Research Opportunity Announcement (ROA): OTA-23-011 Designing a Public-Private Partnership to Support Pediatric Medical Device Development and Commercialization

Participating Organization (s)	National Institutes of Health
Components of Participating Organizations	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) National Institute of Biomedical Imaging and Bioengineering (NIBIB)
ROA Title	Designing a Public-Private Partnership to Support Pediatric Medical Device Development and Commercialization
Activity Code	OT2: Application for an Other Transaction Agreement
Research Opportunity Number	OTA-23-011
Related Notices	NOT-HD-23-018 NOT-EB-22-008
Application Due Date	June 30, 2023
Earliest Start Date	August 1, 2023
Funding Instrument	Other Transaction: An assistance mechanism that is not a grant, contract, or cooperative agreement. Other Transactions awards are subject to the requirements of the NIH Other Transactions Policy Guide
Funds Available and Anticipated Number of Awards	NICHD and NIBIB intend to fund 1 sole source award for approximately $750,000 in FY2023.
Award Budget and Project Period	18 months

Purpose

The purpose of this Research Opportunity Announcement (ROA) is to allow submission of an Application through eRA ASSIST for a sole source Other Transaction (OT) Award to support the Design Phase of a Public-Private Partnership that aims at consolidating the national ecosystem to de-risk and advance Pediatric Medical Device Development and Commercialization. This OT announcement is related to the Notice of Information: NICHD to issue a sole source award to support the Designing a Public-Private Partnership to Support Pediatric Medical Device Development and Commercialization project (NOT-HD-23-018).

Background and Overview

Issue/gap being addressed:

The current, persistent stagnant lack of access to medical device options specifically designed and approved for the pediatric population demands that all sectors that have skills and resources must work together in dramatically new ways to meet an urgent need. Accordingly, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) and the National Institute of Biomedical Imaging and Bioengineering (NIBIB) of the National Institutes of Health (NIH) seek to develop a Public Private Partnership (PPP) among agencies, regulators, and public health officials at all levels of government, life sciences companies, non-governmental organizations, and academic biomedical research institutions to consolidate the national pediatric medical device ecosystem and develop strategies to de-risk development and commercialization of medical devices that address the needs of pediatric populations.

Intent of this FY2023 funding opportunity:

The NIH seeks input from the Foundation for the National Institutes of Health (FNIH) on entering into a potential Other Transaction (OT) agreement with NIH in order to facilitate the development of this partnership to enable new, impactful and timely synergies with other key players in the emerging national ecosystem shaping and develop strategies to de-risk development and commercialization of medical devices that address the needs of pediatric populations. The Notice of Information: “NICHD to issue a sole source award to support the Designing a Public-Private Partnership to Support Pediatric Medical Device Development and Commercialization project” NOT-HD-23-018 was published on June 12, 2023 in the NIH Guide.

Statutory Justification for the use of the Other Transaction Authority:

Section 402(n) of the Public Health Service Act (42 U.S.C. 282(n)), as amended by the SUPPORT for Patients and Communities Act in 2018, authorizes the Director of NIH to approve requests by NIH Institutes, Centers, and Offices (ICOs) to engage in transactions other than a contract, grant, or cooperative agreement with respect to projects that carry out certain objectives. The PMD PPP initiative to be scoped, designed, established, and managed by the FNIH falls under the following statutory justification for use of OT authority: high impact cutting-edge research that fosters scientific creativity and increases fundamental biological understanding leading to the prevention, diagnosis, or treatment of diseases and disorders, or research urgently required to respond to a public health threat ((42 U.S.C. 282 (n)(1)(c))).

Program Components

The project will consist of two phases.

- Phase I – The **Design Phase** will produce a white paper with a detailed plan to build and launch a PPP, focusing on the key primary processes of building the national pediatric medical device ecosystem, including networks of hospitals as well as decentralized systems; optimizing public and private financing and reimbursement for research and development of pediatric medical devices; and creating the self-sustaining entity that will administer and manage the partnership in the public trust.
- Phase II – The **Transition Phase** will serve as a bridge between the Design and a future Implementation Phase.

Proposal Format and Requirements:

The proposal should clearly and fully demonstrate the proposer's capabilities, knowledge, and experience and the budget proposed. Proposers shall provide a separate budget. The Project Plan should be limited to a maximum of 12 pages.

Proposers shall describe activities to be undertaken to develop the partnership, including but not limited to the following major tasks:

- Assemble a governance structure.
- Solicit, receive, manage, steward, and acknowledge donations from partner organizations.

- Establish, convene, and manage a series of virtual meetings at least six workstreams:
    1. ***Hospitals***: addressing the barrier to innovators in gaining timely access to specific pediatric patient populations and to infrastructures adequately equipped and experienced in the design and conduction of clinical studies.
    2. ***Reimbursement***: focused on issues related to overall commercial viability of pediatric devices once marketed.
    3. ***Finance***: focused on developing models and approaches for how a successful PPP involving the support of NIH research programs at the outset can serve as a proof of concept to enable the development of a separate, long-term fiscally self-sustaining entity.
    4. ***Navigation***: focused on how the overall PPP ecosystem will function.
    5. ***Regulatory***: focused on issues related to navigating the current regulatory environment and how regulatory science and regulation can be optimized.
    6. ***Decentralized Health Innovation***: focused on developing novel or adjunctive technologies and approaches for clinical development and validation (e.g., at- home, digital health, remote technologies, eHealth, direct-to-family), particularly for time-sensitive trials that may be appropriate for all-hazards preparedness and response for pediatric populations.
- In coordination with the NIH Institutes and Centers (the *Eunice Kennedy Shriver* National Institute of Child Health and Development ("NICHD") and the National Institute of Biomedical Imaging and Bioengineering ("NIBIB")), establish a detailed plan for full execution of the PPP, and describe intermediate milestones for the delivery of this plan to the NIH.
- The NIH expects delivery of the detailed implementation plan by producing a White Paper by Month 9-10 or earlier. Describe a specific timeline and intermediate milestones for the delivery of the plan by this date.
- Provide a detailed budget for costs through this performance period (no longer than 12/31/2024) for each major task required to develop the PPP.
- Provide a budget justification to accompany the detailed budget which shall include an explanation of how FNIH has obtained, or will obtain, the necessary expertise, effort, and resources to carry out the major tasks.

Tasks for FNIH beyond the performance period for this PPP may include coordination, management of research contracts that support the goals of the partnership, or other tasks. These will be negotiated with FNIH as planning for the partnership nears completion. Funding to FNIH for these subsequent tasks will be entirely contingent upon completion of milestones and receipt of appropriations for the government portion of the partnership, recruitment of funds from private partners, and agreements to be arranged with partner organizations.

Award Project Duration:

The period of performance anticipated for this OT award will be an 18-month base period.

Data Sharing Requirements

No data sharing requirement applies to this ROA. It is not expected that this project will gather or develop data.

How to submit the application

NIH uses the eRA Commons system to administer OT awards. If you are selected to participate you may need to submit additional information in eRA ASSIST, you will need to be registered in eRA Commons. Applications must be submitted through NIH's ASSIST site by **5:00 p.m. local time on July 17, 2023** at https://public.era.nih.gov/assist/public/login.era. Paper applications will not be accepted. Applications from institutions must be submitted by an authorized organizational representative. Please, see eRA Training ASSIST for additional guidance about Resource only for Other Transaction Authority (OTA) Users of ASSIST.

Objective review process

Submissions will undergo an objective review process. An OT award will be made if the recipient can sufficiently demonstrate the organization's ability to build and manage a complex, multi-entity public-private partnership that seeks to consolidate a national ecosystem that optimizes the translation of technological advancements into medical devices designed, evaluated, and approved for pediatric populations. An award will be made pending review of plans to deliver a PPP in a timely manner and pending review of the budget.

Reviewer Selection:

Internal NIH experts in the management of extramural awards to spur biomedical R&D via public-private partnerships will provide an objective review of the application/plans provided by FNIH.

Conflict of Interests:

Reviewers shall disclose any conflict of interests (COI) that might preclude their participation in the review process, as per NIH guidelines [https://grants.nih.gov/policy/peer/reviewer-guidelines.htm]. Each NIH reviewer must certify, under penalty of perjury (US Code Title 18, Chapter 47, Section 1001), that to the best of his or her knowledge he/she has disclosed all conflicts of interest that he or she may have with the applications or R&D contract proposals; he or she fully understands the confidential nature of the review process and agrees:

(1) to destroy or return all materials related to it;

(2) not to disclose or discuss the materials associated with the review, the evaluation, or the review meeting with any other individual except as authorized by the Scientific Review Officer (SRO) or other designated NIH official;

(3) not to disclose procurement information prior to the award of a contract; and

(4) to refer all inquiries concerning the review to the SRO or other designated NIH official.

Review Criteria:

Reviewers will weigh in on the qualifications and prior track record of the sole source with similar tasks, qualifications of the Team, likelihood of accomplishing the proposed work in the allotted time, appropriateness of the budget requested. Specific binary questions (Yes/No) are as follows:

1. Does the Applicant have proven track record of performing similar tasks/projects?
2. Are the qualifications of the Team appropriate to support the proposed work?
3. Are the proposed deliverables and milestones adequate to support the proposed work?
4. Is the indicated timeline appropriate for the proposed Scope of Work?
5. Is the requested budget breakdown appropriate for the proposed Scope of Work?
6. Is third-party subcontract work justified?
7. Overall Assessment: __Recommend __Do Not Recommend

Additionally, reviewers will be asked to provide comments and a brief summary supporting their recommendations.

Agency Contacts

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