



Southwest National Pediatric Device Innovation Consortium (SWPDC) Virtual Accelerator Application

Please complete the following form to the best of your ability.

For any questions, please contact Dr. Chester Koh via email at SouthwestPDC@bcm.edu. Thank you!

<http://swpdc.org>

Date *

Primary Contact Name *

Primary Contact Company Role *

Primary Contact E-Mail *

Primary Contact Phone Number *

Current Employer or Affiliation *

Primary Contact Address *

If company address exists, use company address.

Company Name

Company Address

Website

Additional Collaborator 1 Name

If applicable, please provide contact information for any additional collaborators. Otherwise, please skip to Name of Device field.

Additional Collaborator 1 Company Role

Additional Collaborator 1 Mobile Phone

Additional Collaborator 1 E-Mail

Additional Collaborator 1 Current Employer/Affiliation

Additional Collaborator 2 Name

Additional Collaborator 2 Company Role

Additional Collaborator 2 Mobile Phone

Additional Collaborator 2 E-Mail

Additional Collaborator 2 Current Employer/Affiliation

Additional Collaborator 3 Name

Additional Collaborator 3 Company Role

Additional Collaborator 3 Mobile Phone

Additional Collaborator 3 E-Mail

Additional Collaborator 3 Current Employer/Affiliation

Name of Device *

Target Disease or Condition *

Target Population in the US - Incidence *

Target Population in the US - Prevalence *

Pediatric Subpopulation *

Please select all applicable options below

- Newborn (0-1mo)
- Infant (1mo-2yr)
- Child (2-12yr)
- Adolescent (12-21yr)
- All Peds (0-21)

Device Description *

Briefly describe your idea/invention/product in terms that a non-expert in your field would understand (in 500 words or less)

What problem are you solving? *

How is this problem currently addressed? What do people do because your product doesn't exist? *

What is new about how you are solving the problem? *

What are the future plans to advance the device? *

What kind of help are you seeking from SWPDC? *

Please describe any important partnerships or support you have. *

Is this a Medical Device (As defined by the FDA)? *

What stage of development is your product in? *

What is the anticipated FDA Device Product Code? *

Please see: <https://www.fda.gov/medical-devices/classify-your-medical-device/product-code-classification-database>

Intended Use *

In one phrase or sentence, please state the hypothesis/intended use of your product.

Indication for Use *

In one phrase or sentence, please state the indication for use of your product.

What is the anticipated FDA Device Classification? *

Have you received support from any other FDA-funded Pediatric Device Consortia? *

Have you had any contact with the FDA? *

Does the device fulfill an unmet clinical need? *

i.e. no approved/cleared devices

Supplemental Documents

Please attach any documents, decks, or images that would help us better understand your technology or company.

 Drop files here

Disclosure Acknowledgement *

Disclosure Terms and Conditions

SWPDC acknowledges that the submission of this intake form does not grant SWPDC any rights to the work, and any accompanying intellectual property is owned by the submitter (“no strings attached”). All rights to inventions, whether patentable or not, conceived or first actually reduced to practice by one or more applicants will belong to the submitter. Inventorship is decided between and among the team members involved with a given invention. Team members agree to negotiate in good faith the disposition of the joint invention.

The submitter acknowledges that material submitted for review by SWPDC for which the submitter requests support is their own work or is submitted with permission from the entity that has legal rights to the material.

SWPDC may use the submitter’s name, the submitter’s institution, the

project name and the project description for SWPDC's internal tracking and record keeping as well as to comply with reporting requirements mandated by the FDA (as part of our contractual obligation).

About the Southwest National Pediatric Device innovation Consortium (SWPDC):

The Southwest national Pediatric Device innovation Consortium (SWPDC) is a "no-strings-attached" virtual accelerator based at Texas Children's Hospital and Baylor College of Medicine that supports pediatric device innovators nationwide throughout the pediatric device life cycle.

SWPDC is one of five U.S. Food and Drug Administration (FDA) P50 grant-supported pediatric device consortia and is led by Dr. Chester Koh, Executive Director and Contact Principal Investigator.

We support pediatric device innovators both regionally and nationally with product and technology acceleration services and business acceleration services in a "no-strings-attached" manner, with the goals of commercialization and clinical use of novel pediatric medical devices.

The consortium includes clinical, scientific, business, financial, regulatory, reimbursement, engineering, ISO13485 compliant product design & manufacturing, intellectual property, and academic partners in the Houston / Southwest U.S. region, including Texas A&M University, Rice University, University of Houston, Fannin Innovation Studio, local device development firms, and other children's hospitals in the Southwest U.S. region (including Children's Hospital of San Antonio, Children's Health in Dallas, and Phoenix Children's).

SWPDC facilitates the development of pediatric medical devices by coordinating resources within its existing translational and commercialization framework. The consortium recognizes that pediatric device projects may need an extended life cycle in the children's hospital / academic setting before exposure to the external market in order to leverage cost-efficient resources and non-dilutive funding to support the development of viable pediatric devices. SWPDC also works to increase awareness around the need for novel pediatric medical device development, as well as identify and address current barriers to the development and commercialization of pediatric devices with a particular focus on establishing a productive needs-driven pipeline of new pediatric medical devices. The consortium networks its stakeholders with the business, investment, higher education, and philanthropic communities in

the entire Southwest U.S. region and nationally in order to provide pediatric innovators with comprehensive pediatric device development services.

Please check the box below to acknowledge the disclosure:

Submit

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