



Request for Applications:

Project Funding for Translational Research Leading to Biomedical Commercialization

This funding (up to \$40,000 over one year) is intended to support research & development efforts that will lead to the introduction of new products in the healthcare field.

KEY DATES

Biomedical Innovation Program Q & A session	10/13/2014
Letter of intent (LOI) deadline	11/12/2014
LOI decision	12/8/2014
Full application deadline (if invited)	2/4/2015
Application presentation (if invited)	3/17/2015
Scientific/administrative review of full applications completed	3/20/2015
Funding must start between	5/1/2013 – 6/30/2014

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 (up to \$40,000 over one year) 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 Technology Transfer and Business Development and the SOM Research Roadmap, and 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 clinicians, 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, voice of consumer studies, and early clinical trials.

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 the vision for the potential product, the importance of the clinical problem, the clinical need for the new technology, the patentability of the solution, and the meaningful affect 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 Program 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 evaluate initial clinical effectiveness (proof of concept). A final phase of the Program's support will be to identify mentorship and career development opportunities that complement commercialization efforts to license the technology.

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 intellectual property (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.**

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), which will be reviewed and evaluated by a Scientific Review Committee composed of experts in clinical science, bioengineering, business development, and technology transfer. In step 2, projects selected by the Scientific Review Committee will be asked to submit a Full Application. In step 3, a small group of finalists will be invited to present to the Scientific Review Committee, who will then select the projects to receive funding.

Review Criteria

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. **Leverage Pilot Funding.** Given the limited amount of funding available for these awards, it is important to demonstrate how this funding will move the technology to the next phase of development.
2. **Impact to Human Health.** It will be important to address how the technology will significantly impact human health. Does the proposed product solve an important problem or remove a critical barrier to progress in the field? If the aims of the project are achieved, how will clinical practice be improved? Who will benefit: the patient, the consumer, the clinician, or the healthcare provider?
3. **Commercial Potential.** Describes the market need for the proposed product, such as the number of patients likely affected, expected savings in health care/societal expenditures, etc. How many potential applications or products could be derived from your invention?
4. **Product Design and Feasibility.** Demonstrates whether an invention is feasible from a testing and manufacturing perspective. Can your proposed product be made? What technical barriers exist and what is your plan to overcome them?
5. **Patentability.** Demonstrates that your invention meets the requirements for filing a patent: novelty, utility, non-obviousness and enablement.
6. **Commercialization Path.** Demonstrates an understanding of exit strategy and how to secure second stage funding. Are there target companies identified as potential partners or licensees? Is this invention something you could start a business around?

Step 1: LOI Submission Guidelines:

Letters of Intent: The LOI is a 1-2 page narrative that provides a general 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 device/solution solve the problem and how/why is it better than everything else on the market, including what clinicians are currently using?

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 pursuing 2nd phase funding - including sponsored research agreements, joint ventures, or additional grants to further commercial development after BIP funding 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 or products/solutions clinicians currently use for this problem.

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. Prior to submitting your Letter of Intent you must submit an [Intellectual Property Disclosure Form](#) to the OHSU Tech Transfer and Business Development office. The Intellectual Property Disclosure Form can be found [here](#).

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 Project Manager, Jonathan Jubera at jubera@ohsu.edu.

The Scientific Review Committee will evaluate the LOIs. Proposals with the highest ranking will be invited to submit a Full Application. Investigators will be notified with the result of the LOI submission on or before November 12, 2014.

Biomedical Innovation Program Q & A Session

All applicants are strongly encouraged to take advantage of the Biomedical Innovation Program Question and Answer Session with OCTRI Director, Eric Orwoll, being held October 13, 2014 from 12:00 – 1:00 in Mac Hall 1162. Representatives from OCTRI, and Technology Transfer & Business Development (TTBD), will also be on hand to answer questions about the program and the application process.

Step 2: Full Application 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 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 to submit a full application must have filed an invention disclosure with TTBD prior to submitting an LOI.
7. Estimated R&D costs to achieve the complete envisioned future clinical product.
8. A plan for obtaining additional sources of funding after OCTRI funding expires in the event that the technology is not ready to be licensed.

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.