



The West Coast Consortium for Technology & Innovation in Pediatrics (CTIP) Catalyzing Pediatric Innovation (CPI) Grant

About the Catalyzing Pediatric Innovation (CPI) Grant

Supported through a pediatric device consortia grant from the FDA, the West Coast Consortium for Technology & Innovation in Pediatrics (CTIP) is pleased to provide grants to support the advancement of innovations in pediatric technology and devices. Funds will be granted to develop pediatric innovation from ideation through commercialization. Funds are available to support the achievement of milestones on the path to development of pediatric innovation in devices and technology.

Up to six grants will be awarded in the range of \$25,000-50,000 per grant for a term of one year.

CTIP will accept letters of intent for the CPI Grant until April 15, 2019. The letter of intent will be considered by the CPI Grant Committee. Based on the comparative merits of all proposals submitted, the most qualified proposals will be designated as semi-finalists. Semi-finalist will be invited to submit a full application.

Criteria:

- Must be a novel pediatric medical device or technology.
- Medical devices must meet the FDA definition of a medical device (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm>).
- Please be aware that there is new draft guidance regarding software versus medical devices can be found at the following link: (<https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM587820.pdf>)
- Development of novel drugs and chemical therapies will not be funded. Process improvement and innovations are also not eligible for funding. In addition, fetal devices / technologies (without other pediatric applications) will not be funded.
- Projects must be a pediatric medical device or technology innovation that leads to improved patient experience, quality, outcomes, or efficiency.
- Eligible projects must have clear achievable milestones for the funding period with specific metrics or deliverables.
- Projects should be short in duration with funding intended to last no more than 12 months.
- No indirect costs will be allowed.

Award amounts:



Awards will be made based on the requested budget in a range of \$25,000 - \$50,000. *The maximum award is \$50,000.* The proposed justification of the requested budget will affect an application's competitiveness.

Use of funds:

Funds may be used for the following:

- Acquisition of equipment, materials and supplies
- Animal studies
- Prototype design and development
- Design and usability studies
- Consulting and contractor fees to cover regulatory assistance, business plan development, competitive analysis, reimbursement strategy, biostatistics, and prototype design
- Research assistant and student time dedicated to the project
- 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 costs or other legal fees
- Marketing and sales

Eligibility:

Any company, group or individual working on the development of pediatric innovation in technology and medical devices within the US is eligible to apply. **Companies or groups that have previously received any form of direct funding or monetary grant from another FDA Pediatric Device Consortium (PDC) are not eligible to apply.** List of PDCs:

<https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/PediatricDeviceConsortiaGrantsProgram/>

Submission Date and Process:

- The submission deadline for the letter of intent is **April 15, 2019**.
- Semi-finalist will be selected by May 15, 2019.
- Semi-finalist will be invited to submit a full application by June 17, 2019.
- Awards will be announced by August 1, 2019.



Application Details:

Letter of Intent: Please include the following elements in the letter of intent (maximum length 1 page, minimum 11-point font):

- Project name (and company name, if applicable) and Innovator(s) (include list of key collaborators)
- Contact Information: primary contact name, email address, phone number and mailing address
- Description of unmet need, proposed solution, and competitive landscape
- Approximate budget and use of funds
- Expected outcomes from the use of funds

Note, letters of intent must include all of the above elements to be considered. Please submit a PDF file of the letter of intent via this link: <https://airtable.com/shrM7kZ9w0ZUpKpOi>

The deadline for receipt of the letters is **April 15, 2019**.

Letters longer than 1 page will not be evaluated.

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 submitted after the application deadline. Applicants submitting proposals requiring IRB or IACUC approval are encouraged to submit their protocols concurrently with the application.

Awards and Post Award Responsibilities:

Award Notification: All applicants will be notified of the final decision regarding their application by August 1, 2019. Successful applicants will receive an award notification package with further details.

Reporting: The grantee will be expected to provide a quarterly progress report every three months after the start date of the 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 included in the award package.



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 CTIP.

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

About The West Coast Consortium for Technology & Innovation in Pediatrics (CTIP):

The West Coast Consortium for Technology & Innovation in Pediatrics (CTIP) is a pediatric medical device accelerator based at Children's Hospital Los Angeles (CHLA) and the University of Southern California (USC). Established in 2011 and first funded by the U.S. Food and Drug Administration (FDA) in 2013, CTIP promotes the commercialization and clinical use of pediatric medical device technology. In August 2018, CTIP was awarded a new \$6.6 million P50 grant from the FDA to continue research and development of MedTech for children (Grant Number: 1P50FD006425-01, PI: Espinoza).

CTIP addresses the most important component missing from pediatric device innovation: simultaneously engaging clinicians, engineers, regulators, hospital administrators, patients and the business community in the process of assessment and development of technology. For portfolio companies, CTIP fosters networking opportunities, direct and indirect financial support and guidance on issues related to, but not limited to, intellectual property, prototyping, engineering, testing, grant writing and clinical trial design. CTIP has a network of children's hospitals, academic institutions, accelerators and incubators across the West Coast to support the commercialization of pediatric medical devices. CTIP network members include the University of California, Los Angeles; Oregon Health & Science University; University of Southern California; University of California, San Diego; University of California, Berkeley; Seattle Children's Hospital; Cedars-Sinai Accelerator; LA BioMed; and Project Zygote. Today CTIP's active portfolio includes more than 50 technologies and pediatric medical devices.

Please submit a PDF file of the letter of intent to via this link:

<https://airtable.com/shrM7kZ9w0ZUpKpOi>. **The deadline for receipt of the letters is April 15, 2019. All received applications will be acknowledged by a return email.**

Questions:

Please address questions to:

Nadine Afari, Program Manager

The West Coast Consortium for Technology & Innovation in Pediatrics – CTIP

info@westcoastctip.org