

# NIH Environmental influences on Child Health Outcomes (ECHO) Program

December 2023

For questions on the findings below or other ECHO Program activities, please email [NIHKidsandEnvironment@od.nih.gov](mailto:NIHKidsandEnvironment@od.nih.gov)

## Providing state-of-the art clinical trials for children living in rural or underserved areas

Infants, children, and adolescents living in rural or underserved areas have less opportunity to participate in clinical research, especially clinical trials.

To address this barrier, 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.



- Provides children from **rural or underserved** populations access to state-of-the-art clinical trials



- Builds **national pediatric research capacity** for states with historically low NIH funding to conduct trials and compete for future funding



- ECHO ISPCTN is made up of research sites in **18 states**: AK, AR, DE, HI, KS, KY, LA, MN, MS, NE, NH, NM, OK, RI, SC, SD, VT, WV.

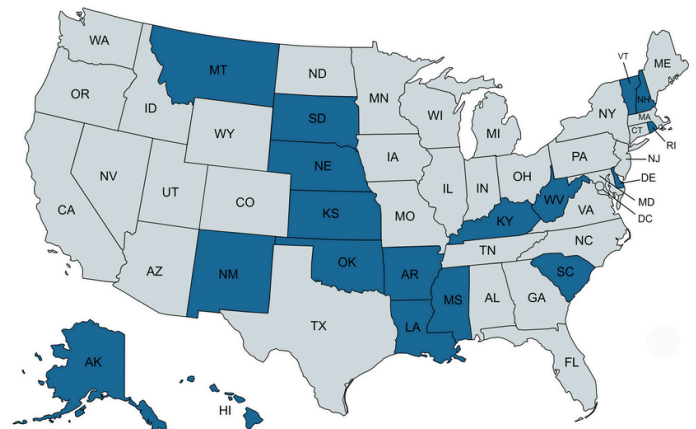
## Featured ECHO ISPCTN clinical trials

### ADVANCING CLINICAL TRIALS IN NEONATAL OPIOID WITHDRAWAL (ACT NOW) RESEARCH STUDIES

The ACT NOW Initiative aims to inform the clinical care of newborns who are exposed to opioids in the womb.

ACT NOW is a collaborative effort of the ECHO ISPCTN and the NICHD Neonatal Research Network (NRN) and is partially supported by NIH Helping to End Addiction Long-term® (HEAL) Initiative. ECHO researchers are part of three ACT NOW studies:

- The ACT NOW Current Experience Study (completed) showed large variation across the country in the care of infants with Neonatal Opioid Withdrawal Syndrome (NOWS), suggesting that new standards of care are needed.<sup>1</sup>
- The ACT NOW Eat, Sleep, Console (ESC) Study (1st phase completed) showed that a simpler approach to assessing and caring for these newborns results in much shorter hospital stay and less need for medication.<sup>2,3</sup>
- The goal of the ACT NOW Weaning Clinical Trial (ongoing) is to help clinicians safely reduce doses of morphine or methadone prescribed to infants with NOWS.



**PHASE I RESULTS FROM THE EAT, SLEEP, AND CONSOLE (ESC) STUDY:**

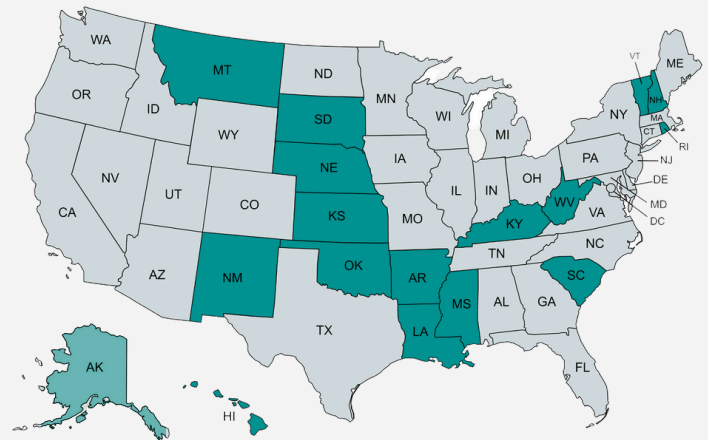
**The state of Washington has announced a new policy to require ESC implementation by January 2025**



- Until now, there hasn't been strong evidence to support a standard approach to the care of babies with neonatal opioid withdrawal syndrome (NOWS). Hospitals have had widely different approaches.
- The ESC clinical trial, conducted in 26 hospitals in 18 states, gives hospitals an evidence-based care approach for babies with NOWS. **Compared with usual care using traditional approaches, the ESC care approach substantially decreased the time until infants are medically ready for discharge, without increasing adverse outcomes through early infancy.**
- **ESC also reduced use of opioid medications to treat these babies** by enhancing newborn function through the use of nonpharmacologic caregiver-led approaches like holding, swaddling, and rocking.

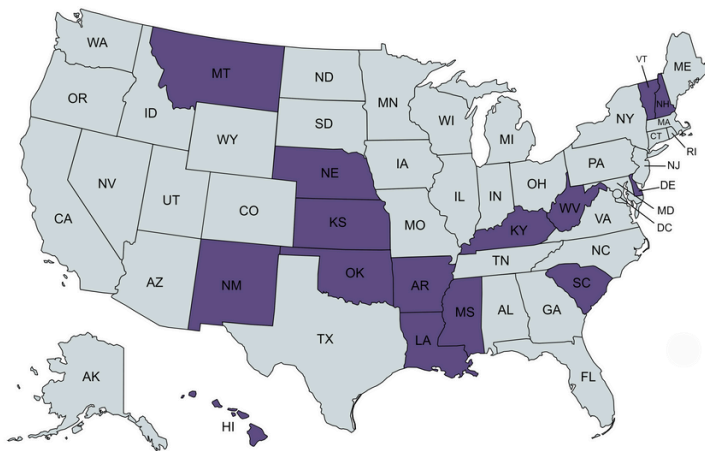
**BRONCHIOLITIS RECOVERY AND THE USE OF HIGH EFFICIENCY PARTICULATE AIR (HEPA) FILTERS (BREATHE) STUDY (ongoing)**

BREATHE is a multi-center ECHO ISPCTN Clinical trial 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 air filtration units with or without HEPA filters in the child's sleep space and a common room. Researchers follow the children for respiratory outcomes for approximately 6 months.



**BREATHE is designed to reduce barriers to participation for rural participants** by not requiring participants to visit a distant study site. Research staff conduct all study activities and data collection remotely.

**RESULTS FROM THE VITAMIN D ORAL REPLACEMENT IN ASTHMA (VDORA1) STUDY**



The overall objective of the VDORA1 study was to determine **how much Vitamin D supplementation children with asthma and overweight or obesity need** to correct low vitamin D levels. Children with overweight or obesity tend to have more severe asthma symptoms as well as lower vitamin D levels than other children. Helping these children reach adequate vitamin D levels could be a **cost-effective way to help their asthma symptoms** by lowering inflammation in the lungs. This study showed that the dose of vitamin D supplementation needed to provide adequate blood levels in these children is relatively high but feasible.<sup>4,5</sup>

1. Site-Level Variation in the Characteristics and Care of Infants With Neonatal Opioid Withdrawal.
2. Eating, Sleeping, Consoling for Neonatal Opioid Withdrawal (ESC-NOW): a Function-Based Assessment and Management Approach study protocol for a multi-center, stepped-wedge randomized controlled trial
3. Eat, Sleep, Console Approach or Usual Care for Neonatal Opioid Withdrawal.
4. Pharmacokinetics of Oral Vitamin D in Children with Obesity and Asthma
5. Vitamin D Oral Replacement in Children with Obesity Related Asthma: VDORA1 Randomized Clinical Trial.