OREGON CLINICAL & TRANSLATIONAL RESEARCH INSTITUTE

Biomedical Innovation Program (BIP) Device, Diagnostic & Software

REQUEST FOR APPLICATIONS

The Oregon Clinical & Translational Research Institute (OCTRI) in partnership with OHSU Technology Transfer and OHSU Collaborations and Entrepreneurship, is accepting letters of intent for the Biomedical Innovation Program (BIP) Device, Diagnostic, and Software track.

PROGRAM OVERVIEW

BIP Device, Diagnostic, and Software supports the development and commercialization of novel and innovative technologies which aim to improve healthcare delivery. Proposed medical device and diagnostic technologies should address a significant clinical problem, achieve cost savings, improve research efficiency, or improve quality of patient care.

Grants will be awarded on a competitive basis, with budgets not to exceed \$40,000. Additionally, each awardee will be assigned a project manager and a mentor to advise and help accelerate their project towards commercialization. Projects will typically be supported for a 12-month period; predetermined milestones and quantitative metrics of success will be evaluated on a regular basis.

APPLICATION PROCESS OVERVIEW

- Submit a <u>Technology Disclosure Form</u> to OHSU Technology Transfer.
- 2. Review the application resources on the BIP webpage.
- 3. Register for the BIP Application Support Workshop on 9/8/22.
- 4. Submit a letter of intent (LOI) that is no more than <u>2 pages</u> long. Please use the **template** provided in page 3. Letters of support are encouraged (up to 2) and do not count toward the page limit. Submit your LOI via REDCap by clicking <u>here</u>.
- 5. 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.
- 6. 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.

KEY DATES

Letter of Intent (LOI) due: 9/27/22 Q&A with reviewers: 10/27/22 Full application due: 11/18/22 Final presentation: 12/13/22

NEED ASSISTANCE WITH YOUR APPLICATION?

To learn more about the BIP or to schedule a consult, please contact:

Jonathan Jubera, M.B.A. Senior Project Manager jubera@ohsu.edu

REGISTER FOR THE BIP APPLICATION SUPPORT WORKSHOP ON 9/8!!! Eventbrite link

APPLICATION RESOURCES ARE AVAILABLE AT:

www.ohsu.edu/octri-bip



REVIEW CRITERIA

- Leverage pilot funding: How will this funding move the technology to the next phase of development?
- 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?
- Market need addressed: 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?
- 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?
- Innovation and novelty: Is the technology novel, useful, non-obvious, and enabled?
- Commercialization potential: 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?
- Strength of team: The investigators must have the requisite skills and experience to carry out the project successfully.

Additionally, project plans which allocate part of the award budget to support commercial planning activities will be viewed favorably. These may include:

- Primary market research interviews with target audiences for envisioned product.
- Secondary market research, including a competitive landscape assessment.
- Determining requirements and standards for the proposed product.

ELIGIBILITY

BIP Device, Diagnostic, and Software is open to all employees and students of OHSU, with these important caveats:

- If either human subjects or animals are included in the project scope of work, the applicant MUST meet OHSU
 Principal Investigator requirements.
- Non-faculty applicants must submit written approval from their supervisor or department head authorizing "effort" on the grant including the specific amount.

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.

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, 503-805-8179).



BIOMEDICAL INNOVATION PROGRAM (BIP) DEVICE, DIAGNOSTIC, & SOFTWARE - LETTER OF INTENT TEMPLATE

Please use the headings below to complete your LOI before uploading via REDCap. **LOI should not exceed 2 pages**. References and letters of support (maximum of 2) do not count toward the two-page limit and should be uploaded with the LOI.

PRINCIPAL INVESTIGATOR (NAME AND TITLE):

PROJECT TITLE:

BACKGROUND: Briefly describe the significant problem or unmet need to be addressed. (~100 words)

PROPOSED TECHNOLOGY AND 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. What value does your solution provide? (~200 words)

MARKET NEED ADDRESSED: Identify the market for the proposed technology and estimate its size. How many patients could benefit from this technology? Would this technology result in healthcare savings? (~100 words)

COMPETITION: Identify competing solutions clinicians currently use for this problem. How is your technology different and/or superior? (~100 words)

PRELIMINARY DATA: Preliminary data, such as published articles (if any) that support the feasibility of and future clinical demand for the proposed technology. (~100 words)

COMMERCIALIZATION POTENTIAL: Describe a strategy for pursuing additional funding (e.g., sponsored research agreements, industry partners, or additional grants to further commercial development after BIP funding ends). What is the planned or desired commercialization path: licensing the technology to an existing company or forming a startup company? (~100 words)

INNOVATION & NOVELTY: What is the IP status of your proposed technology, including existing invention disclosures, filed patent applications, copyrights, 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 office. The form can be found here. (~50 words)

R&D TIMELINE AND BUDGET: Outline 12-month project timeline and milestones. Estimate total R&D and/or development timeline (i.e., "bench to bedside" time). Include 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. **Please include commercial planning activities in this section.**

TEAM MEMBERS: List team members, their expertise, and project role.

