M-TRAC 2017

Michigan Translational Research and Commercialization Funding

Request for Proposals

March 21, 2017

The Wayne State M-TRAC program is now accepting applications for gap funding of translational research of novel, high potential technologies in medical devices, biomedical materials and healthcare IT. The goal is to move promising research and technologies forward toward commercialization, either through a startup or license to industry. The awards will provide $50,000-100,000 per project for milestone driven translational research, such as proof of concept studies. In addition to the funding, applicants to the program will also receive consultation and mentoring in the commercialization process from industry and investment experts.

The application process has multiple stages. A 2-page written Letter of Intent is due on April 21, 2017. Selected applicants will be invited by May 5th to submit a full 6-8 page proposal due on Friday, June 16th, 2017. Following review of the full proposals by the M-TRAC Oversight Committee, finalists will be invited to present to the Oversight Committee the first week of September 2017. Award decisions will be announced within one week of the presentations, followed by budget and milestone adjustments as necessary. Projects should be ready to begin October 1, 2017.

Who:	Investigators, clinicians and researchers are all encouraged to apply. Technologies must be disclosed to the Office of Technology Commercialization or assigned to the University.
What:	Projects that involve technology suitable for use in medical devices, including for drug delivery; biomedical materials and techniques intended for use with medical devices; and healthcare information technology, including apps for clinical and wellness indications.
When:	**Letter of Intent Deadline: Friday, April 21, 2017** Invitations for Full Proposals: Friday, May 5, 2017 **Full Proposal Deadline (by invitation): Friday, June 16, 2017** Announcement of Finalists: Monday, July 17, 2017 **Presentation to Operating Committee: First week of September, 2017** Award Announcement: Within one week of presentation Project Kick-off: October 1, 2017
How:	Applications should be emailed as a PDF document to scott.olson@wayne.edu by 5:00 p.m. on the due date. Late submissions will not be accepted. For more information, contact Scott Olson at (313) 577-1714 or scott.olson@wayne.edu.

We strongly suggest contact with Scott Olson prior to submitting your materials.

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MEDC
MICHIGAN ECONOMIC DEVELOPMENT CORPORATION

Guidelines:

Letter of Intent

Your Letter of Intent should be no longer than two pages. Please include the following:

- Problem to be solved
- Clinical/market need
- Technology solution and preliminary data
- Twelve month research plan, with budget
- What is the key question that will be answered in this project?
- Intellectual property status (publications, invention disclosures, patents)

Full Proposal (BY INVITATION ONLY)

The following prompts will help you prepare a competitive proposal. It is important to realize that this is NOT a research proposal, but a commercialization proposal that takes into account the context in which a solution will reach the intended users. If it looks like a research proposal, it is unlikely to be awarded, so please follow the prompts.

Cover Page/Abstract (1 page)

- Title of Project
- Applicant names, titles, email and phone
- School/college, department and address
- Requested award amount and key question that will be answered in project (e.g., "I am seeking $__ to do _____.")
- Clinical/unmet need (1-2 sentences)
- Solution (3-5 sentences)
- Grant request (specify monetary amount requested and milestones in list format)
- Intellectual property (1-3 sentences on current patents, licenses, and/or disclosures, or future plans)
- Regulatory (anticipated FDA device class and filings necessary)

In the body of your proposal, which should be 6-8 pages long, you should address the following areas. In particular, the simple Gantt chart describing milestones is a requirement.

Clinical Need (2 page max) – Discussion of why you believe there is an unmet clinical need. This should include a clear description of the need, how it is currently being met (the "standard of care" or "gold standard"), and why it is lacking. Identify the impact on end users/patients, providers, hospitals, and insurance companies.

Business Opportunity (1 page max) – Describe how your solution will reach the market. Identify companies currently serving the market (competitors), distributors and other influencers. Describe the size of the market in terms of patients affected, size of spend, growth trends, etc. Indicate pricing of current standard of care solutions, if known. Point out how clinicians get information on new solutions (e.g., company representatives, specific conferences, trade associations, significant journals).

Intellectual property (1/2 page max) – Describe status of intellectual property. For example, has the technology been reported to the Office of Technology Commercialization? Has a patent been filed? If so, please include filing dates and patent types. Have you published or submitted for publication on the invention? Provide specifics and timing of publication if known.

Regulatory path (1/2 page max) – Provide any information on regulatory path with FDA (if known). Consider searching the FDA's 510(k), PMA, and IND databases to list similar or predicate devices. Please consult Scott Olson and Technology Commercialization staff for assistance.

Technology Development Plan (2 page max) – Brief summary of technology and the translational research work to be conducted. It is important to showcase how this funding will be used to advance from current

state of technology to future states. Include preliminary or proof of concept data only if it is relevant to the proposed workplan. Specific aims should be represented as milestones on a monthly basis. What is the deliverable for the development plan? What key question will it answer? What happens if a milestone is not achieved (contingency plan)? The plan for technology advancement and next steps following the grant should be clearly explained.

Timeline (1/2 page max or bullets) – Timeline should show milestones over 12 month period, with monthly expenditures tied to budget categories indicated. Use a simple Gantt-type chart for clarity.

Budget (1 page max) – Budgets up to $100,000, should answer the question of how much will it cost to achieve the deliverable identified in the Technology Development Plan. Any personnel on budget must be justified with weekly, hourly estimates of work. Estimates of hours per week should be realistic and experience has shown that work effort over a 12 month timeline will vary for key personnel weekly. Expenditures on budget should directly relate to accomplishment of key milestones, and be readily identifiable on the Gantt chart.

Other (1/2 page max) – Provide details of how the end product will be purchased (e.g., by hospitals, by insurance companies, directly by patients), what the purchasing process involves, and who will influence the purchasing decision. If you have additional funds awarded or pending, please include funding agency, donor, department and dollar amounts along with details on specific aims/milestones to be covered by this funding. Include internal funding if applicable.

CV, Resume or NIH-style biosketch of key personnel

References (optional, do not count in total) – Letters of support from companies, potential licensees.

Scoring Criteria

Your Proposal will be scored by members of the Oversight Committee according to the following criteria, plus your in-person presentation. The Oversight Committee may recommend risk contingency plans, changes to the milestones, or budget modifications. This feedback will be provided regardless of whether you proposal is chosen for funding.

Does the project have commercial merit? Consider the size of the market (e.g., number of cases); does it state the unmet need and position well the proposed solution? How long it will take to reach the market or be licensed? Is the project unique and compelling?

Is the project likely to have an impact? Consider the proposed improvement over existing products; the number of end users who would benefit; shortcomings or lack of current products; the ease of convincing clinicians to purchase; the strength of competing products or workarounds; the likelihood of changing clinical practice.

Will the development plan be successful? Are the milestones and budget appropriate? Is the timeline realistic? Does the team appear to have the required skills to accomplish the project? If it succeeds, will the product be competitive for additional funding?

Other: Consider the quality of the intellectual property. Does the development plan suggest creation of new intellectual property? Are you aware of competing technologies or solutions under development? Are there other considerations that add to or take away from your assessment of the project?