

## Request for Proposals for Target Challenge: 2014-TC-4 Pediatric Pressure Ulcer Prevention Program

The New England Pediatric Device Consortium (NEPDC) invites proposals for novel technologies to reduce, treat, or prevent, pediatric pressure ulcers with clear potential for commercialization.

NEPDC is a multidisciplinary, multi-institutional, collaborative consortium that provides rapid and targeted assistance to innovators seeking to address the needs of children suffering from disease or disabilities.

### Important Dates:

Abstract: Open Submission until September 1, 2014

Application Due (invitation only): September 15, 2014

Award Announcements: Approximately one month following application submission deadline

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### Opportunity:

- Up to 200 hours of NEPDC resource assistance
- Up to \$70,000
- Single Award not to exceed \$50,000
- Up to 2 proposals will be funded

### QUESTIONS?

Visit us at

[www.nepdc.org/challenge.html](http://www.nepdc.org/challenge.html)

### Purpose:

Commercial transition of device(s) that reduce, treat, or prevent, pediatric Pressure Ulcers.

### Background

Approximately 4% of all pediatric hospital patients develop pressure ulcers to one or more parts of the body<sup>1</sup>, with incidence rates as high as 27% reported in some pediatric populations<sup>2-4</sup>. These pediatric pressure ulcers impose a significant health burden that can increase length and costs of hospitalization while predisposing the child to discomfort, infection, sepsis, and treatment that may require surgical intervention<sup>1</sup>.

*The most frequent cause of pressure ulcer formation is interaction between skin and medical devices.* Even the use of routine medical devices with hospitalized pediatric patients can lead to skin breakdown further complicating their care. These devices may include the following:

- Positioning materials
- Respiratory devices
- Tubes and vascular access devices
- Leads and wires
- Casts, braces, wraps and dressings
- Support Surfaces

Conventional medical devices and the means for securing them to patients are not often optimized to meet the specific needs of children. The most common devices implicated in pediatric pressure ulcer development are CPAP (both nasal-CPAP and face-CPAP), IV hubs, pulse oximeters and tracheostomy plates and ties<sup>5-12</sup>.

In contrast to pressure ulcers due to medical device interactions, chronic ulcers (stage II-III) are typically formed due to contact with positioning materials (support surfaces). The body proportions of children are markedly different from adults and often the positioning materials were designed for adult use<sup>13-14</sup>. Hence,

support surface related pressure ulcers in children most often involve the head, in addition to sacrum/coccyx and ankles/heels<sup>3</sup>. Infants and children often sink into low air loss beds designed for adults<sup>1</sup>, and adult specialty beds in turning mode can increase occipital friction and shearing<sup>15</sup>. Pediatric patients with limited positioning options such as BiPAP, CPAP, and ECMO patients are at an even further increased risk for pressure ulcer development<sup>13</sup>. Additionally, pressure ulcers can form during longer surgeries from pressure on the tissue between bony prominences and support surfaces.

Due to the *prevalence* and *significance* of these pressure ulcers, NEPDC is seeking technologies that will reduce, treat, or prevent pediatric pressure ulcers. Ideally these solutions will be available for commercialization within 18 months of the initial grant award.

Through NEPDC grant awards, clients receive both seed funding and access to NEPDC Core Services, providing short-term, concentrated assistance to accelerate the commercialization process. For this Target Challenge NEPDC is offering up to \$70,000 in discretionary funding for no more than two devices, with no one device receiving more than \$50,000 and 200 hours of in-kind assistance.

Depending on each client's unique background and commercialization requirements, our consortium of engineers, researchers, clinicians, and entrepreneurs provide expert guidance in the form of:

- Engineering design and transfer to manufacturing
- Development of intellectual property and regulatory strategy
- Pre-clinical and clinical trial design and execution
- Strategic market planning and business development
- Identifying co-funding opportunities

The NEPDC network, which includes links to industry, academia, and the greater clinical community, has been created to help clients overcome the unique challenges surrounding the development and translation of pediatric and orphan products for clinical and consumer use.

### **Anticipated Deliverables**

To be considered for this NEPDC award, proposals must present a plan of work that will result in either a fully commercialized product or output (e.g. preliminary data, design prototype, business plan) that can then be leveraged for subsequent funding opportunities (federal and/or public sources).

Pediatric pressure ulcer solutions may be linked with one or more of the following contexts associated with pediatric pressure ulcer development:

- Contact with support surfaces
- Contact with respiratory devices
- Contact with tubes and vascular access devices
- Contact with leads and wires
- Contact with casts, braces, wraps, and dressings

### **Submission Procedure**

Due to the diversity and complexity of submitted device development proposals, NEPDC has instituted a two-phase application procedure. Those interested in submitting for the NEPDC Target Challenge are required to first submit an Abstract. These brief product descriptions will be reviewed by the NEPDC Leadership Team on a revolving basis to determine if the product falls within NEPDC's expertise and addresses the goal of this Target Challenge. If selected, applicants will be invited to submit a Full Application. To meet the deadline for full applications, abstracts must be submitted by September 01, 2014.

All applications are submitted electronically through the NEPDC web-based submission system.

<https://nepdc-colab.induct.no/login>

### **Evaluation Criteria**

All applications will be reviewed against the following criteria:

- Potential commercialization of device(s) that reduce, treat, or prevent, pediatric pressure ulcers
- Impact on pediatric quality of life
- Impact on cost of care
- Market and business potential
- Technical feasibility
- Value added by NEPDC assistance

Each proposal is evaluated by at least three reviewers and graded on a categorical scale ranging from 1-5 (5 = best). Following review, a summary of the reviews is provided to each applicant along with a decision letter.

### **Eligibility Requirements**

Eligibility requirements for the Target Challenge Seed Award include the following:

- Technology / device must address pediatric pressure ulcers
- Technology / device must meet the FDA's definition of a medical device

- Technology / devices that have previously received funding from FDA-funded pediatric device consortia are *not eligible*
- Non-domestic (non-U.S.) Entities (Foreign Institutions) are *not eligible*

### **Terms and Conditions**

- Pre-Seed Notification of Award: Approximately three to four weeks following application submission deadline.
- Award eligibility is restricted to concepts classified as pediatric medical devices. To verify your device eligibility, refer to [Federal Food Drug & Cosmetic Act section 201\(h\) section](#).
- Applicants who have received monetary grants for their device from other FDA-funded pediatric device consortia are not eligible for pre-seed or seed awards. This includes the following:
  - Atlantic Pediatric Device Consortium
  - Boston Pediatric Device Consortium
  - MISTRAL Device Consortium
  - National Capital Consortium for Pediatric Device Innovation
  - Pediatric Cardiovascular Device Consortium
  - Philadelphia Regional Pediatric Medical Device Consortium
  - Southern California Center for Technology and Innovation in Pediatrics
  - University of Michigan Pediatric Device Consortium
  - University of California, San Francisco Pediatric Device Consortium
- Intellectual Property associated with devices submitted for review belongs to the inventor, and NEPDC makes no claims to that Intellectual Property. Additionally, submission for grant awards does not constitute public disclosure. One component of the NEPDC assistance process is to help clients ensure that Intellectual Property rights are protected so they can decide the most appropriate commercialization pathway.

### **About NEPDC**

The New England Pediatric Device Consortium (NEPDC) is a non-profit foundation supported by the FDA's Office of Orphan Products Development (Grant #: 1P50FD004907). We are a multidisciplinary, multi-institutional, collaborative consortium that provides rapid and targeted assistance to innovators seeking to address the needs of children suffering from disease or disabilities. NEPDC concentrates on disruptive technologies, incremental technology improvements, as well as pediatric technologies that may have limited market size but high potential for improving the life of a child. For further information please visit our website at [www.NEPDC.org](http://www.NEPDC.org) or contact us at [info@NEPDC.org](mailto:info@NEPDC.org).

### **References**

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