Preliminary Posting of a Funding Opportunity Announcement for Pediatric Device Consortia Grants Program (P50 Specialized Center)

This is a **preliminary posting** of a funding opportunity announcement (FOA) for the Pediatric Device Consortia Grants Program (P50). Interested applicants must apply through Grants.gov. The **formal FOA will be posted shortly** and no applications will be accepted through this preliminary posting. **Please check periodically with Grants.gov for the formal FOA.**

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	U.S. Food and Drug Administration (FDA) NOTE: The policies, guidelines, terms, and conditions stated in this announcement may differ from those used by the NIH. Where this Funding Opportunity Announcement (FOA) provides specific written guidance that may differ from the general guidance provided in the grant application form, please follow the instructions given in this FOA. The FDA does not follow the NIH Page Limitation Guidelines or the NIH Review Criteria. Applicants are encouraged to consult with FDA Agency Contacts for additional information regarding page limits and the FDA Objective Review Process.
Components of Participating Organizations	Office of Orphan Products Development (OOPD)
Funding Opportunity Title	**Pediatric Device Consortia Grants Program (P50)**
Activity Code	P50 Specialized Center
Announcement Type	New
Related Notices	None
Funding Opportunity Announcement (FOA) Number	**RFA-FD-18-004**
Companion Funding Opportunity	None

Number of Applications	See Section III. 3. Additional Information on Eligibility.
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.103
Funding Opportunity Purpose	The intended goal of this FOA is to facilitate the development, production, and distribution of pediatric medical devices. Although the FOA is issued by the FDA's Office of Orphan Products Development, the grant application is intended to encompass devices for all pediatric diseases and conditions, not just those that are rare. Applicants will request funding to serve as a nonprofit consortium to provide expert advising and support services to innovators of pediatric medical devices. The advising and services will focus on the total product life cycle for medical devices from concept, through pre-market development, to commercialization, and replacement by subsequent generation of devices. In addition, consortia should also provide expertise on evidence generation, including use of real world evidence, for pediatric device development. The pediatric population (i.e., neonates, infants, children, and adolescents) for medical devices is defined as individuals who are younger than 22 years of age (that is, from birth through the twenty-first year of life not including the twenty-second birthday) at the time of diagnosis or treatment.

Key Dates

Posted Date	
Open Date (Earliest Submission Date)	January 4, 2018
Letter of Intent Due Date(s)	Not Applicable
Application Due Date(s)	March 7, 2018, by 11:59 PM Eastern Time. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

	Applicants should be aware that on-time submission means that an application is submitted error free (of both Grants.gov and eRA Commons errors) by 11:59 PM Eastern Time on the application due date. **Late applications will not be accepted for this FOA.**
AIDS Application Due Date(s)	Not Applicable
Scientific Merit Review	June 2018
Advisory Council Review	Not Applicable
Earliest Start Date	September 2018
Expiration Date	March 8, 2018
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts*). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.
Applications that do not comply with these instructions may be delayed or not accepted for review.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The development of pediatric medical devices currently lags behind the development of devices for adults. Pediatric patients often differ from adults in terms of their size, growth, development, body chemistry, and disease propensity, adding to the challenges of pediatric device development. There exists a great need for pediatric medical devices, including devices developed originally for pediatric patients as well as existing adult devices adapted for pediatric use. Recent passage of the Food and Drug Administration Reauthorization Act of 2017 reauthorized support of Section 305 of the Pediatric Medical Device Safety and Improvement Act of 2007 for fiscal years 2018 through 2022 which requires HHS to provide demonstration grants to nonprofit consortia to promote pediatric device development. While the consortia themselves are nonprofit entities, their contacts and membership can include for-profit partners. Consortia should partner with external stakeholders if their expertise is needed and justify overhead to these external stakeholders.

The goal of the Food and Drug Administration's (FDA) Pediatric Device Consortia (PDC) Grants Program is to facilitate the development, production, and distribution of pediatric medical devices through funding of nonprofit consortia. These nonprofit consortia will provide a platform of experienced regulatory, business planning, and device development services (such as but not limited to intellectual property advising; prototyping; engineering; laboratory and animal testing; grant-writing; and clinical trial design) to help foster and guide the advancement of medical devices for pediatric patients. A nonprofit consortium will provide expert advising and support services to innovators of pediatric medical devices. The advising and services will focus on the total product life cycle for pediatric medical devices such as understanding the evolution of medical device development from concept, through pre-market development, to commercialization, and replacement by subsequent generation of devices.

The consortia shall demonstrate their ability to perform the following:

- Encouraging innovation and connecting qualified individuals with pediatric device ideas with potential manufacturers;
- Mentoring and managing pediatric device projects through the development process, including product identification, prototype design, device development, and marketing;
- Connecting innovators and physicians to existing Federal and non-Federal resources, including resources from the Food and Drug Administration, the National Institutes of Health, the Small Business Administration, the Department of Energy, the Department of Education, the National Science Foundation, the Department of Veterans Affairs, the Agency for Healthcare Research and Quality, and the National Institute of Standards and Technology;
- Assessing the scientific and medical merit of proposed pediatric device projects;
- Providing assistance and advice as needed on business development, personnel training, prototype development, postmarket needs, and other activities consistent with the purposes of this section; and
- Providing regulatory consultation to device sponsors in support of the submission of an application (e.g., pre-submission, investigational device exemption, premarket notification [510(k)], premarket approval, humanitarian device exemption, etc.) for pediatric devices.

The consortia are expected to provide counsel on how to access various Federal and non-Federal funding resources.

The consortia are expected to be knowledgeable and provide advice on leveraging real-world evidence within the pediatric medical device ecosystem to pediatric device innovators. FDA has published guidance on "Use of real-world evidence to support regulatory decision-making for medical devices." This guidance can be found at https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm513027.pdf.

The consortia are expected to track the type of assistance that is requested by pediatric device innovators and monitor the progression of the pediatric device development with routine data requests to the innovator.

The consortia are expected to be up to date and knowledgeable with news and updates surrounding the regulatory decision-making for medical devices such as guidances, webinars, programs, etc. Similarly, the consortia are expected to attend and participate, if needed, at meetings or workshops convened by or involving the FDA with regards to pediatric devices.

In addition to providing advice and/or assistance on all the above, the consortia may provide funding to directly advance pediatric device projects ("Direct Device Funding"). The activities supported by funding may include, but are not limited to, activities such as prototyping, testing (laboratory and animal), modeling, etc.

The FDA is working to broaden and improve opportunities to leverage real-world evidence for regulatory evaluation of medical devices across their total product lifecycle. The National Evaluation System for Health Technology (NEST) is being developed as a decentralized and federated data integration and sharing system intended to drive down time and cost of evidence generation by increasing the value and use of real world data. NEST has the potential to support a paradigm shift in the pre-market/post-market regulatory evidence generation balance, while creating efficiencies serving the evidence generation needs of all stakeholders in the healthcare system.
The consortia are encouraged to submit real-world evidence demonstration project proposal(s) in the pediatric space that develop, verify and operationalize methods of evidence generation and data use, demonstrate scalability across the healthcare system, and build out critical functions and processes of NEST. Selected proposals may be awarded additional funds ("RWE Demonstration Project Funding") as detailed below. The consortia with RWE demonstration projects that are selected for funding will work collaboratively with the NEST coordinating center (NESTcc).

The pediatric population for medical devices is defined as individuals who are younger than 22 years of age (that is, from birth through the twenty-first year of life not including the twenty-second birthday) at the time of diagnosis or treatment (21 CFR 814.3(s)). The following ranges of pediatric subpopulations can be used as a guide for the development of pediatric medical devices:

- Newborn (neonate) - from birth to 1 month of age
- Infant - greater than 1 month to 2 years of age
- Child - greater than 2 to 12 years of age
- Adolescent - greater than 12 through 21 years of age

The FDA recognizes, however, that the descriptions are somewhat arbitrary and that, in fact, the subject's weight, body size, physiological development, neurological development, and neuromuscular coordination may often be more appropriate indicators than chronological age. The consortia will use their judgment when providing advice and/or assistance to pediatric device innovators regarding the potential benefits of addressing an unmet need in the pediatric population.

The grants are available to any domestic, public or private, nonprofit entity (including State and local units of government). Federal agencies may not apply.

Funds are not intended to be used for general consortium "educational" initiatives including but not limited to university curriculum development, educational videos, or undergraduate, graduate, or fellowship classes.

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument	Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.
Application Types Allowed	New The OER Glossary and the SF424 (R&R) Application Guide provide details on these application types.
Funds Available and Anticipated Number of Awards	The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications. Award(s) will provide one (1) year of support and include future recommended support for four (4) additional year(s) contingent upon annual appropriations, availability of funding and satisfactory awardee performance. FDA/Office of Orphan Products Development intends to fund up to $6,000,000, for fiscal year 2018 in support of this grant program including consortia advising and support services and projects. Of the estimated $6,000,000, approximately $1,000,000 may be used for RWE Demonstration Project Funding (subject to review of merit). It is anticipated that up to five (5) awards will be made. RWE Demonstration Project Funding shall not exceed $500,000 in total costs per consortia.
Award Budget	Application budgets need to reflect the actual needs of the proposed project and should not exceed the following in total costs (direct and indirect): YR 01: $1,500,000 YR 02: $1,500,000 YR 03: $1,500,000 YR 04: $1,500,000 YR 05: $1,500,000 Up to 25% of a consortium's base budget ($1,000,000) may be used for Direct Device Funding. Activities supported by funding may

	include, but are not limited to, activities such as prototyping, testing (laboratory and animal), modeling, etc. Not more than one quarter of total Direct Device Funding can be used to advance a consortium's internally developed device projects. The maximum amount allotted to any consortium-supported project shall not exceed $50,000 per year, except where Direct Device Funding pertains to real-world evidence generation and has been discussed and cleared in advance through OOPD. For RWE Demonstration Project Funding, the maximum amount allotted shall not exceed $500,000 per year.
Award Project Period	The scope of the proposed project should determine the project period. The maximum project period is five (5) years, contingent upon performance during the preceding year, compliance with regulatory requirements (if applicable), and availability of Federal funds.

HHS grants policies as described in the *HHS Grants Policy Statement* will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for FDA support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

The grants are not available to for-profit organizations or foreign entities.
Federal agencies may not apply.

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.
Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.
Foreign components, as *defined in the HHS Grants Policy Statement*, **are not** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. Failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- Dun and Bradstreet Universal Numbering System (DUNS) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM) (formerly CCR) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
    - NATO Commercial and Government Entity (NCAGE) Code – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- eRA Commons - Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for FDA support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of

the SF424 (R&R) Application Guide.

2. Cost Sharing

This FOA does not require cost sharing as defined in the HHS Grants Policy Statement.

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.
The FDA will not accept duplicate or highly overlapping applications under review at the same time. This means that the FDA will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.

Section IV. Application and Submission Information

1. Requesting an Application Package

Buttons to access the online ASSIST system or to download application forms are available in Part 1 of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research Instructions in the SF424 (R&R) Application Guide, except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

For information on Application Submission and Receipt, visit Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications.

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits must be followed with the following exceptions or additional requirements.

All page limitations described in the PHS 398 Application Guide must be followed, with the following FDA exceptions and additional requirements:

For all P50 applications submitted in response to this RFA, the standard PHS 398 instructions are modified.

In particular, Research Plan (Research Strategy [Item 3] per Revision 3/2016 of the PHS 398 Table of Contents is altered as follows:

- Standard item 3 of the PHS 398 Research Plan is replaced by Sections 1, 2 and 3 below.
- The PHS 398 standard page limit for item 3 is replaced by a new limit of 17 pages for Section 1, 8 pages for Section 2, and 5 pages for Section 3.
- Other sections of the standard PHS 398 Research Plan remain unchanged and must be completed following the PHS 398 instructions (see http://grants.nih.gov/grants/funding/phs398/phs398.html).

- The Biographical Sketch section of PHS 398 application should be used to highlight the relevant pediatric device development experience of the consortia leaders and key members. For consortia leaders or key members with a background in business, regulatory, or law, Sections C (Contributions to Science) and D (Additional Information: Research Support and/or Scholastic Performance) should be replaced with a description of practical experiences related to pediatric or medical device development.

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Other Project Information

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Senior/Key Person Profile

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R Budget

All instructions in the SF424 (R&R) Application Guide must be followed with the following additional instructions:

- Applications requesting multiple years of support must complete and submit a separate detailed budget breakdown and narrative justification for each year of financial support requested.

- If an applicant is requesting indirect costs as part of their budget, a copy of the most recent Federal indirect cost rate or F&A agreement must be provided as part of the application submission. This agreement should be attached to the RESEARCH & RELATED Other Project Information Component as line #12 'Other Attachments'.

- If the applicant organization has never established an indirect cost rate and/or does not have a negotiated Federal indirect cost rate agreement, a de minimis indirect cost rate of 10 percent (10%) of modified total direct costs (MTDC) will be allowed. MTDC means all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and subaward and subcontracts up to the first $25,000 of each subaward or subcontract. MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward and subcontract in excess of $25,000.

- In addition to the Budget Pages included in the PHS 398 Application, applicants should include in response to Section 1, an explanation of the criteria that need to be met for Direct Device Funding; and how they will determine how much funding to distribute to each of their supported projects. Also, the consortium will need to explain how it plans to monitor the spending and activities of the recipients of Direct Device Funding; and the methods by which they plan to hold recipients accountable to conduct the funded tasks.

R&R Subaward Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Cover Page Supplement

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Research Plan

All instructions in the SF424 (R&R) Application Guide must be followed.

- Standard item 3 of the PHS 398 Research Plan is replaced by the sections below with corresponding page limits.

Section 1: Overall Description of the Consortium and Accomplishments (maximum of 17 pages)

Overall Description of the Consortium
This section should present both the overall vision and specifics for the consortium as it relates to the goal of the PDC Grants Program such as regulatory, business planning, and other pediatric device developmental services that the consortium can provide to pediatric device innovators. This section should contain the long- and short-term objectives, including how activities supported by the consortium will advance pediatric device development. Resources available to the consortia should be described.

Of importance is a discussion of the business, regulatory, and medical/scientific expertise of the consortium leaders and members. Established relationships between the consortium and manufacturers and academic institutions should be explained. Relevant background information on the consortium leadership's accomplishments pertinent to the goals of pediatric device development should be described.

The consortium's method and approach to evaluating Direct Device Funding should be explained and how funds will be distributed to each of their pediatric device projects. The consortium should explain the individuals or groups involved and why they have specific experience and/or knowledge to make such strategy recommendations. Also, the consortium will need to explain how it plans to monitor the spending and activities of the recipients Direct Device Funding and the methods by which they plan to hold recipients accountable to conduct the funded tasks.

The consortium's familiarity with the Federal system and obtaining funding through Federal and non-Federal sources.

Accomplishments
Please explain any experience that you have had with managing projects for pediatric device development and provide a brief summary highlighting their accomplishments. Additionally, please explain any achievements in successfully guiding a pediatric device(s) to market or into clinical trials or animal testing. This summary should at a minimum include the advice/strategy provided and how it was relevant to the achievement of the pediatric device project.

Section 2: Consortium's Ability to Effectively Provide Services to Pediatric Device Innovators (maximum of 8 pages)

The applicant should specifically address their ability to advise and assist pediatric device innovators who request strategic guidance from the consortium regarding pediatric device development at any stage of the total product life cycle. The applicant shall explain the process for how they would assist pediatric device innovators. The applicant should explain how they evaluate the issue brought to them by a pediatric device innovator and how they will provide the strategic and technical guidance through the regulatory process for the pediatric device and what comprehensive strategy will achieve the device coming to market and reimbursement issues/planning.

The applicant shall describe a scenario where an innovator who has a pediatric device at the concept stage and explain how the consortium will work with the innovator to get the device to market. The applicant shall explain the analysis and advice provided (i.e., business, regulatory, and

medical/scientific expertise) at the stages of device development and through regulatory/marketing/reimbursement.

Section 3: RWE Demonstration Project(s) (maximum of 5 pages)

The applicant is encouraged to propose RWE Demonstration Project(s). The project(s) should include an explanation of how it will contribute to the field of real-world evidence, and specifically within the pediatric medical device ecosystem. The project(s) can range in size and scope but should develop, verify and operationalize methods of evidence generation and data use, and demonstrate scalability across healthcare systems, device types, and manufacturers. The proposed project(s) must all be designed to obtain results that are directly relevant and useful in clinical practice and in advancing pediatric device development. The project(s) should propose how the consortia will work directly with NEST to accomplish these goals. The RWE Demonstration Projects will be reviewed annually to ensure continued funding.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide, with the following modification:

- Generally, Resource Sharing Plans are expected, but they are not applicable for this FOA.

Appendix:

Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PHS Inclusion Enrollment Report

When conducting clinical research, follow all instructions for completing PHS Inclusion Enrollment Report as described in the SF424 (R&R) Application Guide.

PHS Assignment Request Form

All instructions in the SF424 (R&R) Application Guide must be followed.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

Part I. Overview Information contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday, the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons, FDA's electronic system for grants administration. eRA Commons and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to

Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. **Late applications will not be accepted for this FOA.**

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

6. Funding Restrictions

All FDA awards are subject to the terms and conditions, cost principles, and other considerations described in the *HHS Grants Policy Statement*.

Pre-award costs are allowable only as described in the *HHS Grants Policy Statement*.

Additional funding restrictions may be part of the Notice of Award.

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically. If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Guidelines for Applicants Experiencing System Issues. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:
All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to FDA. See Section III of this FOA for information on registration requirements.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

See more tips for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the assigned Grants Management Specialist and responsiveness by components of participating organizations, FDA. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in NOT-OD-13-030.

Section V. Application Review Information

1. Criteria

Responsive applications will be reviewed and evaluated by a panel of experts including but not limited to pediatrics, regulatory, business planning, and device development. In their written critiques, reviewers will be asked to comment on each of the following criteria in order to judge the likelihood that the proposed consortium will have a substantial impact on pediatric device development. By submitting an application in response to this RFA, applicants understand and agree that members of the objective review panel of experts may be provided access to non-public information contained in the grant application, as necessary for evaluation of the application and subject to necessary restrictions on the further disclosure of the information.

A combined score with a maximum of 100 points will be assigned to each application based on the scientific/technical review criteria. All applications will be ranked and those with the highest scores will be considered for awards.

The review panel may advise OOPD about the appropriateness of the proposal to the goals of the PDC grants program and may suggest funding modifications. The following criteria are used by reviewers to assign scores:

1) Overall description of the consortium and accomplishments (50 points)

In evaluating the overall description of the consortium and their ability to accomplish the goals of promoting pediatric device development, as demonstrated to include but are not limited to the following, reviewers will provide a score to reflect their assessment of the consortium:

a) The consortium's organization and approach to facilitate the development of pediatric devices;
b) The consortium's leadership, membership, and affiliations;
c) The consortium's ability to integrate scientific, business, and regulatory considerations and strategic guidance to the pediatric device innovator;
d) The consortium's ability to serve as a resource for pediatric device innovators and what capabilities and affiliations exist to assist with pediatric device development;
e) The consortium's relevant regulatory experience and how its current membership has provided strategic guidance to device development along with knowledge of the regulatory process for navigating the total product lifecycle;
f) The consortium's plan for Direct Device Funding; and
g) The consortium's past accomplishments in successfully in guiding pediatric device(s) through the total product life cycle.

Reviewers will consider the consortium leadership and membership, significance in how the consortium will achieve the goals of advancing pediatric device development, budget proposal, and resources available to the consortium. The reviewers will consider whether the consortium membership includes the expertise that is needed for pediatric device development and not be required to seek significant external assistance outside the membership of the consortium.

2) Consortium's ability to effectively provide services to pediatric device innovators (35 points).

In evaluating the ability of the consortium to effectively provide services to pediatric device innovators, reviewers will provide a score to reflect their assessment of the quality and practicality

that the consortium has the experience, knowledge, approach, resources, and leadership to likely advance pediatric device development to marketing approval and reimbursement. Reviewers will judge whether the consortium can provide effective assistance throughout the total product life cycle and that the consortium has the training and expertise to provide such assistance and not be required to seek significant external assistance outside the membership of the consortium.

3) RWE Demonstration Projects (15 points)

Reviewers will consider the significance on whether the project(s) contributes to pediatric device real-world evidence. Reviewers will consider the approach of the real-world evidence to determine its impact to advance the development of pediatric medical devices. Reviewers will gauge the likelihood of success depending on leadership, resources, and soundness of the proposed project along with the ability to complete the project during the funding period. The reviewers will consider the consortia's plan to work directly with NESTcc to develop, verify, and operationalize methods of evidence generation and data use, demonstrate scalability across the healthcare system, and build out critical functions and processes.

RWE Demonstration Projects will be reviewed annually for continued funding.

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items, but will not give separate scores for these items and should not consider them in providing an overall score.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects.

Inclusion of Women, Minorities, and Children

When the proposed project involves human subjects and/or FDA-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the

use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section.

Biohazards
Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions
Not Applicable

Renewals
Not Applicable

Revisions
Not Applicable

Applications from Foreign Organizations
Not Applicable

Select Agent Research
Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans
Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) Data Sharing Plan; (2) Sharing Model Organisms; and (3) Genomic Data Sharing Plan (GDS).

Authentication of Key Biological and/or Chemical Resources:
For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

Budget and Period of Support
Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process
Applications will be evaluated for scientific and technical merit by an Objective Review Committee using the stated review criteria.

As part of the objective review, all applications:
- Will receive a written critique (Summary Statement).

Appeals of objective review will not be accepted for applications submitted in response to this FOA.

Applications will compete for available funds with all other recommended applications submitted in response to this FOA. The following will be considered in making funding decisions:
- Scientific and technical merit of the proposed project as determined by objective review.
- Availability of funds.

- Relevance of the proposed project to program priorities.
- Relevance of RWE Demonstration Projects to FDA priorities regarding Real-World Evidence.

3. Anticipated Announcement and Award Dates

Successful applicants will be notified of additional information that may be required or other actions leading to an award. The decision not to award a grant, or to award a grant at a particular funding level, is discretionary and is not subject to appeal to any FDA or HHS official or board.

Section VI. Award Administration Information

1. Award Notices

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found in the HHS Grants Policy Statement.

2. Administrative and National Policy Requirements

All FDA grant and cooperative agreement awards include the *HHS Grants Policy Statement* as part of the NoA.

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), FDA awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 "Federal awarding agency review of risk posed by applicants." This provision will apply to all FDA grants and cooperative agreements.

HHS provides general guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see http://www.hhs.gov/ocr/civilrights/resources/laws/revisedlep.html. The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS.

Please see http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html; and http://www.hhs.gov/ocr/civilrights/understanding/index.html. Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html. Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.html or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.

FDA considers the sharing of research resources developed through FDA-sponsored research an important means to enhance the value and further the advancement of research. When research resources have been developed with FDA funds and the associated research findings published, those findings must be made readily available to the scientific community.

Upon acceptance for publication, scientific researchers must submit the author's final manuscript of the peer-reviewed scientific publication resulting from research supported in whole or in part with FDA funds to the NIH National Library of Medicine's (NLM) PubMed Central (PMC). FDA defines the author's final manuscript as the final version accepted for journal publication, which includes all modifications from the publishing peer review process. The PMC archive is the designated repository for these manuscripts for use by the public, health care providers, educators, scientists, and FDA. Please see the FDA Public Access Policy.

Additional terms and conditions regarding FDA regulatory and OOPD programmatic requirements may be part of the Notice of Award.

Cooperative Agreement Terms and Conditions of Award

REPORTING REQUIREMENTS:

Periodic program monitoring will be conducted by FDA on an ongoing basis which may include telephone conversations between the Principal Investigator and the Project Officer/Grants Management Officer/Grants Management Specialist, site visits and the review of written reports.

The Annual Progress Report will be due as part of the Research Performance Progress Report (RPPR) and is due no later than 60 days prior to the start date of the next budget period start date.

Grants with Multiple Years: In order to receive future funding, the grantee is required to submit the Research Performance Progress Report (RPPR). The Annual Progress Report will be due as part of the Research Performance Progress Report (RPPR) and is due no later than 60 days prior to the start date of the next budget period start date. This report should cover all activities/work that took place during the current budget performance period noted in your Notice of Grant Award (NGA).

Financial Reporting:

A. Cash Transaction Reports

The Federal Financial Report (FFR) has a dedicated section to report Federal cash receipts and disbursements. For recipients this information must be submitted quarterly directly to the Payment Management System (PMS) using the web-based tool. Quarterly reports are due 30 days following the end of each calendar quarter. The reporting period for this report continues to be based on the calendar quarter. Questions concerning the requirements for this quarterly financial report should be directed to the PMS.

B. Financial Expenditure Reports

A required Federal Financial Report (FFR) must be submitted annually. FDA now requires all annual financial expenditure reports to be submitted electronically using the Federal Financial Report (FFR) system located in the eRA Commons. This includes all initial FFRs being prepared for submission and any revised FSR/FFRs being submitted or re-submitted to FDA. Paper expenditure/FFR reports will not accepted.

Annual FFRs must be submitted for each budget period no later than 90 days after the end of the calendar quarter in which the budget period ended. The reporting period for an annual FFR will be that of the budget period for the particular grant; however, the actual submission date is based on the calendar quarter. Failure to submit timely reports may affect future funding.

Closeout Requirements (when applicable): A Final Program Progress Activity Report, Final Federal Financial Report SF-425, Final Invention Statement HHS-568 (if applicable), Tangible Personal Property Report SF-428, and Statement of Disposition of Equipment (if applicable) must be submitted within 90 days after the expiration date of the project period.

A non-Federal entity that expends $750,000 or more during the non-Federal entity's fiscal year in Federal awards must have a single or program-specific audit conducted for that year in accordance with the provisions of 45 CFR 75, Subpart F-Audit Requirements. Audits must be completed and submitted electronically to the Federal Audit Clearinghouse (FAC) within 30 days after receipt of the auditor's report(s), or 9 months after the end of the audit period, i.e., the end of the organization's fiscal year, whichever is earlier. If you need information on your organization's obligations, please visit the following website: http://harvester.census.gov/sac/. Valuable information is included under the "Frequently Asked Questions" section of that website.

PRIOR APPROVAL:

All requests that require prior approval must include the award number and bear the signature of an authorized official of the grantee business office as well as that of the PI/PD. Any requests involving budgetary issues must include a new proposed budget and a narrative justification of the requested changes. If there are any questions regarding the need or requirement for prior approval for any activity or cost, the grantee is to contact the assigned Grants Management Specialist prior to expenditure of funds.

The following activities require prior approval by FDA before being implemented by the grantee, its employees, or designee:
Change in scope or objectives
Change in key personnel
Change in grantee organization
Change in key partner organization(s)
Any deviation from the terms and conditions of the award
Carryover of unobligated balances
No cost extensions
Significant rebudgeting of the total funds authorized under the current year's award

ACKNOWLEDGEMENT OF FEDERAL SUPPORT:

When issuing statements, press releases, publications and other documents describing projects or programs funded in whole or in part with Federal money, all awardees receiving Federal funds, including and not limited to state and local governments and recipients of Federal research grants, shall clearly indicate:

Funding for this statement, publication, press release, etc. was made possible, in part, by the Food and Drug Administration through grant XXXXXXXXXX. The views expressed in written materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services; nor does any mention of trade names, commercial practices, or organization imply endorsement by the United States Government.

PROGRAM INCOME:

1. The grantee is required to report any Program Income generated during the Project Period of this grant. Except for royalty income generated from patents and inventions, the amount and disposition of Program Income must be identified on lines 10 (l), (m), (n), and (o) of the grantee's Federal Financial Report (FFR) SF-425.

2. Examples of Program Income include (and not limited to): fees for services performed during the grant or sub-grant period, proceeds from sale of tangible personal or real property, usage or rental fees, patent or copyright royalties, and proceeds from the sale of products and technology developed under the grant.

3. Any Program Income generated during the Project Period of this grant by the grantee or sub-grantee is subject to the Addition Alternative for Program Income and, therefore, must only be used to further the goals of the project for which this grant was awarded.

EQUIPMENT AND PRODUCTS:

To the greatest extent practicable, all equipment and products purchased with FDA funds should be American-made.

PAYMENT MANAGEMENT SYSTEM (PMS):

The Payment Management System is administered by the Program Support Center (PSC), DHHS, and payments for FDA grant awards are made through the Division of Payment Management. Applicant organizations are assigned a 12-digit Entity Identification Number for payment and accounting purposes. That number is an expansion of the 9-digit Employer Identification Number assigned to an organization by the Internal Revenue Service.

Included are the following Links & Instructions for drawing down funds, reporting expenditures, required forms, and the help desk info:

Homepage: http://www.dpm.psc.gov/Default.aspx

Grant Recipient Information:
http://www.dpm.psc.gov/grant_recipient/grant_recipient.aspx?explorer.event=true

Grant Recipient Forms:
http://www.dpm.psc.gov/grant_recipient/grantee_forms.aspx?explorer.event=true

PMS Help Desk: http://www.dpm.psc.gov/help/help.aspx?explorer.event=true

The ONE-DHHS Help Desk for PMS Support is now available Monday – Friday from 7 a.m. to 9 p.m. EST (except Federal Holidays). Phone (877) 614-5533; Email PMSSupport@psc.gov

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)
Finding Help Online: http://grants.nih.gov/support/ (preferred method of contact)

Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading forms and application packages)
Contact Center Telephone: 800-518-4726
Web ticketing system: https://grants-portal.psc.gov/ContactUs.aspx
Email: support@grants.gov

Scientific/Research Contact(s)

Eric Chen
FDA/Office of Orphan Products Development (OOPD)
Telephone: 301-796-6327
Email: eric.chen@fda.hhs.gov

Objective Review Contact(s)

Daniel Lukash
FDA/Office of Acquisitions & Grants Services (OAGS)
Telephone: 240-402-7596
Email: daniel.lukash@fda.hhs.gov

Financial/Grants Management Contact(s)

Daniel Lukash
FDA/Office of Acquisitions & Grants Services (OAGS)
Telephone: 240-402-7596
Email: daniel.lukash@fda.hhs.gov

Section VIII. Other Information

All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement .

Authority and Regulations

Awards are made under section 305 of Public Law 110-85 (42 U.S.C. 282 note), "Demonstration Grants for Improving Pediatric Device Availability", and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.