - Describe the progress achieved during the quarter in a brief narrative.
   - Include a table showing the Research Milestones projected for the year and the % of progress towards achieving them.
   - Explain any problems or issues that have arisen and solutions.
   - Explain any changes to the Research Plan.
   - Summarize major conclusions and the path forward
2. List any project related presentations or manuscripts submitted or published during the reporting period.
3. List and describe any invention disclosure or patent activity during the reporting period.
4. Describe any progress towards project related commercialization, licensing or technology transfer activity during the report period.
5. Describe any project related grants or other funding applications or awards during the project period.