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

<table>
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<th>Event</th>
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<td>Letter of intent (LOI) due</td>
<td>18 September 2019</td>
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<td>Invitations sent for full applications</td>
<td>3 October 2019</td>
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<td>Q &amp; A with review committee</td>
<td>15 October 2019*</td>
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<td>Full applications due (if invited)</td>
<td>24 October 2019</td>
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<td>Application presentation (if invited)</td>
<td>5 December 2019*</td>
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<td>Awards announced</td>
<td>6 December 2019</td>
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*These dates are tentative and subject to change

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 OHSU Technology Transfer and OHSU Collaborations and Entrepreneurship, is accepting letters of intent for the Biomedical Innovation Program’s (BIP) Device, Diagnostic, and Software track. Through this funding mechanism, OCTRI intends to support and accelerate the delivery of healthcare technologies from academia to the marketplace. Project budgets should not exceed $40,000. Projects will typically be supported for a one-year period; predetermined milestones and quantitative metrics of success will be evaluated on a regular basis.

This funding mechanism is supported by the OHSU Foundation/University Venture Development Fund (UVDF). It is open to all OHSU faculty and qualified employees who meet eligibility guidelines.

The BIP offers tailored and dedicated project management. The involvement of BIP staff is a crucial part of success for the early-stage projects that are targeted by this particular funding mechanism. The project management staff monitor progress, identify and mitigate barriers to success, and provide access to mentors and experts that can help move the project forward.
APPLICATION PROCESS OVERVIEW

Proposal submission is a three-stage process:

1. Submit a letter of intent (LOI) that is no more than 2 pages long. Letters of support are encouraged and do not count toward the page limit. Prior to submitting your LOI, please submit a Technology Disclosure Form to Technology Transfer.

2. Projects selected to advance will be invited to participate in a Q&A with review committee members and to submit a 5-page, full application.

3. Finalists will be invited to present to the review committee, after which, final funding decisions will be made.

All letters of intent 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

Please download the required LOI template here, which contains the full instructions for completing.

Reminders:

- Please limit LOIs to 2 pages. Letters of support (maximum of 2) are encouraged and do not count toward the 2-page limit.
- Prior to submitting your letter of intent, please submit a Technology Disclosure Form (note: a Technology Disclosure Form will need to be submitted to Technology Transfer before any intellectual property analysis can be conducted).

Submit your LOI via RedCap by clicking here:

ONLINE REDCAP SUBMISSION FORM
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.

FOR PROJECTS INVOLVING HUMAN SUBJECTS RESEARCH AND/OR LIVE VERTEBRATE ANIMAL STUDIES: In addition to IRB/IACUC approval, the National Center for Advancing Translational Science (NCATS) must approve human subjects research and/or live vertebrate animal projects before any funding can be released. Applicants are strongly urged to complete the required components of the NCATS submission(s) during the application phase to reduce the time to funding. Please contact Bridget Adams, OCTRI Regulatory Knowledge and Support Manager, for a list of the required elements and assistance: adamsb@ohsu.edu; 503-494-5077.

PROPOSAL PRESENTATION

Instructions and a presentation template 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 an OHSU Executives-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).