



**MIDWEST
PEDIATRIC DEVICE
CONSORTIUM**

**The Midwest Pediatric Device Consortium (MPDC)
Pediatric Device Innovation Grant**

Overview:

Supported by the FDA Office of Orphan Product Development, the Midwest Pediatric Device Consortium (MPDC) provides Pediatric Device Innovation Grants to support the advancement of innovations in technology and devices specifically developed for use in the pediatric population. Funds will be granted to support milestone achievement in pediatric project at any step along the development pathway, from ideation through commercialization.

In the Fall 2024 Grant Cycle, grants will be awarded in the range of \$10,000-\$250,000 per grant. Maximum awards are \$50,000 exclusively sponsored by the MPDC but may increase with added commitment from other PDC collaboration or external sponsors.

All companies that submit an Initial Application will have an opportunity to meet with the MPDC to discuss available resources, funds, and opportunities outside the grant in an effort to enhance pediatric device development. This may include advisement, council, and execution of small SOWs provided by additional MPDC fund in addition to industry partner and clinician access.

Submission Date and Process:

MPDC will accept Initial Applications for the Grant until midnight on August 31, 2024. The Initial Applications will be reviewed by MPDC Selection Committee. The MPDC will invite approved companies to fill out a Full Application, which will be accepted until September 30, 2024. The application will be reviewed by the Advisory Council and final decisions made by the Executive Committee. Based on the comparative merits of all proposals submitted, the most qualified proposals will be chosen for award recipients.

Phase 1

- Initial Applications and Review

Phase 2

- Full Applications and Advisory Council Review

Phase 3

- Final Leadership Review and Decision



- The Initial Application submission deadline for this cycle is **August 31, 2024**, at midnight.
- MPDC Selection Committee will review Initial Applications for recommendation of a Full Application in mid-September.
- If requested, Full Applications will be due **September 30, 2024**, at midnight.
- Applications are reviewed by the MPDC Advisory Council and Executive Committee from October 1 – **October 31st, 2024**.
- Awards will be announced in **November 2024**.

Application Details:

Applications are completed and submitted online using application link below:
https://mpdc.smapply.us/prog/mpdc_1/

Phase 1: Initial Application Form

- Section 1: Contact and Company Information
- Section 2: Product Overview and Status
- Section 3: Developmental Resources Needed
- Section 4: Written Answers and Uploaded Documents to general questions about unmet clinical need, product development, team, and overall strategy.

Phase 2: Final Application Form

The Final Application expands on the initial application through in-depth written answers about the following topics.

- Section 1: Product Impact
- Section 2: Further Description of Needs
- Section 3: Budget and Funding
- Section 4: Business, Reimbursement, Funding, Verification and Validation, Regulatory, and IP Strategies.

Note: Some sections of the application have word limit restrictions. Being clear, direct, and concise, with an emphasis on key points to be communicated to MPDC, is encouraged. Applications must include all the requested elements to be considered for funding.

Scoring Rubric:

Proposed projects are scored using ratings in the following categories:

Phase 1: Initial Application

- Feasibility and Significance
- Unmet Clinical Need and Competition
- Progress to date
- Funding to date
- Project team

- Use of Grant Funding
- Regulatory Strategy
- Intellectual Property Strategy

Phase 2: Full Application

- Feasibility and Significance
- Unmet need and Competition
- Progress to date
- Funding to date
- Project team
- Use of Grant Funding
- Funding Strategy
- Business Strategy
- Regulatory Strategy
- Verification and Validation Strategy
- Reimbursement Strategy
- Intellectual Property Strategy

Online Application Process

All MPDC Applications are processed online through the Nationwide Children's Hospital account in SurveyMonkey Apply. All prospective applicants are required to create a SurveyMonkey Apply account (free) to access, edit, and return to both initial and full applications. **Please see the 'Appendix' at the bottom of this document for SurveyMonkey Apply Instructions.**

Project Criteria:

- The award must support the development of a novel pediatric medical device or technology.
- Projects must be a pediatric medical device or technology innovation that leads to improved patient experience, quality, outcomes, or efficiency.
- Medical devices must meet the FDA definition of a medical device.
(<https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device>)
- For guidance regarding software as a medical device, applicants are directed to:
(<https://www.fda.gov/medical-devices/digital-health/software-medical-device-samd>)
- Development of novel drugs and chemical therapies are not eligible for funding. Process improvement and process innovation are also not eligible for funding. Fetal devices / technologies (without other pediatric applications) will not be considered.
- Successful applications will include clear and achievable milestones for product development during the funding period, with specific metrics or deliverables being defined.
- **Projects should be achievable within the funding period, which is limited to 12 months.**
- Grants are funded with allocated Direct Device Funding (DDF) from the MPDC's FDA Pediatric Device Consortium grant. Activities supported by this DDF include, but are not limited to, prototyping, testing, modeling, clinical trials, and other product development needs. DDF funding cannot be used to support overhead or facilities and administrative (indirect) costs of awardees. Institutions with a federal indirect cost rate agreement must submit documentation signed by the authorized institutional official acknowledging that an application budget submitted in response to this funding opportunity announcement will not include indirect cost.

Use of Awards:

PDI grant funds may be used for the following purposes:

MPDC Description 8.2.24

- Acquisition of equipment, materials, and supplies
- Animal studies
- Prototype design, development, and manufacture
- Design and usability studies
- Consulting and contractor fees to cover regulatory assistance, business plan development, marketplace competitive analysis, reimbursement strategy, and biostatistics support.
- Research assistant and student time dedicated to the project (Stipend and Benefits)
- Software programming and development
- Computer software and database purchases
- Specialized, dedicated hardware
- Project-specific administrative and project management resources may be funded where appropriate.

Funds may **not** be used for:

- Reimbursement of investigator and co-investigator time, salaries, or benefits
- Travel and conference fees
- Patent-related costs or other legal fees
- Marketing and sales

Awards and Post Award Responsibilities:

Award Notification: All applicants will be notified of the final decision regarding their application by **2024**. Successful awardees will receive an award notification package with further details.

Distribution of Direct Device Funding:

Funding distribution will be based on the institution and FDA guidelines. This will be discussed in the package upon recipient.

Reporting: Grantee will be required to provide progress reports every three months after the start date of their projects. The reports will include both work progress and funds encumbered. At the conclusion of the grant, a Final Report must be submitted. Further details regarding reporting will be discussed upon award receipt.

Intellectual property. Any intellectual property belonging to the innovator or company will remain its own property irrespective of funding decision.

Joint funding. If additional funding is obtained from other sources during the course of the grant, grantees are expected to notify MPDC.

Additional support through MPDC: Project applicants, regardless of ultimate funding decision, may be eligible for additional types of support through MPDC. Support available includes consulting services for regulatory assistance, business plan development, grant writing, competitive analysis, reimbursement strategy, biostatistics, and prototype design.

Compliance:

Human Subjects Protection and HIPAA Compliance. All research projects that involve human subjects research must be submitted and approved by an Institutional Review Board (IRB) prior to initiation of the research.

Animal Studies. All research projects that involve animal research must be submitted and approved by

the Institutional Animal Care and Use Committee (IACUC) prior to initiation of the animal experiments.

Additional Application Materials. Additional materials such as Institutional Review Board (IRB) and IACUC approvals may be requested of successful applicants prior to issuance of an award.

Appendix

SurveyMonkey Apply Account Registration Instructions

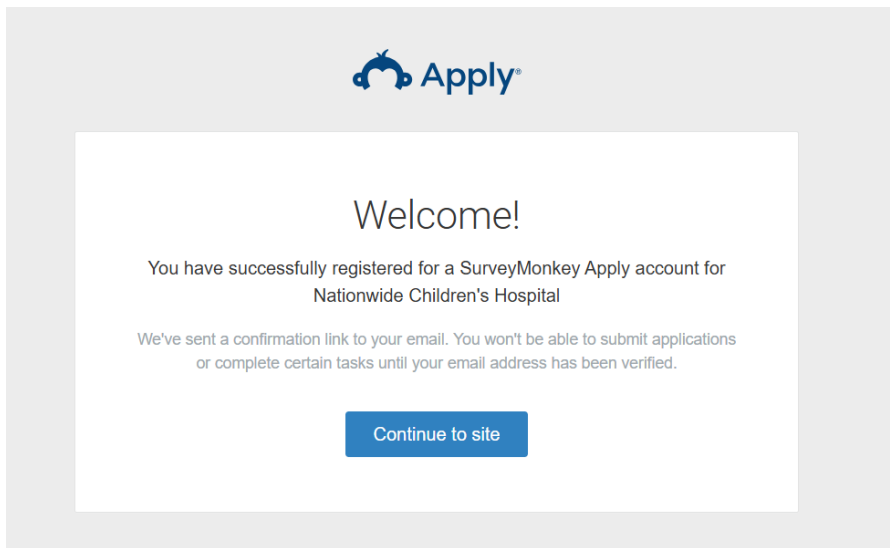
- This will be the screen that pops up when you click on the application link. Please click the 'register' button in the top right corner. Register as an individual, NOT an organization.

The screenshot shows the top of the registration page. In the top right corner, there are two buttons: "Log In" and "Register". The "Register" button is highlighted with a red circle. Below the buttons is the logo for the "MIDWEST PEDIATRIC DEVICE CONSORTIUM" with "Nationwide Children's Hospital" written underneath. The main content area is split into two columns. The left column is titled "Testing - MPDC grant" and contains a paragraph of text describing the grant. The right column is titled "Typical award is \$50K (range \$25K-\$250K)" and features a blue "APPLY" button, which is also highlighted with a red circle. Below the button, it says "Individual applicants can apply.", "Opens Jun 12 2024 12:00 AM (GMT)", and "Deadline Aug 31 2024 12:00 AM (GMT)". At the bottom of the page, there is a blue footer bar with "POWERED BY Apply" on the left and "Copyright © SurveyMonkey | Privacy | Terms" on the right.

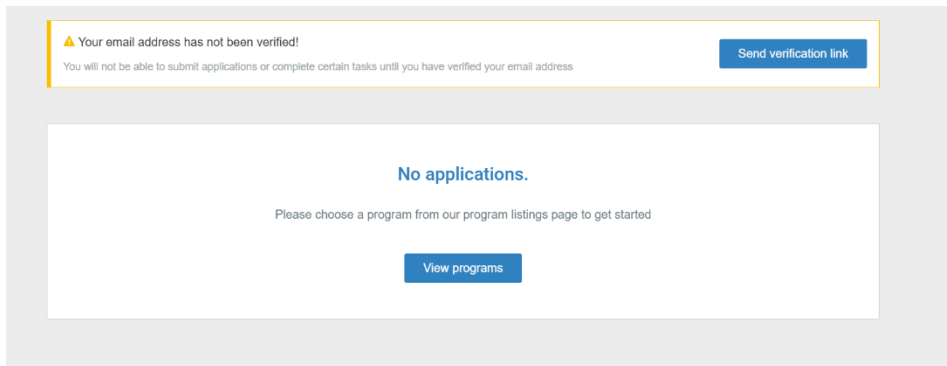
- This is the page you will see when you click 'Register'

The screenshot shows the registration form. At the top left, there is a link "< Return to Nationwide Children's Hospital". At the top right, there is a link "Already have a SurveyMonkey Apply account? LOG IN". The main heading is "Register for an applicant account" with the "Apply" logo above it. Below the heading is a "Register with" section with a red button containing a "G" icon. Underneath is an "OR" separator. There are two radio button options: "Register as an individual" (which is selected) and "Register as an organization". Below these are input fields for "First name", "Last name", "Email", "Password", and "Confirm password". Each of the last three fields has a small eye icon to the right, indicating a password toggle.

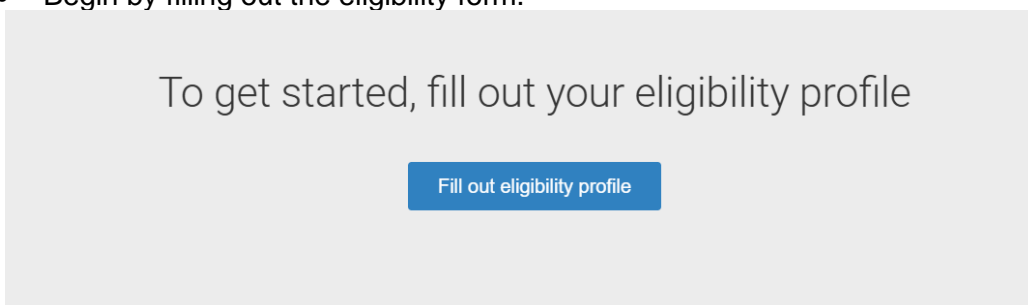
- After you create your account, you should see this screen. Click 'Continue to site.'



- After you verify your email, click 'View Programs'



- Begin by filling out the eligibility form.



Eligibility:

Any company or group working on the development of pediatric medical devices based in the US is eligible to apply. If you have questions regarding eligibility, please contact MPDCinfo@pedsinnovation.org to clarify before submitting your application.

- After eligibility is filled out, this screen will pop up. Click on 'More.'

MIDWEST PEDIATRIC DEVICE CONSORTIUM

Programs

Search programs..

Testing - MPDC grant

Accepting applications from Jun 11 2024 08:00 PM (EDT) to Aug 30 2024 08:00 PM (EDT)

Individual applicants can apply.

Typical award is \$50K (range \$25K-\$250K)

MORE >

1 - 1 of 1 Programs

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- Click on 'Apply.'

MIDWEST PEDIATRIC DEVICE CONSORTIUM

Testing - MPDC grant

Supported by a pediatric device consortium grant from the FDA, the Midwest Pediatric Device Consortium (MPDC) provides Pediatric Device Innovation grants to support the advancement of innovations in technology and devices specifically developed for use in the pediatric population. Funds will be granted to support milestone achievement in pediatric innovation at any step in the development pathway from ideation through commercialization.

Value

Typical award is \$50K (range \$25K-\$250K)

APPLY

Individual applicants can apply.

Opens
Jun 11 2024 08:00 PM (EDT)

Deadline
Aug 30 2024 08:00 PM (EDT)

POWERED BY Apply

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- Note: we recommend typing your answers out in a separate document to avoid technical issues.
- You may add a collaborator to work on the same application as show in green.

Nationwide Children's Hospital Programs My Applications McKay Noll

0 of 1 tasks complete

Last edited: Aug 2 2024 09:44 AM (EDT)

REVIEW SUBMIT

Deadline: Aug 30 2024 08:00 PM (EDT)

MN McKay Noll (Owner)
mckay.noll@gmail.com

Add collaborator


Testing - MPDC grant Preview


MPDC-0000000016

Status: Initial Application

APPLICATION ACTIVITY

Your tasks Instructions

 [Fill out the Initial Application](#)
Deadline: Aug 30 2024 08:00 PM (EDT)

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<https://mpdcsmapply.us/hsk/295572/frm/2588934/e/>

Nationwide Children's Hospital Programs My Applications McKay Noll

0 of 1 tasks complete

Last edited: Aug 2 2024 09:49 AM (EDT)

REVIEW SUBMIT

Deadline: Aug 30 2024 08:00 PM (EDT)

MN McKay Noll (Owner)
mckay.noll@gmail.com

Add collaborator


Testing - MPDC grant Preview


MPDC-0000000016

Status: Initial Application

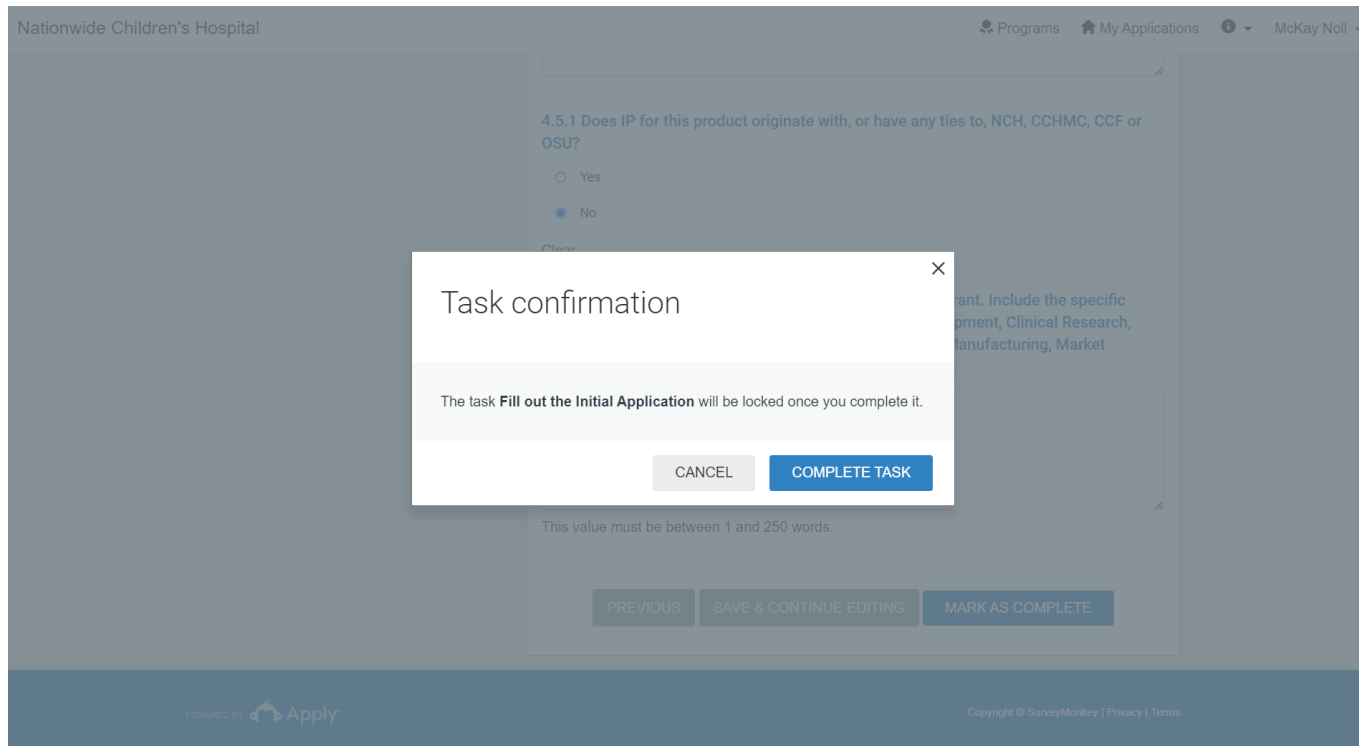
APPLICATION ACTIVITY

Your tasks Instructions

 [Fill out the Initial Application](#)
Last edited: Aug 2 2024 09:49 AM (EDT)

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- **Note: once you hit complete task, you will no longer be able to modify your application. Your application is not submitted until you click ‘Submit’ on the application dashboard.**



- **Clicking ‘Submit’ officially turns in your application.**

