



Southern California Consortium for Technology and 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 Southern California Consortium for Technology and 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, 2018. 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- Please be aware that there is new draft guidance regarding software versus medical devices can be found at the following link: (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 are not eligible to apply.**

Submission Date and Process:

- The submission deadline for the letter of intent is **April 15, 2018.**
- Semi-finalist will be selected by May 15, 2018.
- Semi-finalist will be invited to submit a full application by June 15, 2018.
- Awards will be announced by August 1, 2018.

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 or Word file of the letter of intent to info@scctip.org. The deadline for receipt of the letters is April 15, 2018.

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, 2018. 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 Southern California Consortium for Technology and Innovation in Pediatrics (CTIP):

CTIP was established in 2011 to support and foster collaboration in pediatric device and technology development. Since 2013, CHLA received grant support from the FDA as a pediatric device consortium to advance pediatric device development and enable CTIP to function as a pediatric device accelerator. CTIP is dedicated to promoting and advancing the commercialization of pediatric medical devices by serving innovators and companies and by engaging clinicians, engineers, patients and the business community in the process of assessment and development of novel technologies related to pediatric care. CTIP provides feasibility analysis tools, resources, and services as well as assembles and educates pediatric product development teams. CTIP has relationships with key stakeholders in the medical device ecosystem including medical centers, innovators, parents, and patient advocacy groups. CTIP has supported nearly 100 pediatric device projects since its inception. Today CTIP's active portfolio includes more than 30 technologies and pediatric medical devices.

Please submit a PDF or Word file of the letter of intent to info@scctip.org. The deadline for receipt of the letters is April 15, 2018. All received applications will be acknowledged by a return email.

Questions:

Please address questions to:

Kathryne Cooper, Program Adviser

Southern California Consortium for Technology and Innovation in Pediatrics – CTIP

info@scctip.org