Twin Cities Campus

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# Pediatric Device Innovation Consortium (PDIC) Office of Discovery and Translation (ODAT)

# Pediatric Medical Device Translational Grant Program – 2014

# **Request for Applications**

#### PROGRAM OVERVIEW

The purpose of this funding program is to support the development of pediatric medical devices with the ultimate goal of improving pediatric patient outcomes and quality of life through technology driven medical solutions.

This funding opportunity differs from traditional internal award programs in that each funded investigator will partner with ODAT and the PDIC to establish a detailed work strategy, receive frequent feedback, and access comprehensive internal and external services to accomplish each developmental milestone in a timely fashion.

Submission of a brief letter of intent (LOI) is required. The purpose of the LOI is to confirm applicant eligibility, ensure the project is at the appropriate stage to fit with the purpose of this funding mechanism, and enable the identification of reviewers with applicable expertise.

#### AWARD

It is anticipated that up to 3 projects will be funded through this program in 2014. Each funded project will be awarded a maximum of \$50,000 direct costs for one year. No indirect costs are allowed.

#### SUBMISSION PROCESS AND PROGRAM DEADLINES

| RFA issued            | March 12, 2014           |
|-----------------------|--------------------------|
| LOI due               | April 10, 2014 (5:00 pm) |
| Invite full proposals | April 22, 2014           |
| Full proposals due    | May 22, 2014 (5:00 pm)   |
| Awards announced      | July 2014                |
| Funding initiated     | August 2014              |

#### EXAMPLES OF APPLICABLE PROJECTS

Projects must involve development of pediatric specific technology. The technology may be applicable to adult applications but funding must be for progress on pediatric use.

- 1. Development of a looks-like and works-like prototype
- 2. Bench testing a medical device prototype for proof-of-concept

- 3. Animal model or cadaver testing for proof-of-concept and development of product
- 4. Assistance with FDA submissions
- 5. Pilot studies in humans

# **ELIGIBILITY**

- 1. U.S. citizens, permanent residents, and non-permanent residents are eligible.
- The principal investigator (PI) must have a faculty appointment at the University of Minnesota at the time of grant submission. Eligibility includes affiliated faculty at the VA, HCMC, Regions Hospital, and the Children's Hospitals of Minnesota. Faculty members holding adjunct appointments are ineligible.
- 3. The PI must hold a doctorate degree (MD, PhD, DVM, DO, DDS, PharmD).
- 4. Applications can be submitted by a PI with no previous NIH funding, pending NIH funding, or an active NIH award.
- 5. An application can originate from a single PI, or a PI and one or more co-investigators (co-I).
- 6. If the application has a PI and co-I, they can be from outside the University, different colleges, a single college, or the same department within a college. *Collaborative projects between industry, private, and academic groups are particularly encouraged.*

# PRE-APPLICATION

A mandatory LOI is due on April 10, 2014. The letter (one page maximum) should include:

- 1. Project title
- 2. PI name and contact information
- 3. Co-investigator(s) name(s)
- 4. Identification of unmet pediatric medical need being addressed. To the extent possible, please include a description of the disease or condition to be treated, diagnosed, or prevented, an overview of the current standard of care including available drugs and devices, and why development of a new technology is necessary.
- 5. Description of the technology and specific phase of development to be supported by this funding.

# Please submit your LOI through the following link by April 10, 2014 at 5:00pm:

z.umn.edu/ctsifunding

We will notify applicants on or before April 22, 2014 if they are invited to submit a full proposal. At that time, further instructions for proposal submission will be provided.

# Please contact Sandra Wells at 612-625-3073 or <u>smwells@umn.edu</u> with any questions about this funding program.

## FULL PROPOSAL CONTENT

- 1. Proposal (maximum of 6 pages, including Executive Summary, Figures, and Tables, excluding References)
  - a. Executive Summary (maximum of 1/2 page)
    - Briefly describe the unmet need being addressed, the significance and potential clinical impact of the proposed project, and the project objectives with measurable criteria for success.

- b. Background and Strategy
  - i. Background and Significance

Describe the significance of the unmet need being addressed, the current standard of care, and the potential impact of the proposed research. Provide supporting evidence for the project objectives.

- *ii. Strategy* Describe the proposed objectives, approach, expected outcome and specific, measurable criteria for success.
- iii. Timeline
  - Provide a timeline for key project tasks and milestones.
- *iv.* Collaborations and Other Sources of Support List any research collaborations and/or other sources of funding related to the proposed research program.
- c. Translation Plan<sup>1</sup>
  - i. Clinical Impact

Describe how the outcome of the proposed project could be applied to inform clinical decisions and/or improve care. Describe how this new technology fits into the current treatment paradigm for the target disease setting. Discuss the expected improvement over current standard of care Provide an estimate for the number of patients that could be impacted through the development of this new therapy, diagnostic, or treatment approach.

*ii.* Development Plan

Describe the expected next steps after the successful completion of the proposed project milestones (e.g. patents, clinical trials, regulatory approvals).

iii. Intellectual Property

List existing intellectual property (e.g. patents, copyrights) based on current projects with references and status (e.g. disclosure, patent application, out-licensed). Describe the potential of generating intellectual property after the successful completion of the project milestones. To the extent known, include any other intellectual property that may be related to this project. List any existing competing products or other research or development programs that may result in new similar technologies.

iv. Strategic Partnerships

Provide a brief description of existing partnerships with organizations related to the project. Include both formal and informal relationships as well as consulting agreements. Describe potential strategic partnerships that may be beneficial in the development of a resulting product.

- v. For projects including a clinical or animal component, please list the status of institutional regulatory approvals.
- d. References (not included in page limit)
- Proposed Budget (\$50,000 maximum per proposal) Note: Submission of a Proposal Routing Form (PRF) is not required. Use the following form: PHS 398 Form Page 4, "Detailed Budget for the Initial Period" http://grants.nih.gov/grants/funding/phs398/phs398.html

<sup>&</sup>lt;sup>1</sup>Not all of the information requested in this section may be applicable or known. Please provide as much of the requested information as possible.

|   | Allowable | Not Allowable |
|---|-----------|---------------|
| PI Salary                                     |           | Х             |
| Postdoc Salary                                | Х         |               |
| Consultants                                   | Х         |               |
| Administrative Support                        |           | Х             |
| Supplies                                      | Х         |               |
| Operating, laboratory, and medical services   | Х         |               |
| Equipment                                     | Х         |               |
| Software                                      | Х         |               |
| Personal Computers                            |           | Х             |
| Mailing                                       |           | Х             |
| Travel (restricted to reaching project sites) | Х         |               |
| Research Staff Support (e.g. technician)      | X         |               |

- 3. Budget Justification
  - a. Clearly and fully justify all costs.
- NIH BioSketch of Principal Investigator(s), Co-Principal Investigator(s) and Co-Investigator(s) (4 page maximum; use NIH Form "PHS 398/2590") <u>http://grants1.nih.gov/grants/funding/2590/biosketch.doc</u>
- 5. Letters of Support

## REVIEW PROCESS

- 1. A review team will evaluate eligible applications based on several considerations, including:
  - a. Pediatric Need: Does the technology meet a specific pediatric need that does not have an adequate solution on the market?
  - b. Pediatric Impact: Does the problem being addressed provide answers to serious medical problems in children with the potential of significantly improving pediatric outcomes, reducing complications of care, or increasing quality of life? (Note: Projects that focus on clinician or patient convenience will be considered but will not take priority for funding.)
  - c. Feasibility: Is the proposed work focused on technology development rather than further research? Is the project focused and achievable in one year?
  - d. Does the individual PI or the investigative team have the necessary expertise to conduct the proposed work?
- Applicants whose proposals receive the highest scores will be granted an interview with the PDIC Advisory Panel to address issues raised in the proposal review and receive critical input.
- 3. Applications selected for funding will be strongly encouraged to make appropriate revisions on their experimental plans reflecting feedback from the interview.

## FUNDING PERIOD EXPECTATIONS

- 1. The PDIC Advisory Panel will facilitate progress toward achieving project milestones throughout the funding period.
- 2. Grantees will provide the PDIC/ODAT with a copy of any institutional regulatory approvals related to the project prior to initiation of the award.
- 3. Where applicable, grantees will provide the PDIC/ODAT with the NIH-required five point Vertebrate Animal Section.

- 4. Where applicable, grantees will register, submit, maintain, and update study information through ClinicalTrials.gov.
- 5. Throughout the funding period and following completion of the award, grantees will respond to periodic requests to update the status of the project.
- 6. A final report will be submitted following the completion of the award.

## POST-AWARD EXPECTATIONS

It is expected that each project will make significant progress toward one of the following outcomes:

- 1. Licensing of IP: Part of this agreement will include that the product may be used as the buyer sees fit, but must include a pediatric application should it go to market.
- 2. Formation of a start-up company: Resources are available through the UMN Venture Center and Office for Technology Commercialization.
- 3. Product taken directly to market: This may occur solely through the PDIC or in partnership with industry.

## QUESTIONS

Questions may be directed to: Sandra Wells, Ph.D. – Assistant Director, CTSI Office of Discovery and Translation <u>smwells@umn.edu</u>