IDeA States Pediatric Network
ECHO A program supported by the NIH

ECHO
Environmental influences on Child Health Outcomes
A program supported by the NIH

Improving Access to Pediatric Clinical Trials in Vermont (IMPACT VT)
UVM Site for the ECHO ISPCTN

The goal of the ISPCTN is to provide medically underserved and rural populations with access to state-of-the-art clinical trials, apply findings from relevant pediatric cohort studies to children in IDeA state locations, and build pediatric research capacity at a national level. Funding also supports professional development of faculty-level pediatricians and their support teams in the conduct of clinical trials research in the ISPCTN.

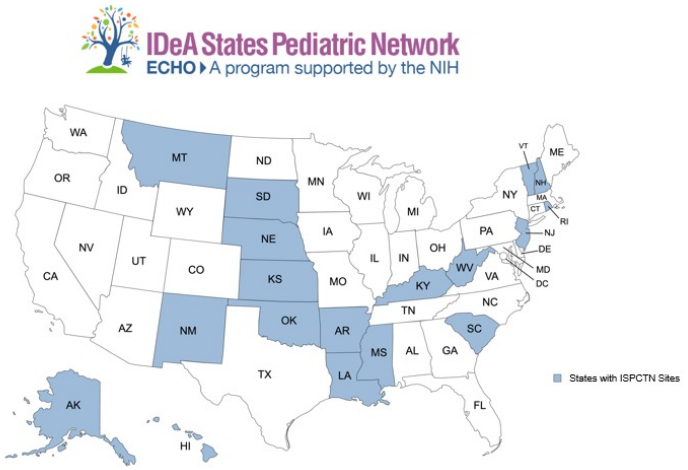
Impact of ISPCTN in VT

Since the start of the ISPCTN in 2016, the Network has developed and implemented 9 studies. University of Vermont investigators have led 3 of these studies:

Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome (ACT NOW) Studies to inform care of infants with prenatal opioid exposure (PI: Leslie Young, MD)

- Multicenter Observational Study of Infant Care and Variations in Clinical Practice
- Eating, Sleeping, Consoling for Neonatal Opioid Withdrawal (ESC-NOW) Clinical Trial - in the field now

Bronchiolitis Recovery and the Use of HEPA Filters (BREATHE) – in the field now (PI: Kelly Cowan, MD)



Program Overview

Infants and children living in rural areas are less likely than those living elsewhere to have a chance to enroll in clinical research, especially clinical trials. Because of this, the ECHO Program paired with the NIH IDeA States Program to create the ECHO IDeA States Pediatric Clinical Trials Network (ISPCTN). This network ensures that children in states with historically low NIH funding have access to clinical trials as part of ECHO.

The ECHO ISPCTN is made up of research sites in 18 states. The network helps address disparities in pediatric research by including children from rural and/or underserved populations in clinical trials, and by building pediatric research capacity in states with historically low NIH funding.

The ECHO ISPCTN aims to enhance pediatric clinical trial access at state and national levels and to help carry out well-designed clinical trials in children. The Network has the following goals:

- Provide medically underserved and rural populations access to state-of-the-art clinical trials in ECHO's five areas of child health (pre/peri/postnatal, upper and lower airway, obesity, neurodevelopment, and positive health).
- Build the national capacity to conduct pediatric clinical trials by providing professional development, team support and infrastructure building for ECHO researchers and other research faculty outside of ECHO.

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| Website: echochildren.org/idea-states-pediatric-clinical-trials-network |

Success Stories



Eat, Sleep, Console for Neonatal Opioid Withdrawal (ESC-NOW) is a multicenter clinical trial conducted as part of the Advancing Clinical Trials in Neonatal Opioid Withdrawal (ACT-NOW) Collaborative, a collaboration between the ECHO ISPCTN and the NICHD Neonatal Research Network and funded by the Helping to End Addiction Long-term (HEAL) Initiative. The ESC–NOW study was conducted at 26 sites across the country and looked to compare usual care to the Eat, Sleep, Console (ESC) care approach, an approach that uses a function-based assessment of withdrawal severity and emphasizes non-pharmacologic care/supportive care and the empowerment of families in the care of their infants. Over 1300 infants were enrolled in the study, which showed that when compared to usual care infants cared for with the ESC care approach were ready for discharge from the hospital 6.7 days earlier and were 63% less likely to receive an opioid medication as part of their treatment. The primary outcomes for this study were published in the New England Journal of Medicine (https://www.nejm.org/doi/pdf/10.1056/NEJMoa2214470?articleTools=true). The long-term follow-up portion of the study is ongoing (anticipated completion summer of 2024).

BREATHE

Bronchiolitis Recovery and the Use of HEPA Filters (BREATHE) is a multi-center ECHO ISPCTN trial that aims to determine if indoor air filtration improves respiratory symptoms in children under 12 months of age who have been hospitalized for bronchiolitis. After two weeks of baseline indoor air quality measurements, the caregiver of the child participant installs an air filtration unit intervention with or without HEPA filters (in the child's sleep space and a common room). Children are followed for respiratory outcomes for approximately 6 months. The study's enrollment target is 228 babies. BREATHE is designed to reduce barriers to participation for rural participants in that there will be no required study visits to a distant study site, and all study activities and data collection will be conducted remotely. Participants are be identified in hospitals in ISPCTN states, maximizing the chances that rural and medically underserved populations are represented. The BREATHE study is co-chaired by Kelly Cowan, MD (UVM) and Erin Semmens, PhD (University of Montana)

ISPCTN Funding for UVM

Program/Grant Name	Type / Institution	FY	Cong District	Amount
Improving Pediatric Access to Clinical Trials in Vermont (IMPACT VT) (PI: Cowan/Young, 5UG1OD024955)	University of Vermont	2020-2025	VT	$2,144,990
Improving Pediatric Access to Clinical Trials in Vermont (IMPACT VT) (PI: Cowan, 5UG1OD024955)	University of Vermont	2016-2020	VT	$1,787,839
			Total Funds	**$2,144,990**