TO: UMMS and UMass Lowell Faculty, Staff, and Students with an interest in medical device innovation

FROM: Katherine Luzuriaga, MD, Director, University of Massachusetts Center for Clinical and Translational Science (UMCCTS)
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RE: MEDICAL DEVICE INNOVATIONS PROGRAM

INTRODUCTION

The UMass Center for Clinical and Translational Science (UMCCTS), Office of Innovation and Business Development (OIBD), and the Office of the Vice Chancellor for Research and Innovation (OVCRI) are pleased to announce a funding call for the Medical Device Innovations Program (MDIP). This funding opportunity is designed to identify pressing health care problems and partner with cross-campus colleagues with engineering or technology expertise to generate solutions.

PURPOSE

This program supports projects that are inter-campus in orientation and directed toward creating a transdisciplinary team to solve a pressing clinical or health care need with a medical device. By providing seed funding to outstanding faculty members, this fund facilitates the development of faculty-to-faculty networks within the University system, thereby leveraging the considerable expertise and resources that exist on the individual campuses. It is assumed that successful projects will attract additional funding from extramural sources.

REVIEW PROCESS AND OVERSIGHT

This grant program is managed by the leadership of the UMCCTS, OIBD, and OVCRI. Funding decisions are based upon the scientific merits and potential impact of the proposals.

ALLOWABLE USE OF FUNDS

Project awards (up to $10,000) can be requested. Funds are typically used for student/postdoc support, reagent costs, materials and supplies, use of consultation/core services, and small equipment. Check with the appropriate research office to be sure that student and postdoc costs are properly budgeted (tuition, fees, fringe benefits). PI support is allowed. Indirect costs are not allowed.
APPLICATION PROCESS

Phase 1: Pre-Proposals for Faculty Seeking Technology Solutions to Clinical Problems

In 2 pages or less, list the name of the PI, other key personnel, contact information, title of project, and a brief scientific summary of the clinical problem. Describe any preliminary data generated to date and a clear and concise hypothesis/research question for this project. Describe the type of additional expertise (engineering, prototyping, regulatory, etc.) that is required to move the project forward. List (if known) investigators, facilities, and resources at the other campus that could be utilized for the project.

➢ Please email a PDF version of your application to Nate Hafer, UMCCTS Director of Operations at nathaniel.hafer@umassmed.edu by Wednesday, August 2, 2017 by 5:00 pm EST

Phase 2: Pre-Proposals for Faculty with Technology and Engineering Solutions

Clinical problems will be posted on the UMCCTS website by August 4, 2017 for review by investigators with technology and engineering solutions. Interested investigators should propose an approach to solving a problem in the following format: in 2 pages or less, list the name of the PI, other key personnel, contact information, title, and a brief scientific summary of the technology. Describe any preliminary data generated to date and a clear and concise description of the technology’s capabilities. Describe the type of additional expertise (pre-clinical, clinical, regulatory, etc.) that is required to move the project forward. List (if known) investigators, facilities, and resources at the other campus that could be utilized for the project.

➢ Please email a PDF version of your application to Nate Hafer, UMCCTS Director of Operations at nathaniel.hafer@umassmed.edu by Monday, August 21, 2017 by 5:00 pm EST

Phase 3: Preliminary Review and Match-making

Potential matches will be reviewed by faculty with input from the leadership of the UMCCTS, OIBD, and OVCRI. Selected proposals will be invited to submit a full proposal and will receive preliminary feedback including suggestions for collaborators.

Phase 4: Full Proposal Instructions (for selected applicants)

1. **Research Plan**: This section should not exceed 4 pages (references do not count towards the page limit).

The format of the research plan should be:

- Names of investigators, including each investigator’s institution and role (e.g. PI, co-investigator, etc.).
- Executive summary: A brief paragraph (project abstract) summarizing what you wish to accomplish, how it will be done, and why you are excited about doing it.
- Specific aims: Specify 1-3 major aims to be addressed.
- Background, significance, and market opportunity, including discussion of translational significance.
- Preliminary studies (if applicable).
- Approach/experimental plan. Explain the “what” and the “how” in sufficient detail to allow the average scientist to assess your idea. Include things like hypotheses to be tested, plans for assay development, proposed analogs, criteria for assessing new models, possible pitfalls and mitigation strategies, etc. Explain why the results to be obtained are the critical ones needed to move the solution forward towards potential commercialization.
- Project timeline: identify key project milestones and go/no-go decisions and target timelines for achieving them.
- Intellectual property considerations (if applicable).
- Plans for future development.
2. NIH-format Biosketch (5-page format) for each investigator.
3. Budget, broken down by institution, with budget justification (complete a PHS 398 form page 4 and 5 for each participating institution). Indirect costs are not allowed. PI/Co-I support is allowed.
4. Statement of the need for IACUC, IRB, COI or any other review/approval and whether such approvals have been obtained, or the timeline for obtaining necessary approvals. (1 page max).
5. Letters of Support as appropriate (no page limit).
6. All applicants must be UMCCTS members. Membership is free and entails completion of a short online form at http://www.umassmed.edu/ccts/about/membership/
7. Presentation slide deck (5 slides maximum) describing the project. Do NOT include confidential information.

➢ Full Proposals should be submitted as a single PDF document to Nate Hafer, UMCCTS Director of Operations at nathaniel.hafer@umassmed.edu by Wednesday, September 13, 2017 5:00 pm EST.

Phase 5: Reception, Poster Session, and Presentation at the M2D2 Worcester Grand Opening and Ribbon Cutting Ceremony

Full proposal applicants will be invited to present their idea at a networking and pitch event to be held the week of September 18th at UMass Medical School, Worcester, providing a 5-minute presentation to a panel of judges followed by 1-minute of Q&A. This event will be open to the public (complete details are pending finalization and will be announced at a later date).

CRITERIA FOR AWARDS

The evaluation criteria that are used to review proposals include the following:

- Intellectual Merit – Reviewers will judge the likelihood that the proposed project will have a substantial impact on the pursuit of the goals of the UMCCTS, which is to advance our understanding of biological systems, to improve the control of disease, to enhance health, and to train the next generation of clinical and translational researchers.
- Inter-Campus Collaboration – projects that are multi-campus in orientation will receive additional consideration for funding.
- Growth Opportunity – projects demonstrate the opportunity to attract and secure outside funding and achieve market success.

KEY DATES

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<thead>
<tr>
<th>Event</th>
<th>Date</th>
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<tbody>
<tr>
<td>Funding Opportunity announced</td>
<td>Friday, July 14, 2017</td>
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<tr>
<td>Phase 1 - Pre-Proposal submission deadline</td>
<td>Wednesday, August 2, 2017</td>
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<tr>
<td>Clinical Problems posted to website</td>
<td>Friday, August 4, 2017</td>
</tr>
<tr>
<td>Phase 2 - Pre-Proposal submission deadline</td>
<td>Monday, August 21, 2017</td>
</tr>
<tr>
<td>Full Proposal and Slide Deck Materials submitted (for selected applicants only)</td>
<td>Wednesday, September 13, 2017</td>
</tr>
<tr>
<td>Networking and Pitch Event</td>
<td>Week of September 18, 2017</td>
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Finalists deliver 5-minute pitches to panel of judges with 1 additional minute of Q&A