



ECHO

Environmental influences
on Child Health Outcomes

A program supported by the NIH

IDEA States
Pediatric Network

Study Summary

Best Practices for Conducting Clinical Trials with Indigenous Children in the United States

Author(s): Jennifer Shaw, Erin Semmens, May Okihiro, Johnnye Lewis, Matthew Hirschfeld, Timothy VanWagoner, Lancer Stephens, David Easa, Judith Ross, Niki Graham, Sara Watson, Edgardo Szyld, Denise Dillard, Lee Pyles, Paul Darden, John Carlson, Paul Smith, Russell McCulloh, Jessica Snowden, Sarah Adeky, Rosalyn Singleton

Why was this study conducted?

The United States (US) population includes nearly 7 million Indigenous people, including:

- 5 million American Indian and Alaska Native (AI/AN) people, and
- 1.5 million Native Hawaiian and other Pacific Island people.

Indigenous people in the US have lower life expectancies and higher disease burdens than other groups. Indigenous children have high rates of health conditions, such as asthma, obesity, and respiratory infections, compared to the general population. Few pediatric clinical trials have included Indigenous children. However, many of these children live in rural communities where interventions are often most needed. Children can respond to medicines and other health interventions differently based on their backgrounds. This paper highlights the reasons why Indigenous children may be excluded from trials and offers suggestions for improvement.

What was done?

The authors describe key ethical issues around conducting trials with Indigenous children. They review four case studies and provide guidance for conducting clinical trials involving Indigenous children.

What was found?

Based on their experience and a review of existing literature, the authors make three main recommendations for researchers conducting clinical trials involving Indigenous children:

1. Engage with Indigenous communities early and over the long-term to build trust and shared goals
2. Build capacity among Indigenous communities for leading and partnering on research studies
3. Support Indigenous community ownership of data and oversight of research conducted with Indigenous children

What do the results mean?

Clinical trials are needed to build evidence for child health interventions. Indigenous children must be included in clinical trials to reduce health disparities and improve health outcomes in these populations.

These studies should be done in partnership with communities using established practices of community-engaged research.

Appreciation: The authors thank the Environmental influences on Child Health Outcomes (ECHO) program, the Office of the Director, National Institutes of Health, for supporting this research.

You can read the full publication here: <https://ajph.aphapublications.org/doi/10.2105/AJPH.2021.306372>

The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.