

# Concept Proposal: The IDeA States Pediatric Clinical Trials Network (ISPCTN)---Network Renewal

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**ECHO** Environmental influences  
on Child Health Outcomes

**NIH** National Institutes of Health  
Environmental influences on Child Health Outcomes (ECHO)

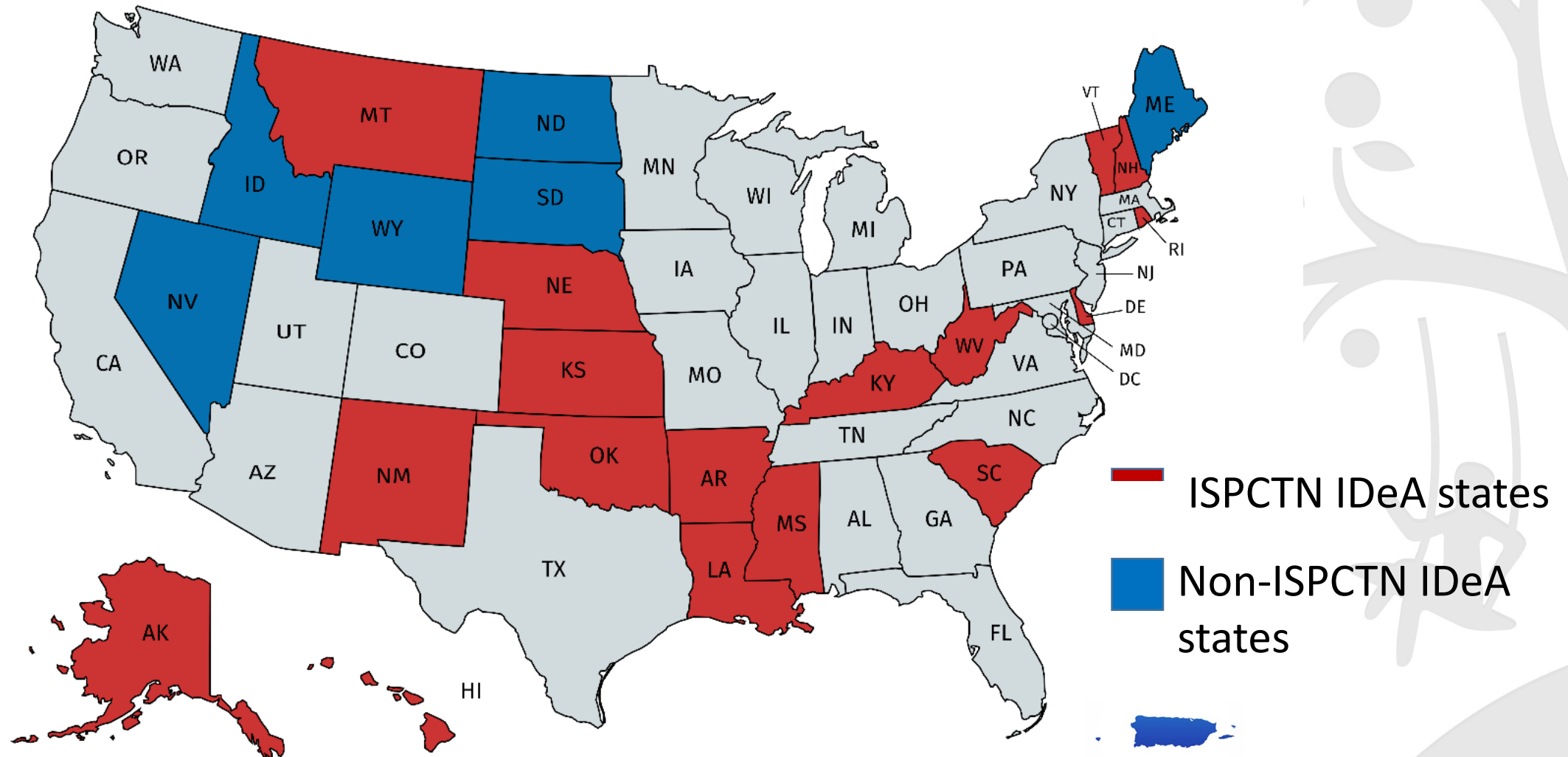
# Mission Statements

- **Two main components of ECHO**
  - **ECHO Cohorts**
  - **IDeA States Pediatric Clinical Trials Network (ISPCTN)**
- **ECHO Mission:** To enhance the health of children for generations to come
- **ISPCTN Goals:**
  - To provide medically underserved urban and rural populations access to state-of-the-art clinical trials
  - To build pediatric research capacity within IDeA States



# Institutional Development Award (IDeA) States

- Program builds research capacities in states that historically have had low levels of NIH funding
- Enhances the ability of investigators to compete successfully for additional research funding
- Serves the research needs of medically underserved communities.



# What have we accomplished in 2 years?

- **Clinical Trials & Development Projects**
  - 2 trials ongoing—both pharmacokinetics
  - Opioid-related
    - 1 observational study (medical record abstraction) completed—analysis phase
    - 2 trials in development as part of Helping to End Addiction Long-Term (HEAL) Initiative
  - Multiple pilot projects in development
- **Capacity Building**
  - Structure—Data Coordination and Operations Center increased staff/knowledge; Network governance structure; Research teams, Equipment, and Space
  - Process—Governance processes, Single IRB, Professional Development (network wide and site specific), New investigators, Collaborations with other IDeA programs, and ECHO Cohorts
  - Outcomes---Trials, Analyses, Posters, Presentations, Manuscripts, Grants submitted

# Rationale for ISPCTN Renewal: Trials and Capacity Building in IDeA States

- Children in rural communities in IDeA states:
  - Experience worse health outcomes
  - Are under-represented in clinical trials
- IDeA states institutions need capacity building to learn how to develop and implement clinical trials.
- IDeA states institutions still struggle to compete for NIH grant funding
  - ~ \$ 1.9 billion to IDeA states\*
  - ~ \$25 billion to non-IDeA states\*



# Approach—Network Structure

- Remain at current size
  - 1 RFA for 17 clinical sites
  - 1 RFA for Data Coordination and Operations Center
- Both open competition among IDeA states institutions
- Cooperative agreements
- 5 years
- Start in 2020



# Approach—Clinical Trials

- Continue clinical trials
  - Minimum of 3 multicenter clinical trials over 5 years
- Data Coordination and Operations Center responsibilities:
  - resource allocation for trials, data management, analysis, and data sharing
  - protocol development assistance
- Clinical sites responsibilities:
  - develop and implement trials
  - As part of application, propose a protocol for a multicenter trial
  - Propose and implement a plan to engage rural communities in trials



# Approach—Capacity building

- Both Clinical Sites and Data Coordination and Operations Center would propose and implement capacity building plan for junior faculty, senior faculty, and research coordinators.
- All applicants encouraged to collaborate with:
  - In-state IDeA Program Infrastructure for Clinical and Translational Research awardee institution (IDeA-CTR)
  - Or in-state Clinical and Translational Science Award awarded institution (CTSA)
  - Or other collaborators but majority of each award must stay in IDeA states.



Questions or thoughts?



ECHO