

# ECHO Research Program

## Ongoing Collaborations with Native American Tribes

### NIH Tribal Advisory Council

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NIH Office of the Director  
4 October 2018*

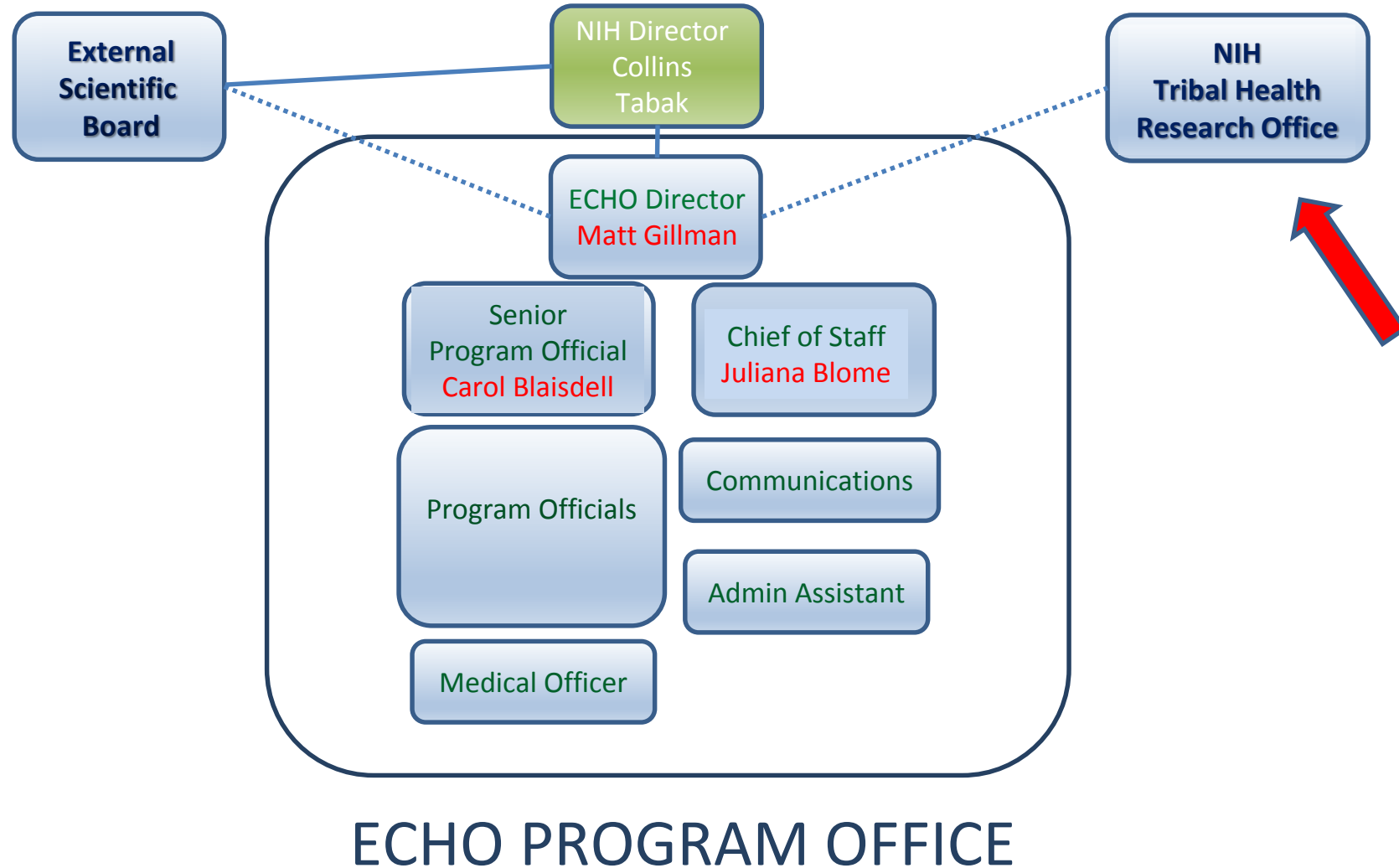
# Today

- Obtain your advice on continuing collaborations
- ECHO Cohorts
  - Ongoing discussion/negotiation with Navajo Nation
    - Data sharing principles and protections
- IDeA States Pediatric Clinical Trials Network
  - In collaboration with Alaska Native Tribal Health Consortium
    - Paths to get work started
    - Data/biospecimen sharing
    - Intellectual property
    - Protection of human subjects (IRB)
  - *Question for TAC: Others with relevant experience?*

# Principles

- ECHO committed to consulting with/listening to Tribal Nations
- Collaborations with AI/AN partners
  - Attend to cultural, historical, sovereignty issues
  - Research that both
    - Serves AI/AN communities directly
    - Enhances the ECHO commons for consortia-wide research

# Support & Guidance



# ECHO

## Nationwide Research Program

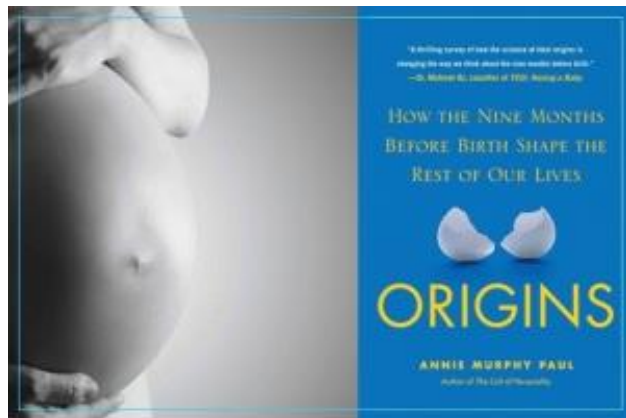


# *Mission*

Enhance the health of children for  
generations to come



# A good start to life...



Joseph Tart/EHP



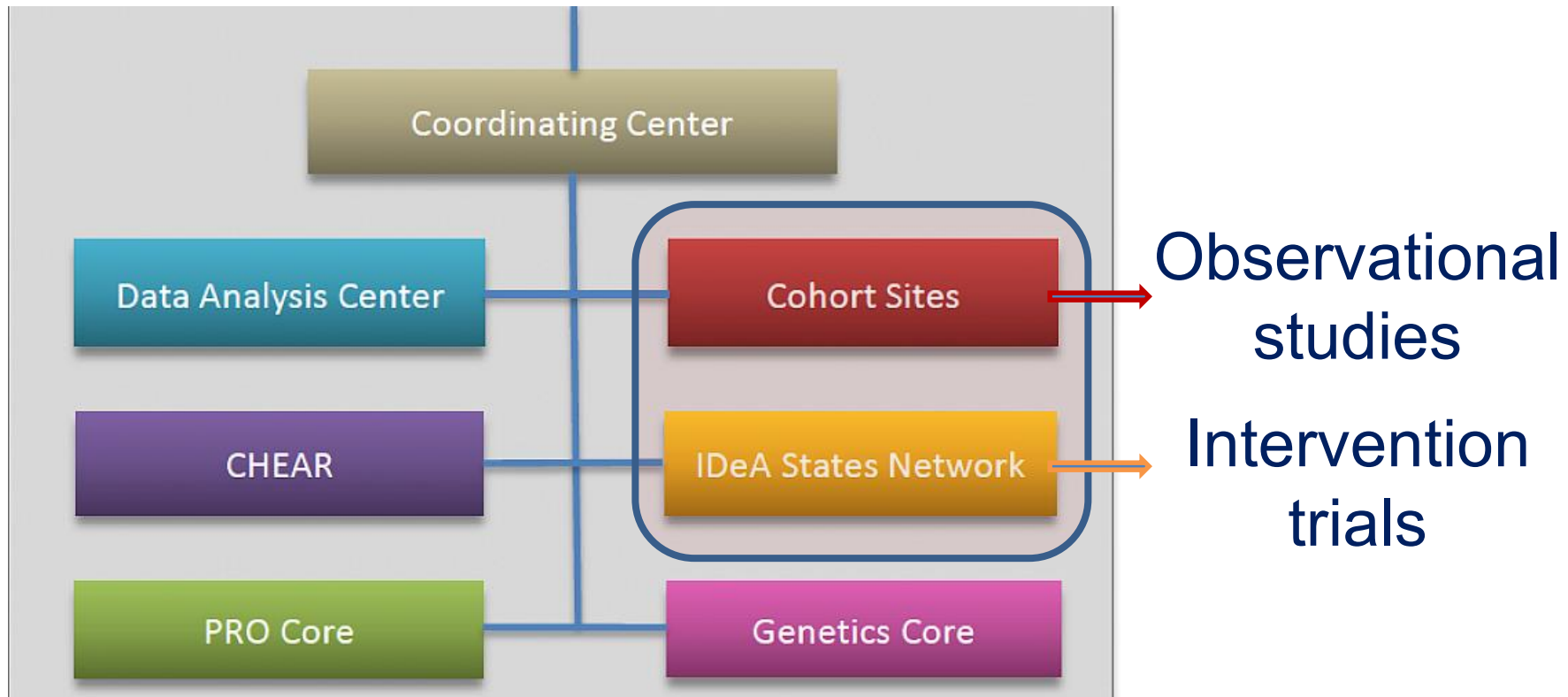
...can last a lifetime...

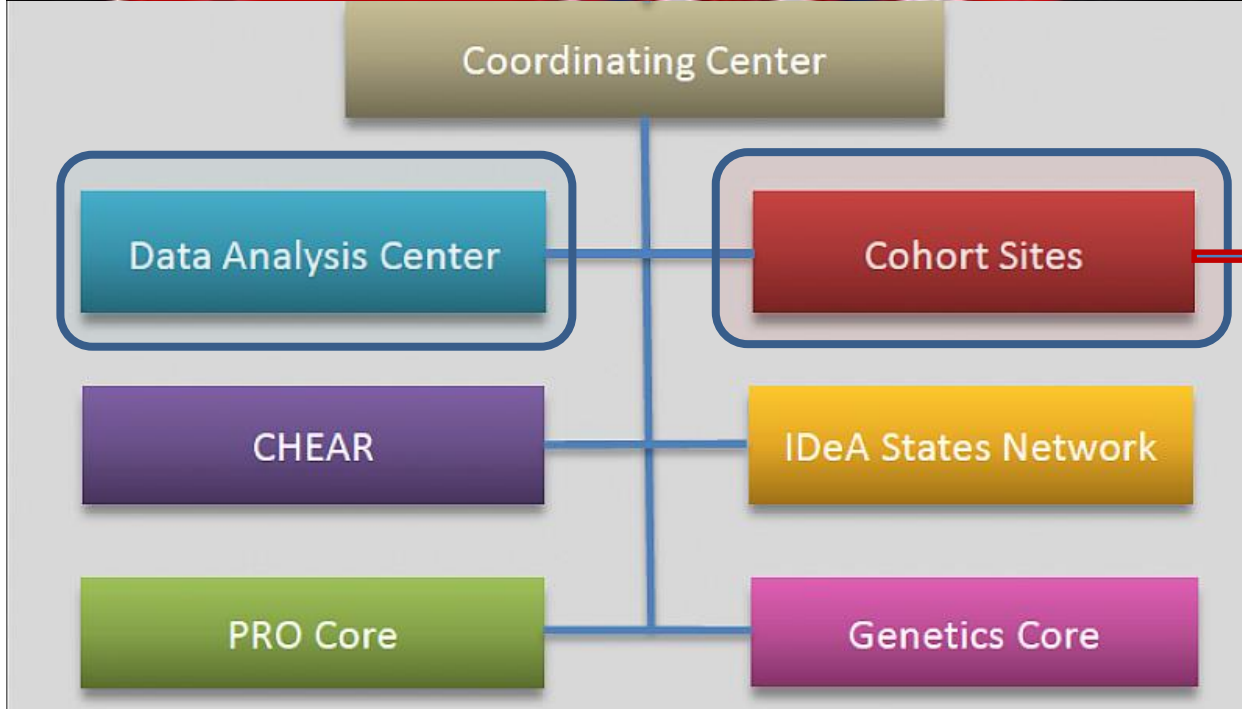


...and over many generations



# ECHO Components





Longitudinal studies of mothers & children

# ECHO Cohorts

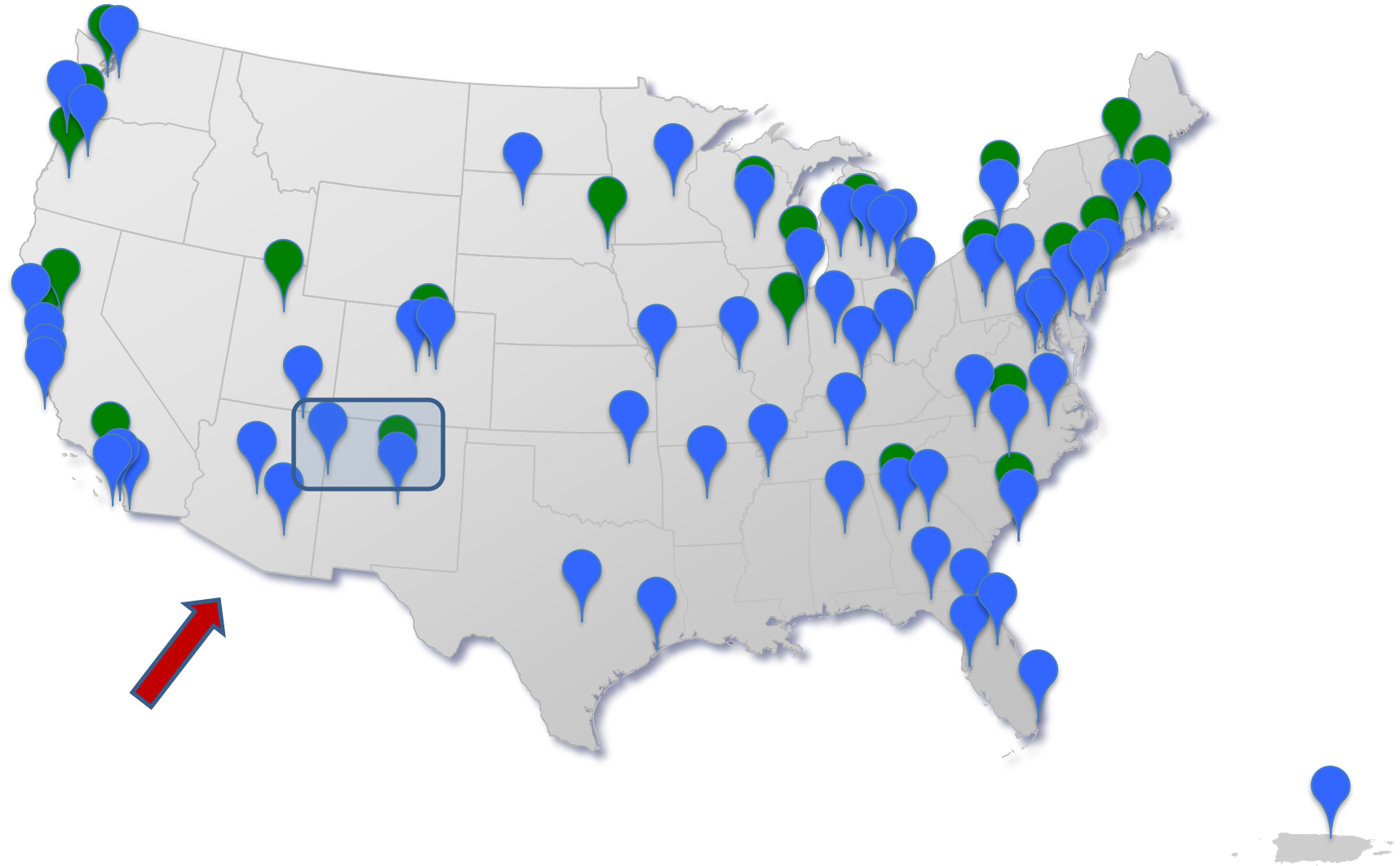


31 grant awards  
68 Principal Investigators  
69 cohorts

-Majority started prenatally-



## One of these Cohorts is the Navajo Birth Cohort Study





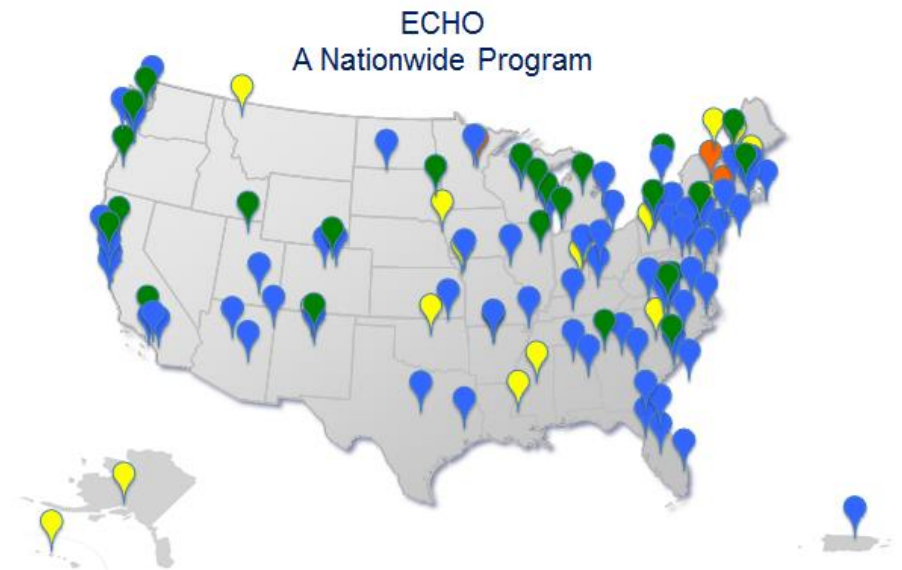
# ECHO-wide Cohort

Weaving together 60+ individual cohorts



# Promise of ECHO-wide Cohort

- 50,000+ children and their families
  - Address research questions that no single cohort, or even a few cohorts, can answer alone.
  - Broad impact on practices, programs, policies
  - Informs interpretation of individual findings, e.g., NBCS





# The ECHO-wide Cohort

Data sharing has great potential *benefit...*

- Answer questions that NBCS cannot quite do on its own...
  - ...Which have benefit for Navajo mothers and children
- And contribute to nationwide consortium for enhancing health of all US children

# The ECHO-wide Cohort

## ...but also *risks*

- Analyses that
  - Violate privacy
    - Identify individuals and their own characteristics
  - Unfairly label/stigmatize Navajo peoples
    - Havasupai case as an example
    - Special protections
- Draft agreement among Navajo Nation, NBCS, ECHO adds protections against these risks

# Working with Navajo Nation

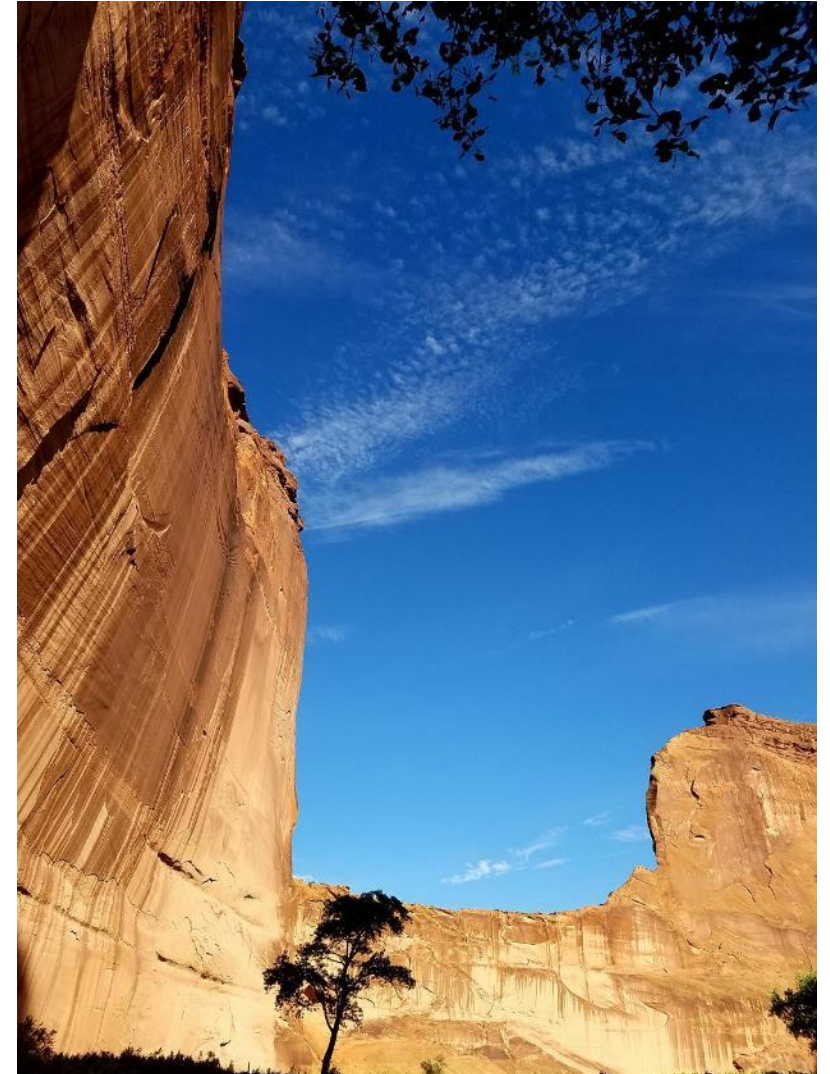


Welcomed by Navajo peoples several times in 2017 and 2018

# Data-sharing protections for Navajo Birth Cohort Study

## Principles

- Find common ground
  - Develop approaches together
- Try them on small scale
- Evaluate them
- Make corrections
- Go from there
- May serve as example for others



# Draft Agreement

- Not genetic data, not biospecimens
- No ancestry analyses
- Individual-level NBCS data in only 3 places
  - Navajo Nation, University of New Mexico
  - Data Analysis Center @ Johns Hopkins Univ.
    - Deidentified data, in separate location
      - Geocodes/addresses stay at UNM
    - Does the data analysis



# ECHO Data Analysis Center

## Johns Hopkins/RTI

Receives, stores, and analyzes data





# ECHO Data Analysis Center

## Johns Hopkins/RTI

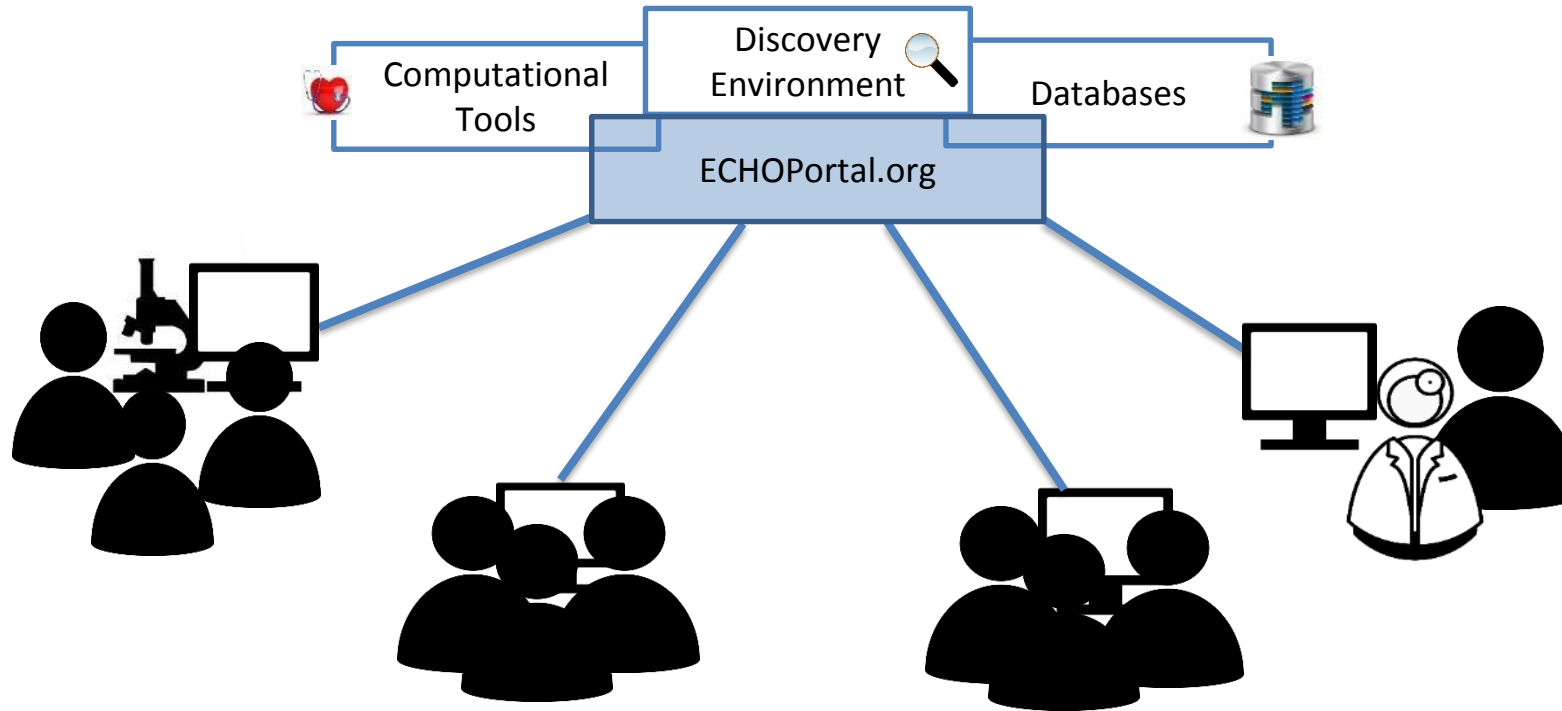
Receives, stores, and analyzes data



*Data Safety & Security*

# ECHO-wide Cohort Data Platform

## Restricted access via ECHOPortal.org



Researchers have controlled access—only to parts relevant for their specific work

- 2-factor authentication—prove identity twice before logging in

# ECHOPortal.org

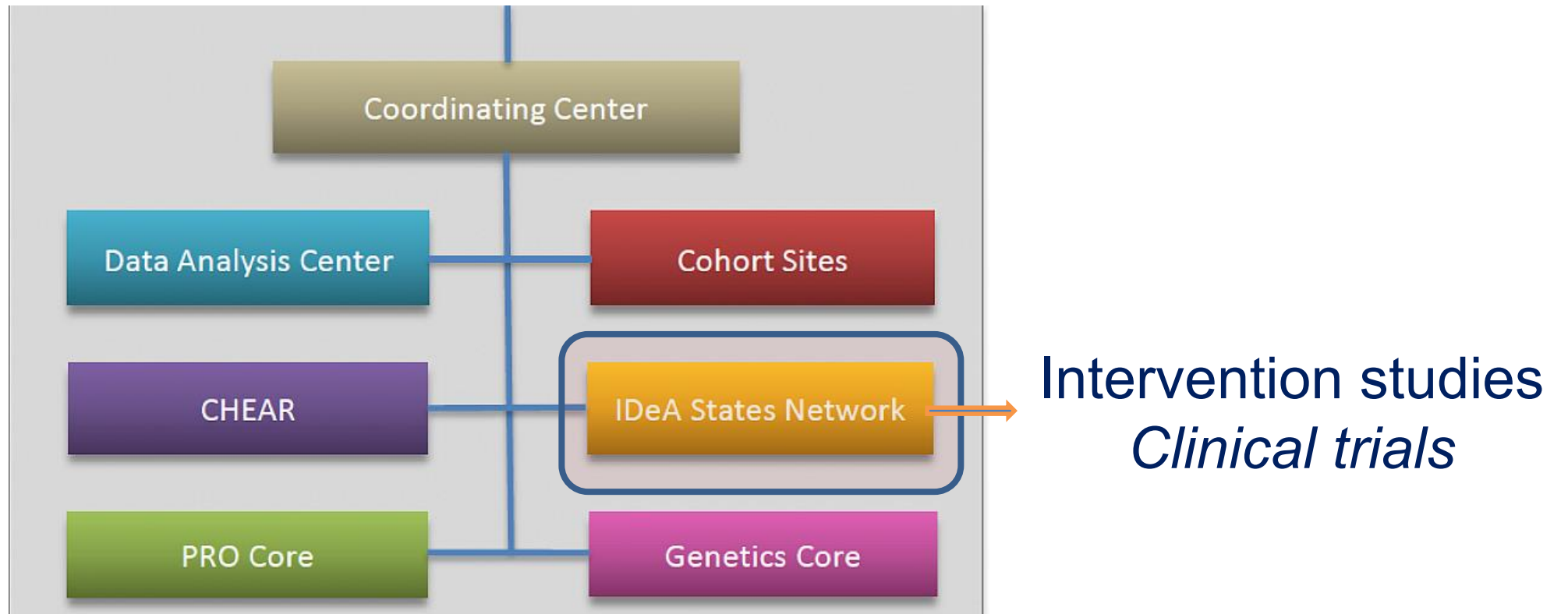
## Purpose-built security and functionality

- Security controls
  - Meet data standards in which risk is severe if information compromised
- Data
  - Encrypted
  - Stay in restricted data vault
- Tracking of all user actions
- Independent security audit, continuous monitoring

# Draft Agreement

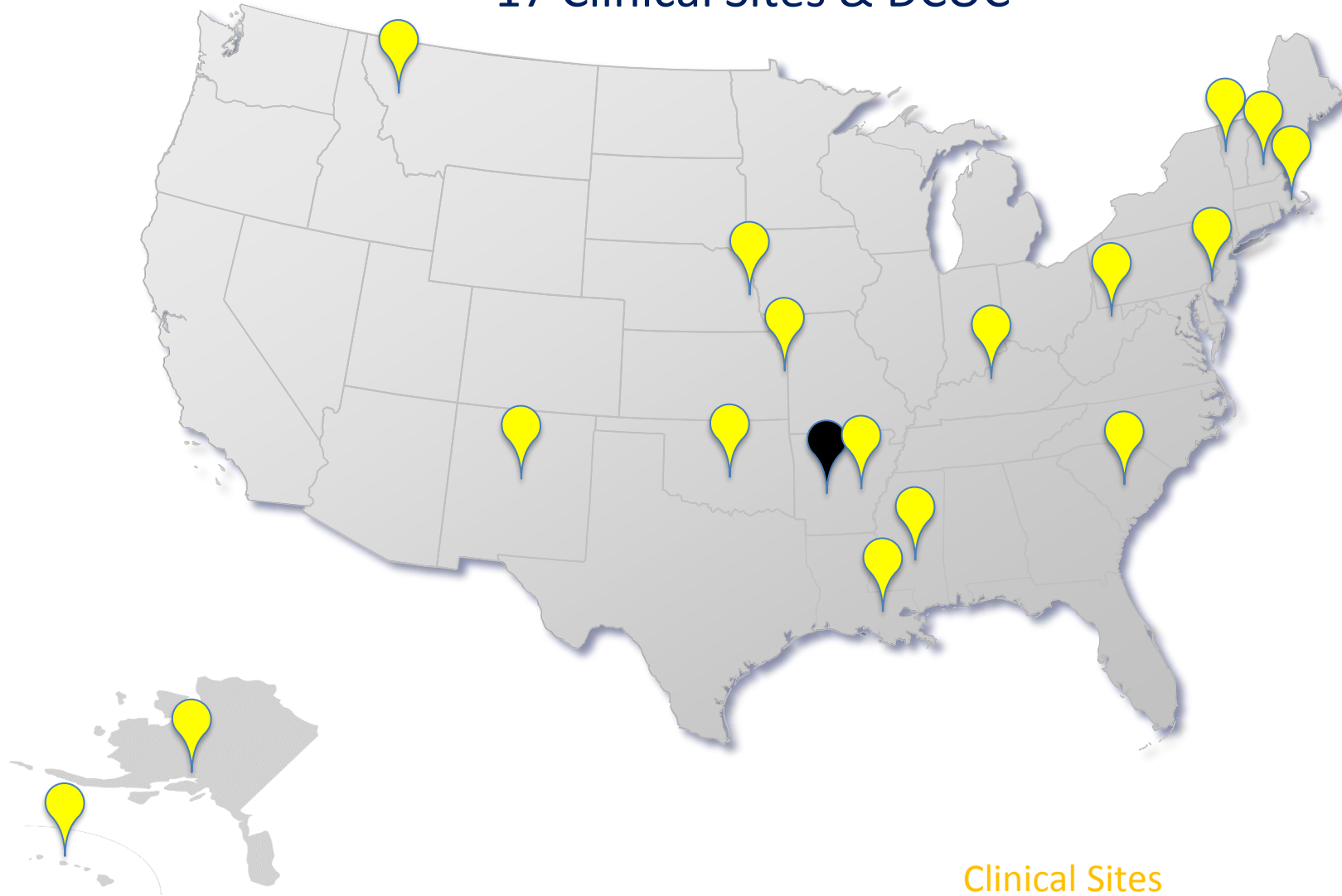
- To start, only principal investigators (not co-investigators) of the 31 grants lead papers
  - Group results only, not individual data
  - Expand later if goes well
- Navajo Nation Human Research Review Board (IRB) reviews manuscripts
  - Before investigator submits to journal for publication
- Navajo Department of Health reviewing agreement

# ECHO Components



# IDeA States Pediatric Clinical Trials Network

## 17 Clinical Sites & DCOC



Clinical Sites

Data Coordinating and Operations Center (DCOC)



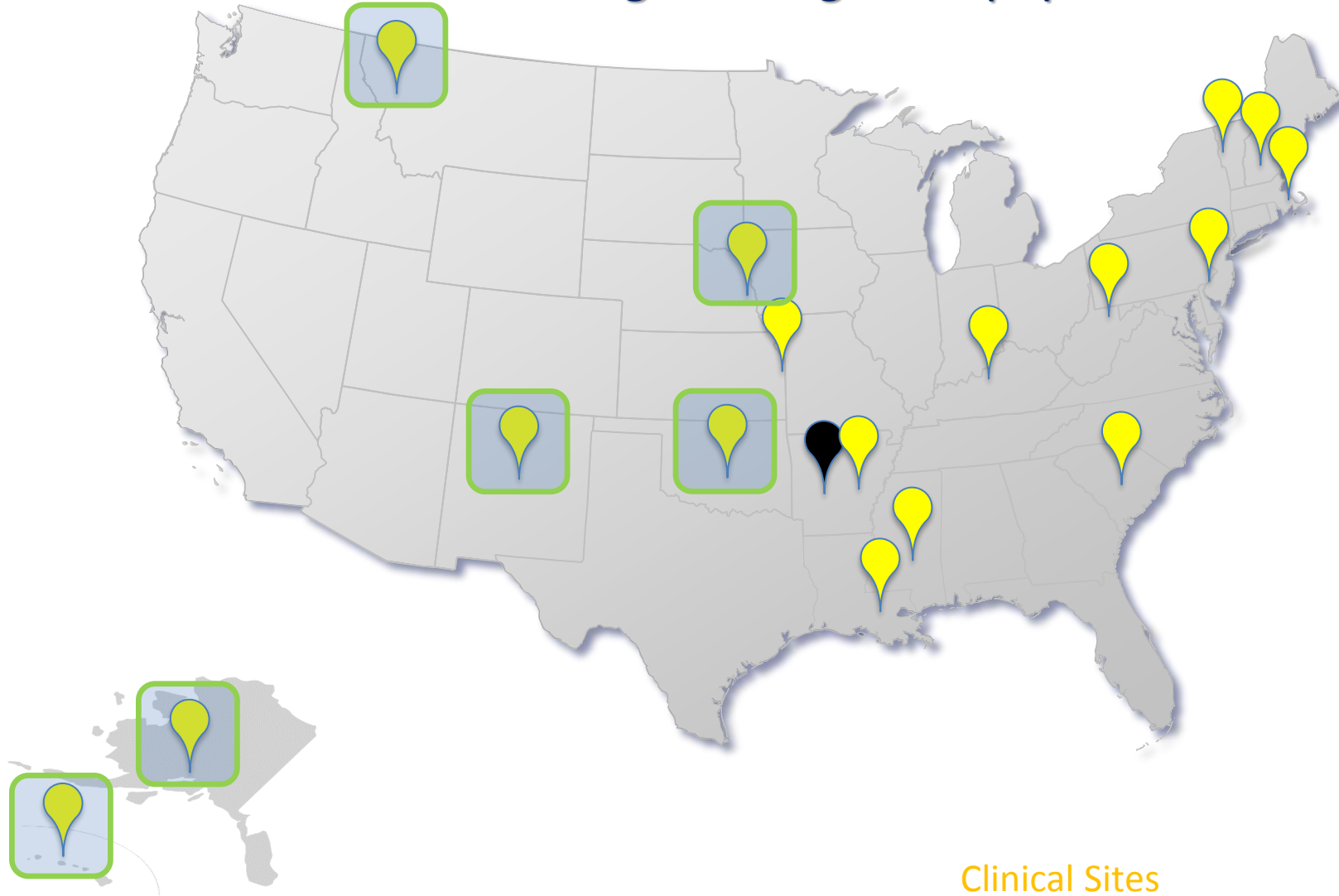
# IDeA States Pediatric Clinical Trials Network

## Goals and Progress

- Provide access to state-of-the-art clinical trials
  - Medically underserved and rural populations
- Build national pediatric research capacity
  - To conduct clinical trials
    - professional development
    - infrastructure and team support
- New network
  - 1 trial underway
  - 1 starting fall 2018
  - 3 in development

# IDeA States Pediatric Clinical Trials Network

## 6 states with high % indigenous populations



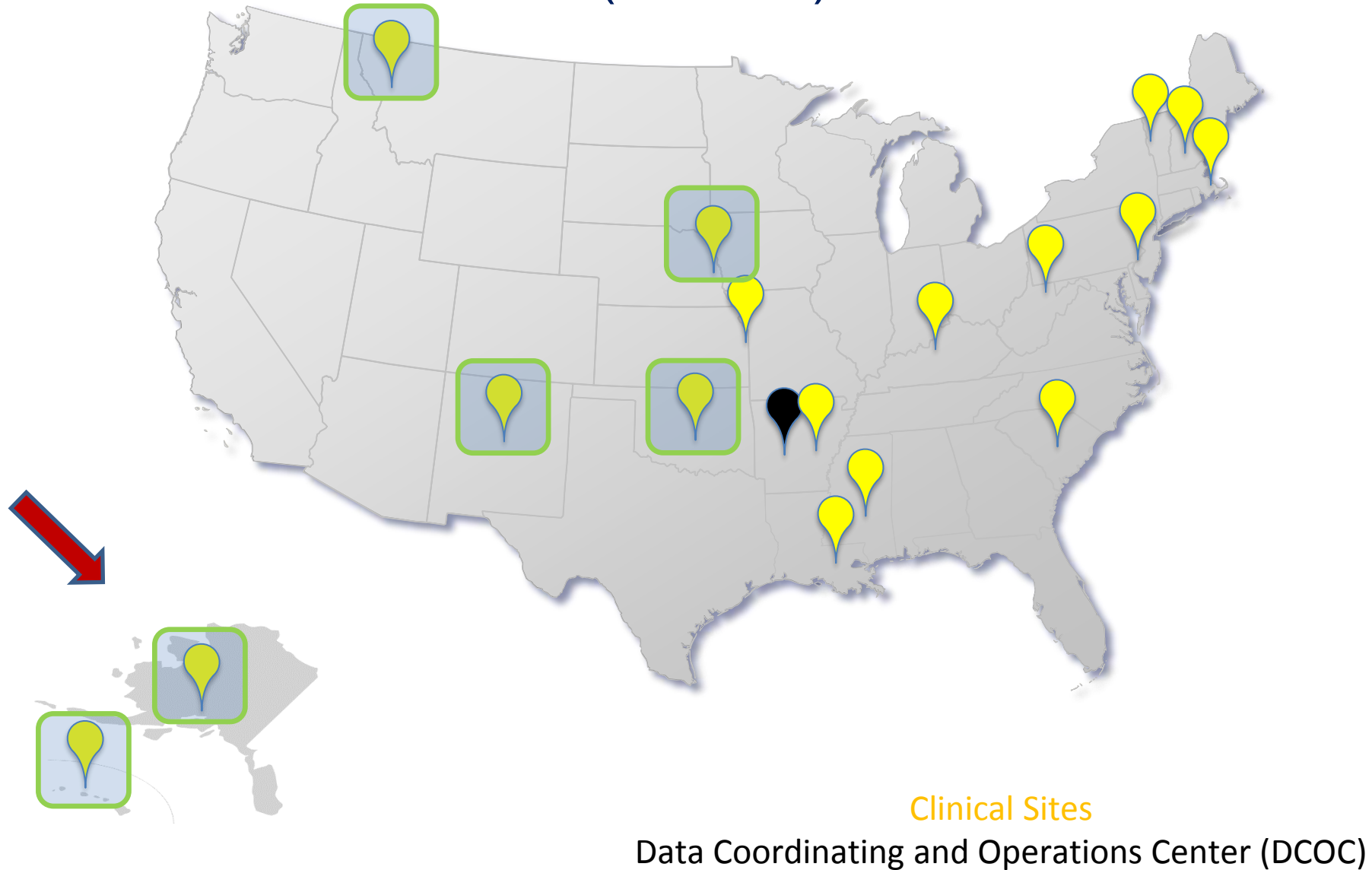
## Clinical Sites

## Data Coordinating and Operations Center (DCOC)

# IDeA States Pediatric Clinical Trials Network Stakeholder Working Group

- Working with indigenous populations
  - Working with AI/AN/NH researchers and community members
  - Enumerating principles and policies
  - Future—community-based participatory research strategies

# One Network Clinical Site is Alaska Native Tribal Health Consortium (ANTHC)



# ANTHC Participation in Initial Clinical Trials

- How the body handles medications in routine pediatric practice (POPS)
- ACT NOW—Accelerating Clinical Trials for Neonatal Opioid Withdrawal Syndrome
  - Part of new NIH Helping to End Addiction Long-term Initiative
    - Current Experience—how clinical practice varies right now
    - 2 clinical trials that ISPCN is developing
- Chose not to participate in trial of vitamin D supplements in children with asthma and obesity

# ANTHC-ISPCTN Paths to Success So Far

- Principal Investigator (Ros Singleton) Co-chair, Data Sharing and Biospecimen Working Groups
  - Developing policies for both
  - Respect sovereignty, address historical/cultural concerns via partnership
- Contracts to get work started
  - Even before all issues solved
  - Flexible collaboration of ANTHC, Data Coordinating and Operations Center, NIH
- “Data masking” to protect confidentiality ANTHC participants
  - Mix Alaska Native data with “Other race/ethnicity” if high enough risk to
    - Identify individual participants
    - Stigmatize AN tribes
  - Keep AN separate if benefit of research to participants and tribes outweighs risk



# ANTHC-ISPCTN Outstanding Issues

- Intellectual Property (IP)
  - Inventions coming from ANTHC participant data
    - ANTHC hoped to own IP, *but...*
  - US law: IP goes to inventor, not source of data
  - Working together to come up with creative solutions
    - Learning about the law together!
- Protection of human subjects—Institutional Review Boards (IRBs)
  - ISPCTN using central IRB
    - Aligned with NIH guidance
  - ANTHC does not cede to a central IRB
    - Culture, history, sovereignty
  - Moving toward resolving in mutually beneficial way
    - Some delay in starting studies

# Summary

- We continue to learn
  - Your advice continues to be crucial
    - Best ways for...
      - NIH ECHO Program Office and
      - Investigators
- ...to build relationships with Tribal Nations and collaborate to address concerns

# IDeA States Pediatric Clinical Trials Network

## Outstanding Issues

- Paths to get work started
- Data/biospecimen sharing
- Intellectual property
- Protection of human subjects (IRB)

*Question for TAC: Others with relevant experience?*