OREGON CLINICAL & TRANSLATIONAL Research Institute

TECHNOLOGY TRANSFER & BUSINESS DEVELOPMENT

Request for Applications (RFA)

Biomedical Innovation Program
Device, Diagnostic, & Software Track

This funding will support translational research & development efforts that lead to the introduction of new products to the health care field.

KEY DATES

Letter of intent (LOI) due	09/19/17
Invitations sent for full applications	10/04/17
Full application due (if invited)	10/31/17
Application presentation (if invited)	12/07/17

OCTRI is funded by a grant from the NIH National Center for Advancing Translational Sciences. NIH funding decisions may influence the disbursement of BIP Awards.

PROGRAM OVERVIEW

The Oregon Clinical & Translational Research Institute (OCTRI) in collaboration with the Office of Technology Transfer and Business Development (TTBD) is accepting letters of intent for the Biomedical Innovation Program's (BIP) Device, Diagnostic, and Software track. The BIP provides up to $40,000 over 12 months and close project management in order to accelerate the delivery of health care technologies from academia to the marketplace. This funding mechanism is supported by the Office of the Senior Vice President for Research, GE Healthcare, Welch Allyn, and is offered in partnership with the School of Medicine's Research Roadmap. OHSU faculty and qualified employees outlined in the eligibility guidelines for principal investigators are welcome to apply.

The BIP is designed to identify and foster creative solutions for unmet health care problems. Critical elements of successful proposals include a well-developed idea or vision for the end product and strong collaborations between clinicians, scientists, and engineers. Proposals should describe a significant clinical problem; an innovative idea for a device, diagnostic, or software to address the problem; engineering approaches to realize the concept; and a well thought out plan to achieve the desired outcome.

The BIP supports early-phase experiments intended to yield a prototype or proof-of-concept results. It is not intended to support basic biomedical research. Funded projects should aim to yield clinically useful products in a relatively short period – between 3 to 5 years.

A central component of the BIP is project management. The BIP project manager tracks progress, breaks down barriers, and identifies follow-on funding opportunities. Awardees will also have access to a pool of experienced mentors and other opportunities that complement efforts to commercialize the technology.

GENERAL PROGRAM GUIDELINES

- Funding preference is given to those projects for which follow-on funding from other sources and commercialization activity (e.g, licensing) is likely.
- Budgets may include costs for outside engineering and prototype development; salary; study staff; laboratory tests; costs to generate preliminary data and other expenses, such as animal care costs, research assays, and supplies; and study-specific travel. Departmental cost sharing is not permitted. If a PI plans to do more than oversee the work being done, a minimum of 1% effort needs to be committed and salary requested.
- If your project includes human subject research, the National Center for Advancing Translational Sciences (NCATS) requires that in addition to obtaining IRB approval, you must obtain clearance for your project from NCATs prior to your award set up. OCTRI staff will assist you in submitting your project information to NCATs. For more information about this, you may contact Bridget Adams (adamsb@ohsu.edu).
- Any intellectual property (IP) rights 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).
- Applicants must meet OHSU PI eligibility requirements.

APPLICATION PROCESS OVERVIEW

There are four steps to the BIP application process:

1. Please submit a Technology Disclosure Form to TTBD.
2. Submit a letter of intent (LOI) that is no more than 2 pages long. LOIs will be scored by a Review Committee, which includes entrepreneurs, industry experts, clinical scientists, engineers, business development and technology transfer professionals.
3. Projects selected by the Review Committee will be invited to submit a full application.
4. A small group of finalists will be invited to present to the Review Committee, after which, final funding decisions will be made.

All LOIs and full applications are treated as confidential documents. Confidentiality agreements are in place with all members of the Review Committee.

REVIEW CRITERIA

1. Leverage Pilot Funding: How will this funding move the technology to the next phase of development?
2. Impact to Human Health: Does the proposed work aim to solve an important problem or remove a critical barrier to progress in the field? How will the project move the technology closer to benefiting human health?
3. Commercial Potential: What is the market need (number of patients likely affected, expected savings in health care/societal expenditures, etc.)? How many potential applications or products could come from the proposed technology?
4. Project Design and Feasibility: Is the proposed work feasible? What types of expertise will be leveraged to move the technology forward? What are the potential barriers, and what is the plan to overcome them?
5. Patentability: Is the technology novel, useful, non-obvious, and enabled?
6. Commercialization Path: What is the commercialization strategy and path(s) to secure additional funding? Are there target entities identified as potential partners or licensees? Is there interest and potential for creating a start-up?

LETTER OF INTENT (LOI) SUBMISSION GUIDELINES

OCTRI staff is available to assist you with your LOI and the submission process. Letters of support (maximum of 2) are encouraged but not required, and do not count toward the 2-page limit. No appendices are permitted.

The LOI (please limit to 2 pages) should include:

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.
2. Preliminary data, such as published articles (if any) that support the feasibility of and future clinical demand for the proposed technology.
3. A likely total R&D and/or product development timeline (i.e., "bench to bedside" time). Is this a 1-2 year project expected to yield proof of concept? Describe a strategy for pursuing additional funding (e.g., sponsored research agreements, joint ventures, or additional grants to further commercial development after BIP funding ends).
4. A gross estimate of the direct R&D costs for study personnel, minor equipment, and supplies (do not add in the university overhead) for the award period.
5. Identification of similar commercial products or solutions clinicians currently use for this problem. How is your technology different?
6. The IP status of your proposed technology, including existing invention disclosures, filed patent applications, shared IP ownership with others, patents awarded and/or technologies licensed, and third party IP. Prior to submitting your LOI, you must submit a Technology Disclosure Form to the OHSU Technology Transfer and Business Development office. The form can be found here.

Submit your letter of intent to OCTRI via a REDCap survey at:
https://octri.ohsu.edu/redcap/surveys/?s=7KLRKDHFHK

Please direct all questions to the Project Manager, Jonathan Jubera (jubera@ohsu.edu).

FULL APPLICATION SUBMISSION

Instructions and a link to an online application form will be provided to those applicants who are invited to submit full applications. Biosketches are required and letters of support are encouraged, and do not count toward the 5-page limit. The proposal should build on the LOI and must include a complete discussion of the following items **(5-page maximum):**

1. The unmet or poorly met clinical need, 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 market metrics for your proposed product, such as the number of patients likely affected, expected healthcare savings.
3. The envisioned future health care industry product, including a description of the technological solution and the advantages it would have compared to current approaches.
4. The expected R&D timeline to create the proposed product.
5. Specific quarterly and yearly milestones and the plan for their achievement.
6. Intellectual property status, strategy, and future plan. Include invention disclosures, filed patent applications, IP ownership shared with others, patents awarded and/or technologies licensed, and third party existing IP related to your proposed technology.
7. Estimated R&D costs to achieve the complete clinical product.
8. A plan for obtaining additional sources of funding in the event that the technology is not ready to be licensed when BIP support is exhausted.

PROPOSAL PRESENTATION

Instructions and a presentation format will be provided to finalists. Each applicant will have 10 minutes to present the main points of his/her application. The brief presentation will be followed by a 15-minute question and answer period. Applicants invited to present will be required to attend at least one coaching session with BIP staff and OHSU Entrepreneurs In Residence prior to the final presentation.

POST-AWARD PROCESSES

All award recipients will be required to submit progress reports using guidelines that will be provided at a later date.

QUESTIONS?

Please direct all questions Jonathan Jubera (jubera@ohsu.edu) or the Research Navigator program (503-418-9790, octri@ohsu.edu).