



UCSF–STANFORD

Pediatric Device Consortium

Pediatric Device Innovation Grant By The Midwest and UCSF-Stanford Pediatric Device Consortia

Overview:

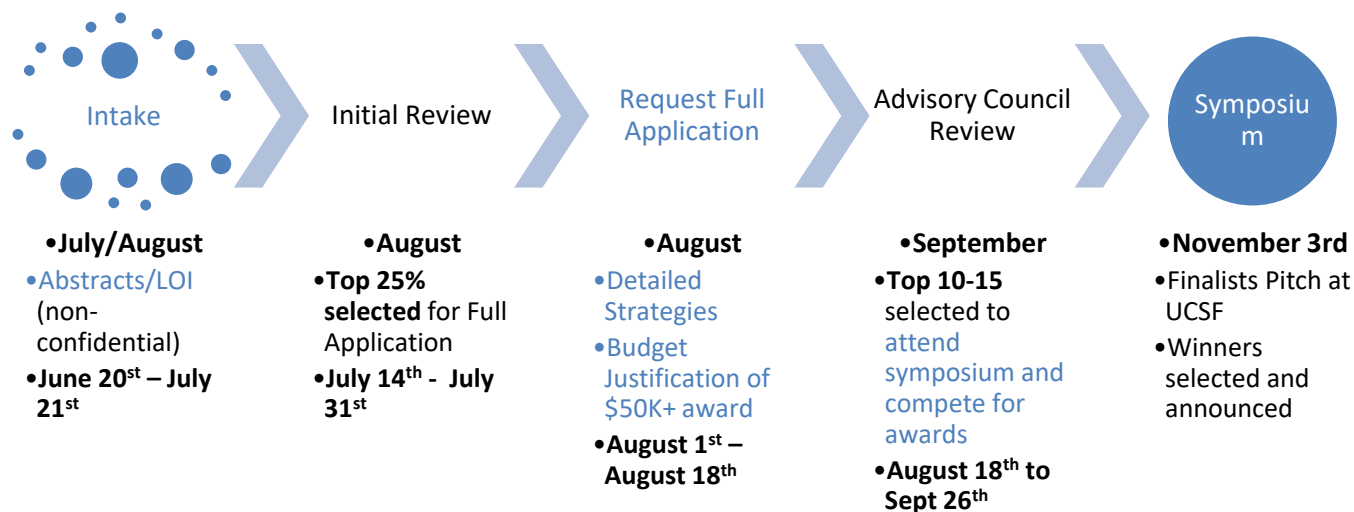
Supported by the FDA Office of Orphan Product Development, the Midwest and UCSF-Stanford Pediatric Device Consortia jointly provide Pediatric Device Innovation Grants to support the advancement of innovations in technology and devices specifically developed for use in the pediatric population. Funds will be granted to support milestone achievement in pediatric projects at any step along the development pathway, from ideation through commercialization.

In the Fall 2025 Grant Cycle, grants will be awarded in the range of \$10,000-\$100,000 per grant. Maximum awards are \$100,000 exclusively sponsored by the MPDC and UCSF/S grant.

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 funds in addition to industry partner and clinician access.

Submission Date and Process:

Initial applications for the Grant will be accepted until midnight on July 21st, 2025. The Initial Applications will be reviewed by a joint MPDC UCSF/S Selection Committee. Approved companies will be invited to fill out a Full Application, which will be accepted until August 18th, 2025. The full application will be reviewed by the Advisory Council and final decisions made by the Executive Committee. Finalists will be chosen to attend a symposium taking place on November 3rd, 2025. Based on the comparative merits of all proposals submitted, the most qualified proposals will be chosen for award recipients.



- The Initial Application submission deadline for this cycle is **July 21, 2025**, at midnight.
- PDC Selection Committee will review Initial Applications for recommendation of a Full Application in the end of July.
- If requested, Full Applications will be due **August 18th, 2025**, at midnight.
- Applications are reviewed by the PDC Advisory Council and Executive Committee from August 18th – **September 26th, 2025**.
- Awards will be announced on **November 3rd 2025**.

Application Details:

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

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 and UCSF/S, 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:

- 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 **November 3rd, 2025**. 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.

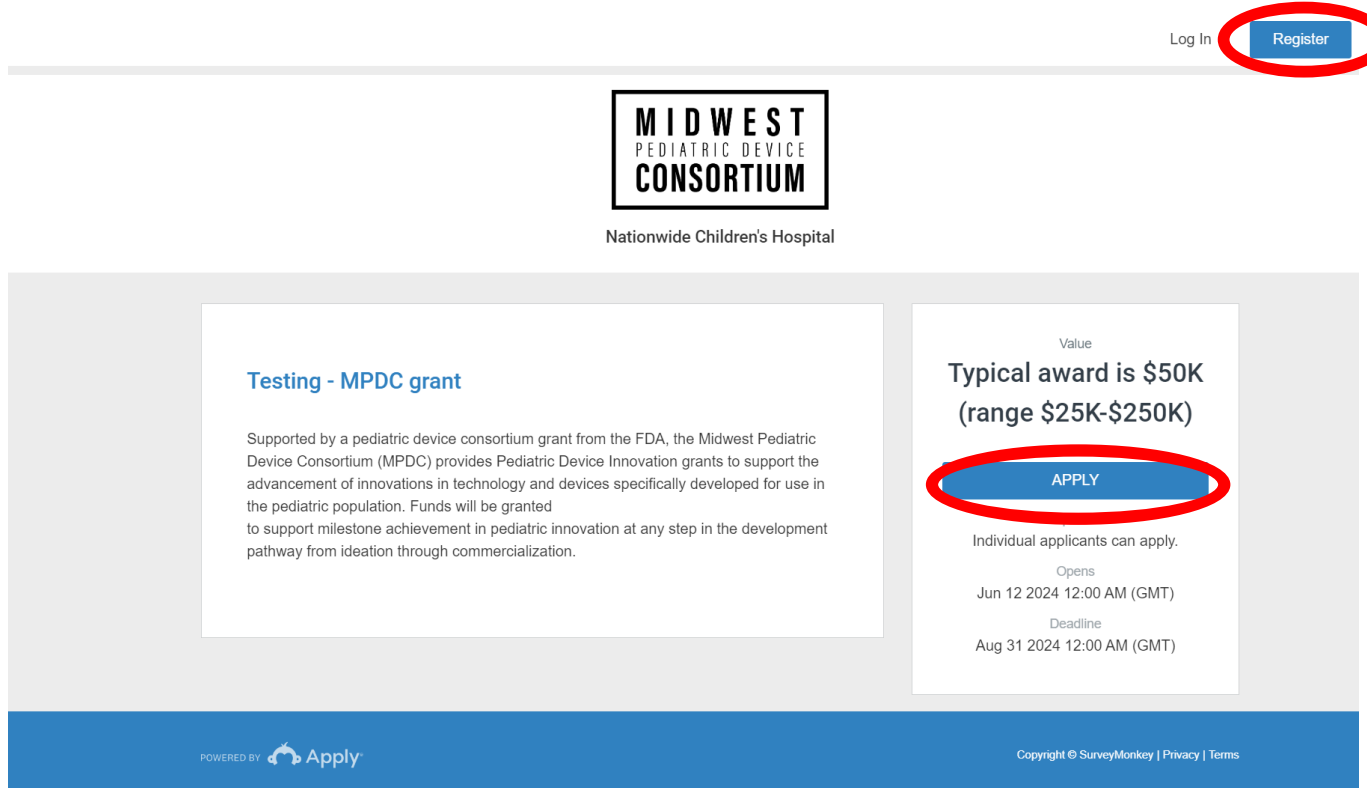
Animal Studies. All research projects that involve animal research must be submitted and approved by the Institutional Animal Care and Use Committee (IACUC) prior to initiation of the animal experiments.

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

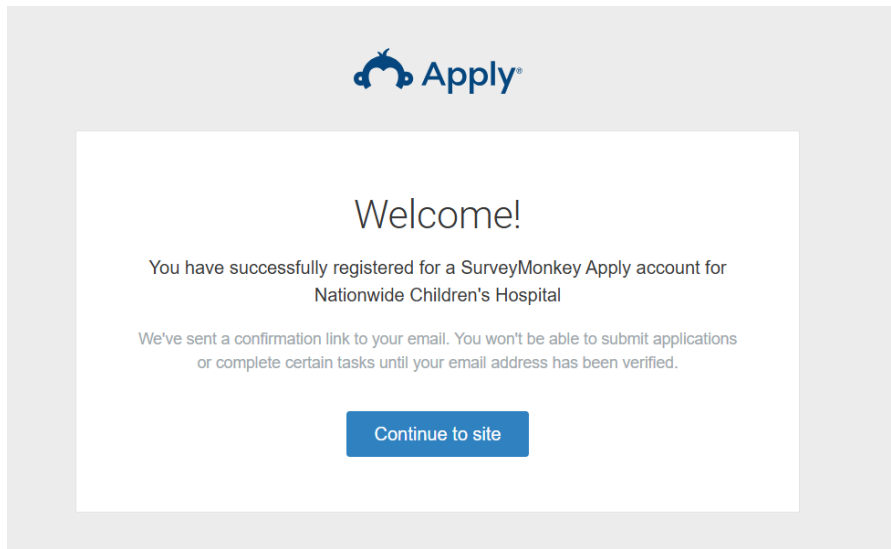
- This will be the screen that pops up when you click on the application link. Please click the 'register' button in the top right corner. Register as an individual, NOT an organization.



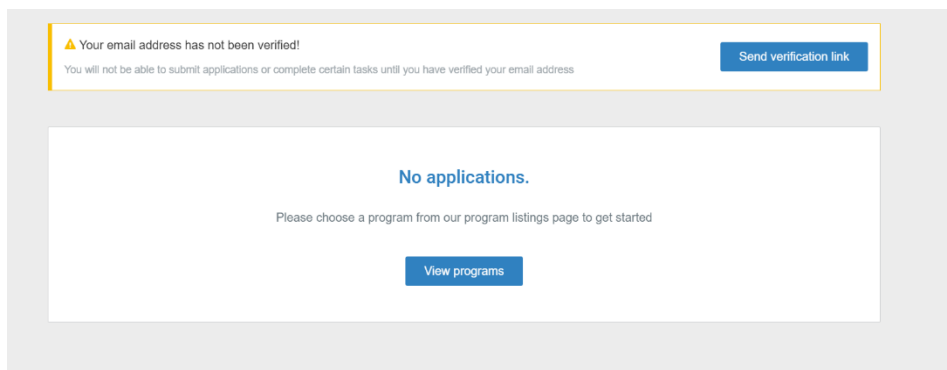
- This is the page you will see when you click 'Register'

The screenshot shows the 'Register for an applicant account' page. At the top, there is a link to 'Return to Nationwide Children's Hospital' and a 'LOG IN' button for existing users. The main heading is 'Register with' followed by a red button with a 'G' logo. Below this, there is an 'OR' separator and two radio button options: 'Register as an individual' (selected) and 'Register as an organization'. The form fields include 'First name', 'Last name', 'Email', 'Password', and 'Confirm password', each with a corresponding input field and a toggle for password visibility.

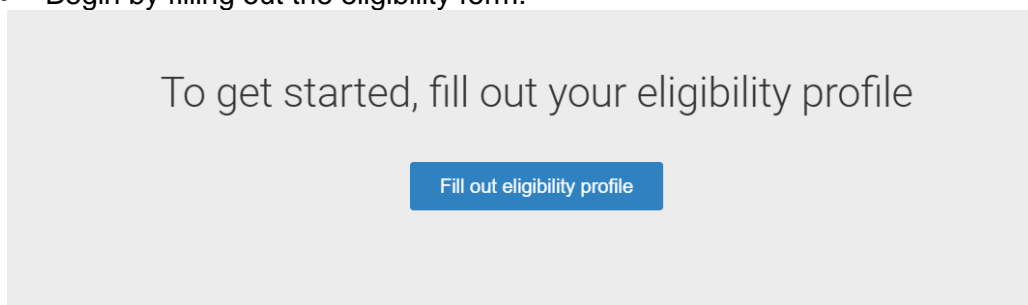
- After you create your account, you should see this screen. Click 'Continue to site.'



- 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.'

Nationwide Children's Hospital

Programs My Applications McKay Noll

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.'

Nationwide Children's Hospital

Programs My Applications McKay Noll

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)

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PDC Grant Description 6.20.25

- 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 [🔗](#)


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/tsk/395572/rm/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 [🔗](#)


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.**

The screenshot shows a 'Task confirmation' modal dialog box in the center of the screen. The dialog has a title bar with a close button (X). The main text inside the dialog reads: 'The task **Fill out the Initial Application** will be locked once you complete it.' At the bottom of the dialog are two buttons: 'CANCEL' and 'COMPLETE TASK'. The background is a blurred view of the application dashboard, showing a form with a question '4.5.1 Does IP for this product originate with, or have any ties to, NCH, CCHMC, CCF or OSU?' and radio buttons for 'Yes' and 'No'. Below the question is a text area with a word count limit: 'This value must be between 1 and 250 words.' At the bottom of the background form are three buttons: 'PREVIOUS', 'SAVE & CONTINUE EDITING', and 'MARK AS COMPLETE'. The top of the dashboard shows the header 'Nationwide Children's Hospital' and navigation links for 'Programs', 'My Applications', and a user profile 'McKay Noll'. The footer of the dashboard includes 'POWERED BY Apply' and 'Copyright © SurveyMonkey | Privacy | Terms'.

- Clicking ‘Submit’ officially turns in your application.

The screenshot shows the application dashboard for 'Nationwide Children's Hospital'. The top navigation bar includes 'Programs', 'My Applications', and a user profile 'McKay Noll'. The main content area is divided into two columns. The left column shows a progress bar for '1 of 1 tasks complete', the last edited time 'Aug 2 2024 09:50 AM (EDT)', and a deadline 'Aug 30 2024 08:00 PM (EDT)'. Below this are buttons for 'REVIEW' and 'SUBMIT', with the 'SUBMIT' button circled in red. The right column shows the application details for 'Testing - MPDC grant' with ID 'MPDC-0000000016' and status 'Initial Application'. It has tabs for 'APPLICATION' and 'ACTIVITY'. Below the tabs is a section titled 'Your tasks' with a green checkmark icon and the text 'Fill out the Initial Application' and 'Cannot be modified'. The footer of the dashboard includes 'POWERED BY Apply' and 'Copyright © SurveyMonkey | Privacy | Terms'.

