

Collaboration with AI/AN Partners in the NIH *ECHO* Program

Tribal Advisory Committee

*Matthew W. Gillman, MD, SM, Director
Environmental influences on Child Health Outcomes
14 March 2018*



Thank you for inviting us back to TAC to listen
to your advice



Asking TAC Advice

1 year ago

- ECHO committed to consultation with Tribal Nations
- Collaborate with our AI/AN partners
 - Attend to cultural and historical issues
 - Research that both
 - Serves AI/AN communities directly
 - Enhances the ECHO commons for consortia-wide research

Asking TAC Advice

- ECHO committed to consultation with Tribal Nations
- Collaborate with our AI/AN partners
 - Attend to cultural and historical issues
 - Research that both
 - Serves AI/AN communities directly
 - Enhances the ECHO commons for consortia-wide research
 - Sharing data and biospecimens
 - » Work in progress

Questions We Discussed

Sharing data and biospecimens

- What data and specimens tribal communities able to share
 - With whom
- Conditions of use by
 - ECHO investigators
 - Wider scientific community
- Privacy, safety, security
- Duration of storage/use
 - Final disposition, ownership

What's happened since 1 year ago

- Your advice key to progress
- At NIH
 - Work closely with THRO
 - ECHO came back to TAC in September 2017
 - Communication, historical issues, building trust
 - Personal journeys
- In ECHO generally
 - Data (and biospecimen) sharing policies ratified
 - Stakeholder working group
 - Principles of engagement

What's happened since 1 year ago



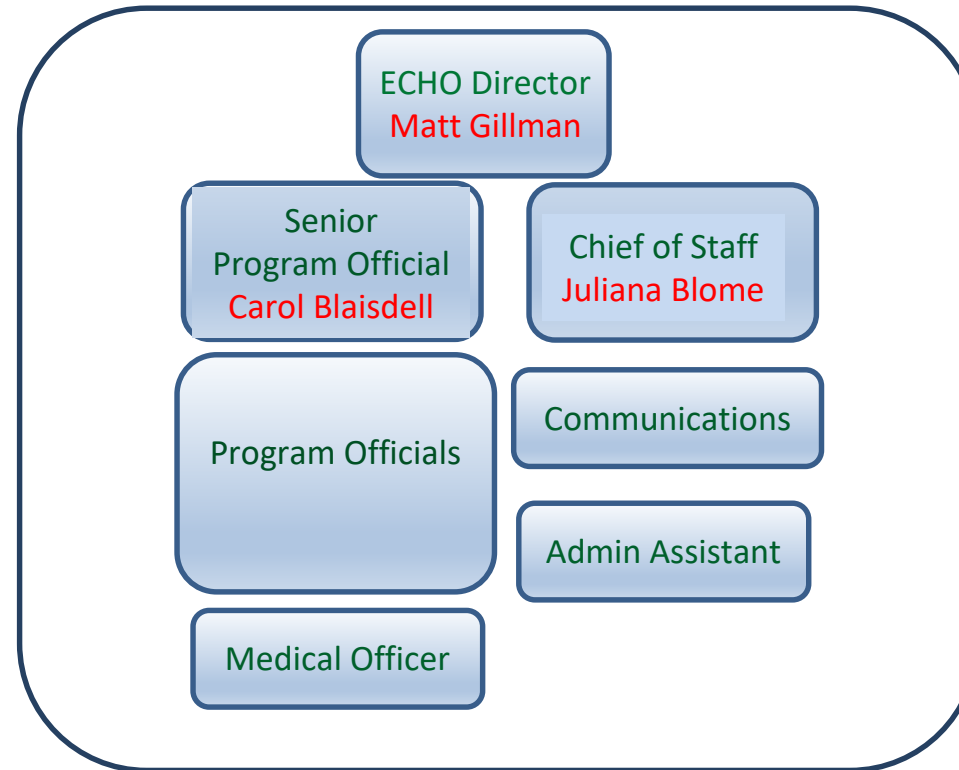
- At NIH
- In ECHO generally
- With AI/AN partners in ECHO
 - Privileged to have learned a lot!



Today

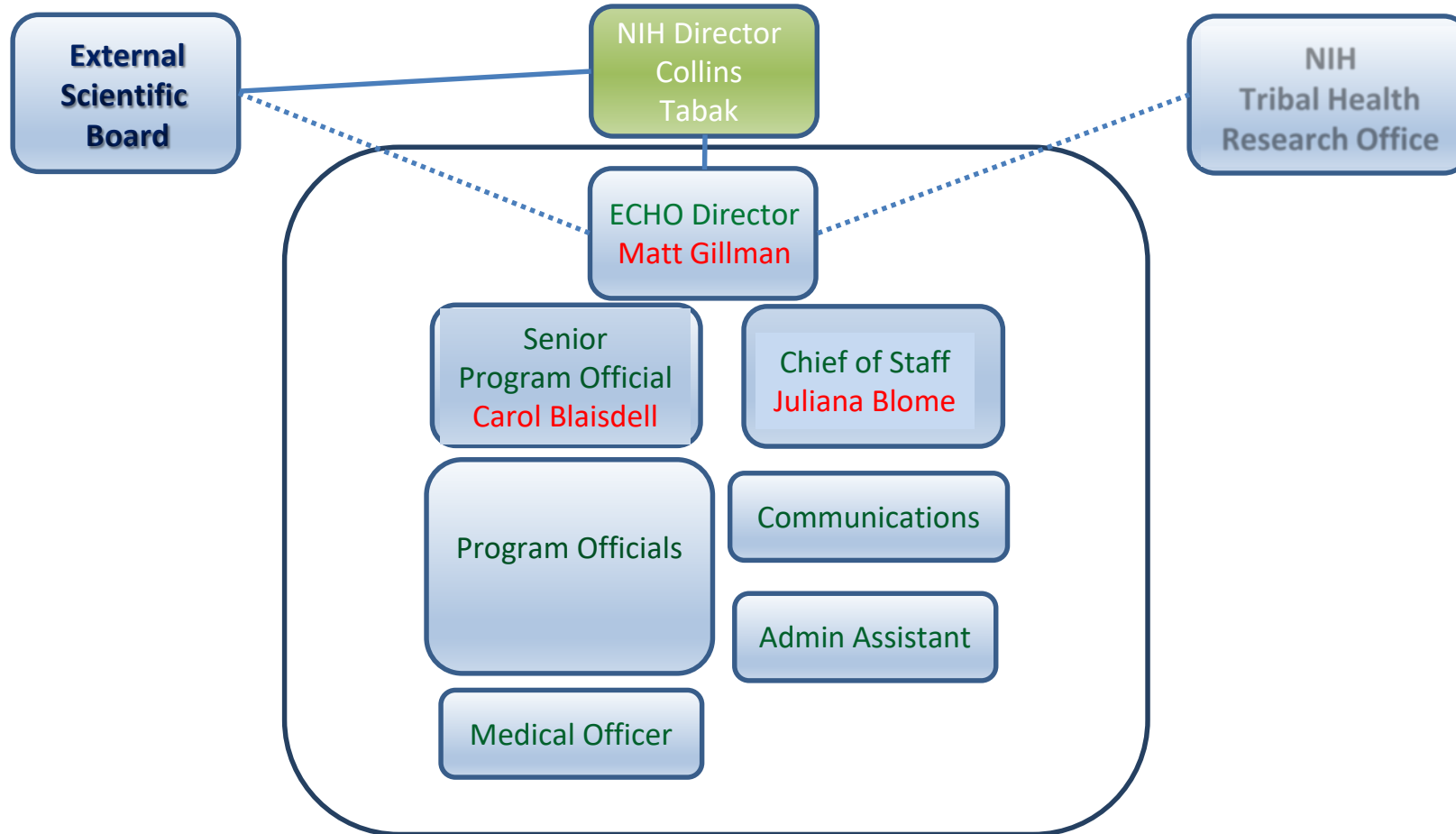
- ECHO summary
- Engagement strategies
- Ongoing work with Navajo Nation on data sharing

ECHO Senior Leadership



ECHO PROGRAM OFFICE

Support & Guidance



ECHO PROGRAM OFFICE

Support & Guidance

- External Scientific Board
 - Reports to NIH Director
 - **Includes Dr. William Freeman, Northwest Indian College**

Environmental influences on Child Health Outcomes (ECHO) *Mission*

Enhance the health of children for
generations to come



ECHO

A Nationwide Program



Guiding Principles

- **Teamwork**

Working well together

- **Impact**

Research that has an impact on health

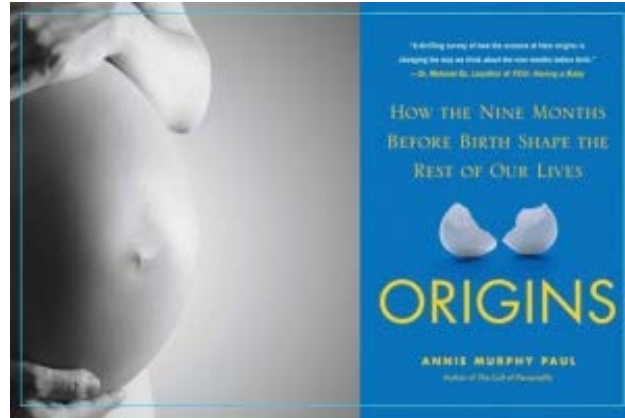
- **Responsibility**

Scientifically & ethically sound research

- **Value**

Good stewardship, return on investment

A good start to life...



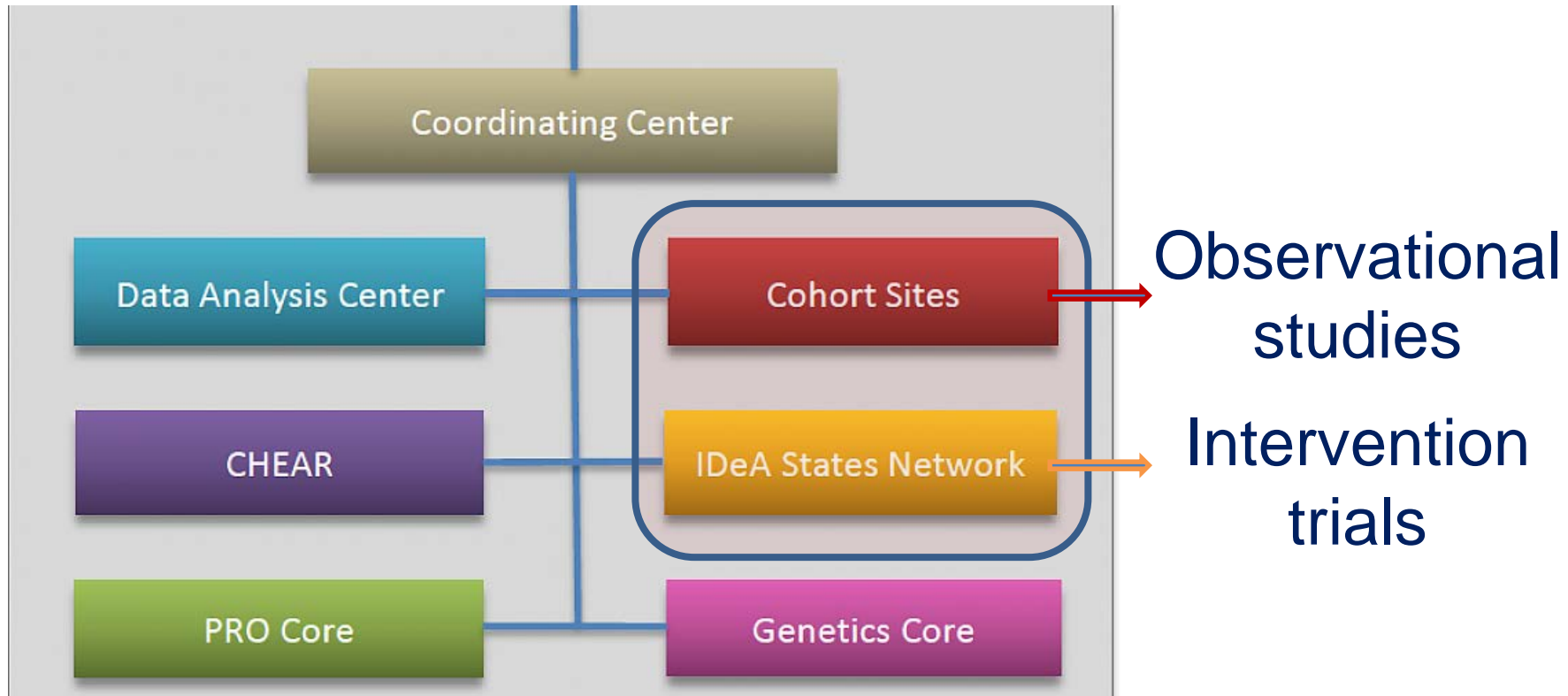
Joseph Tart/EHP

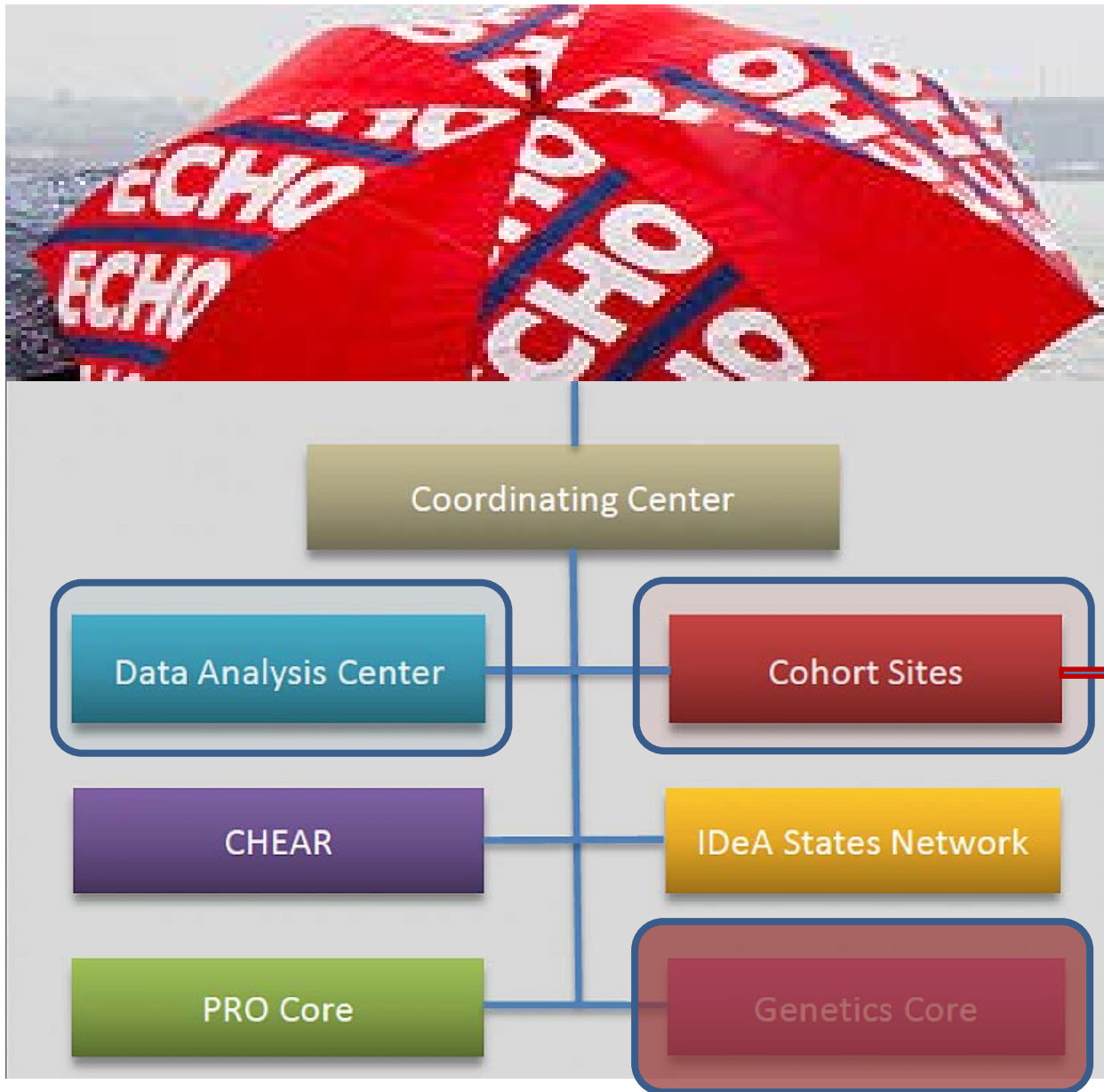
...can last a lifetime...



...and over many generations

ECHO Components





Longitudinal studies of mothers & children

ECHO Cohorts

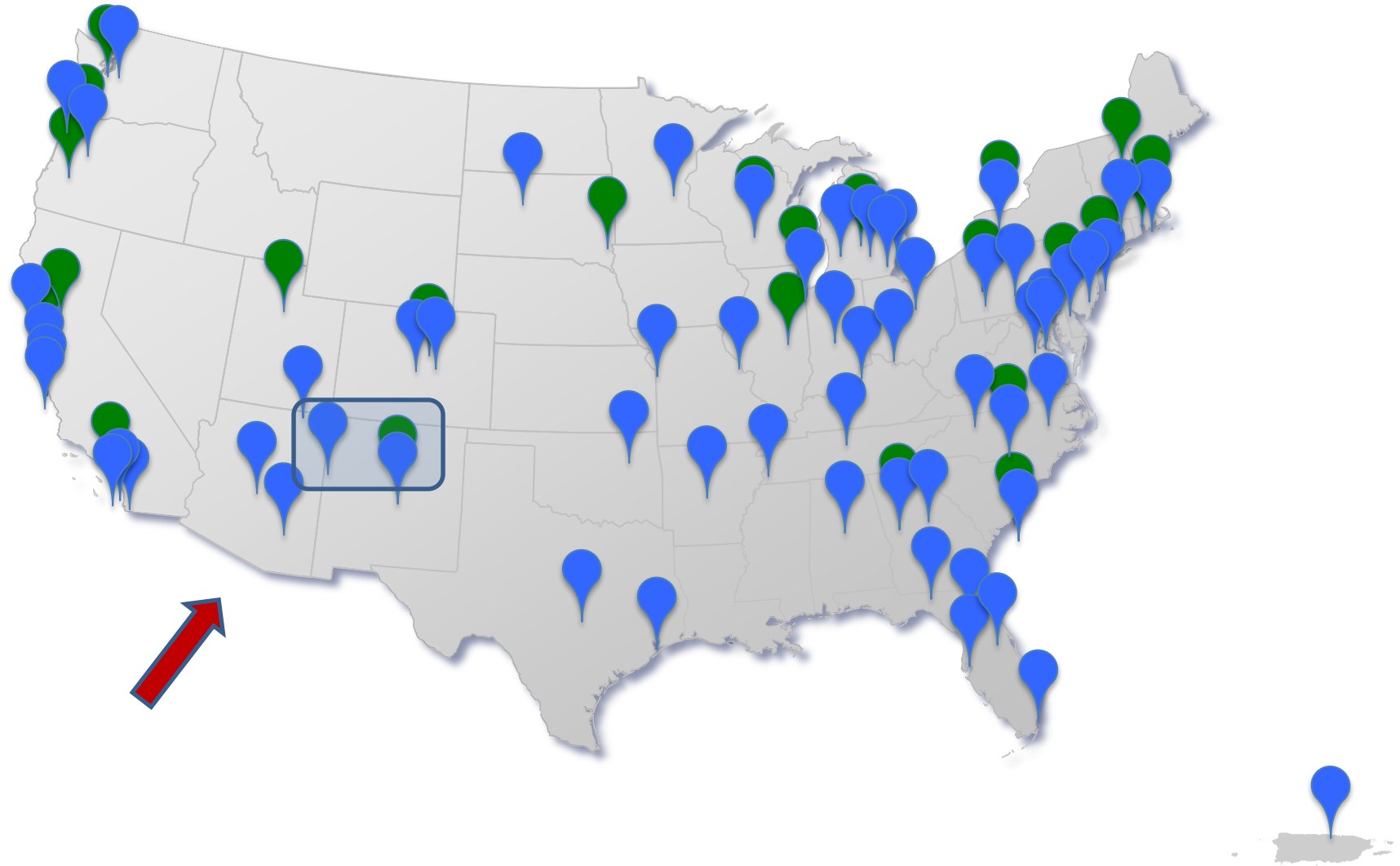


35 grant awards
74 Principal Investigators
83 cohorts

-Majority started prenatally-

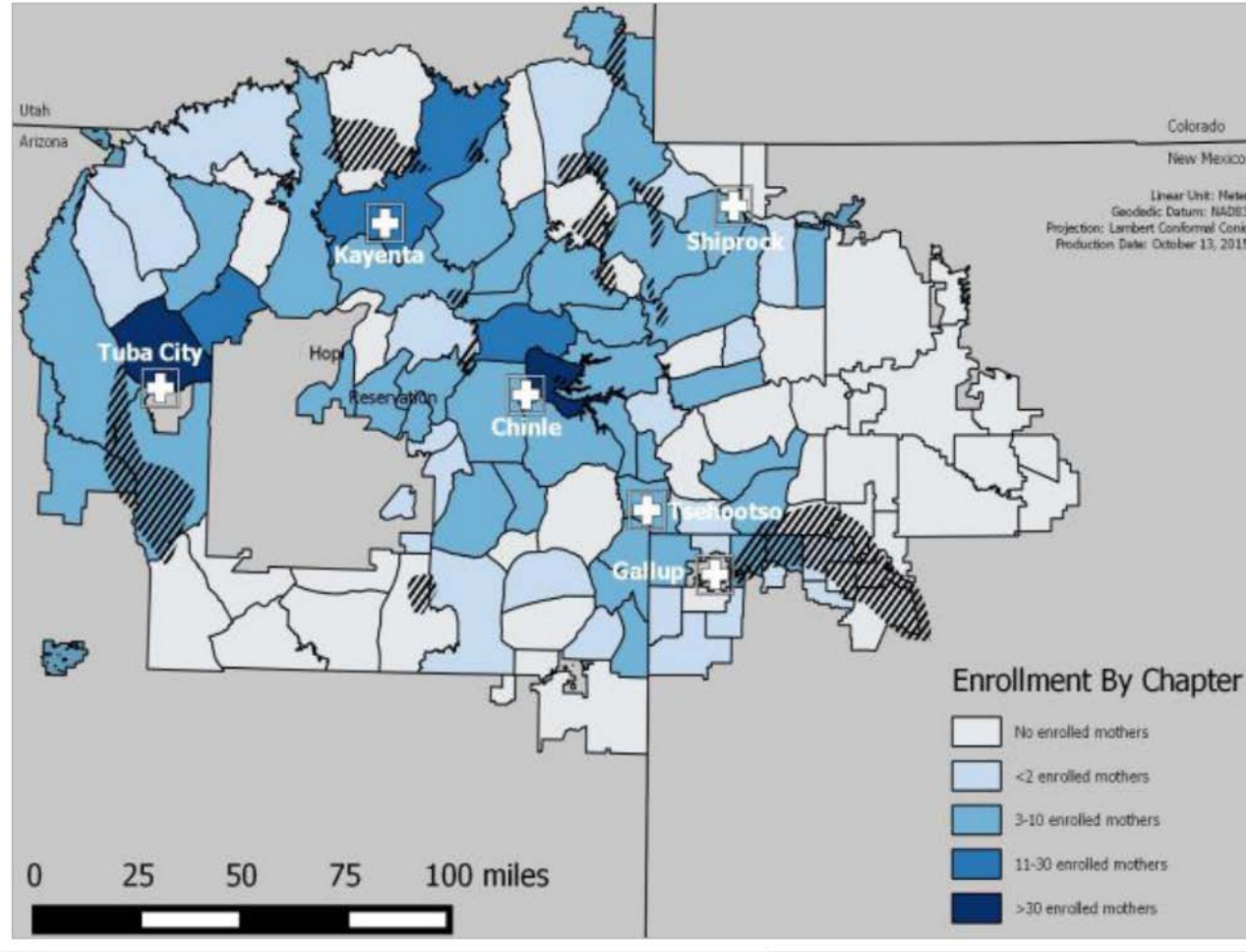


One of these Cohorts is the Navajo Birth Cohort Study



Navajo Birth Cohort Study

J. Lewis, PI; M-G. Begay & D. Begay, Collaborators



Families followed from prenatal period through early to mid-childhood

Navajo Birth Cohort Study



Uranium and other metals, often from abandoned mines

Navajo Birth Cohort Study



Uranium and other metals, often from abandoned mines

Examine relationships of exposure to metals in pregnancy with

- Brain development
- Excess weight gain

And how development of the immune system explains the relationships

Navajo Birth Cohort Study

- Addresses concern of Navajo Nation
 - Individual cohort analysis, N ~1000
 - Could inform further mitigation activities

Navajo Birth Cohort Study

- Addresses concern of Navajo Nation
 - Individual cohort analysis, N ~1000
 - Could spur further mitigation activities
- Analyses across multiple cohorts
 - N ~ 10,000s
 - Contribute to broader understanding of metals & other exposures and important child health outcomes
 - With large sample of children, see how relationships vary by
 - Race/ethnicity
 - Socioeconomic position
 - Girls vs. boys
 - Geography

Navajo Birth Cohort Study

- Addresses concern of Navajo Nation
 - Individual cohort analysis, N ~400
 - Could spur further mitigation activities
- Analyses across multiple cohorts
 - N ~ 10,000s
 - Contribute to broader understanding of metals & other exposures and important child health outcomes
- Inform
 - Policies with impact on many populations
 - Further interpretation of NBCS data for benefit of Navajo Nation

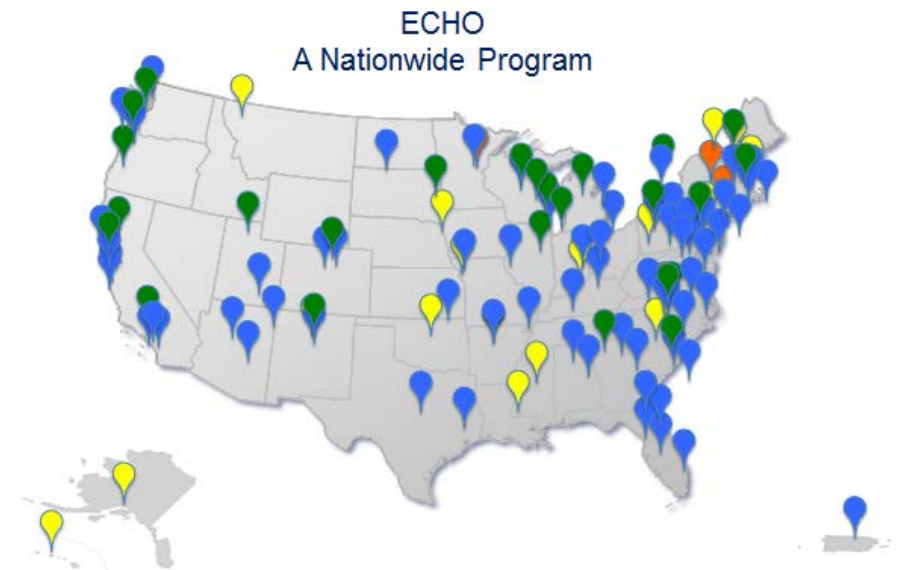
ECHO-wide Cohort

Weaving together 83 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
 - Protections in place
 - Can be strengthened
 - Unfairly label Navajo peoples
 - Havasupai case as an example
 - Special protections

Working with Navajo Nation



Welcomed by Navajo peoples in August, November, December 2017

Working with Navajo Nation



Working with Navajo Nation

- Program-specific agreement
 - No change in NIH or Navajo Nation *policies*
- Flexible, start small, see how it goes
- Start with non-biospecimen, non-genetic data
- Committed to “getting to yes”

	Data sharing	Biospecimen use	Genetics data sharing
Policies/broad agreements			
Specific agreement between ECHO-wide Cohort and Navajo Birth Cohort Study	✓		

Group Meeting Dec 2017

- Navajo Nation
 - Chair Beverly Becenti-Pigman
 - Del. Walter Phelps
 - Chair Jonathan Hale
- Navajo Nation and NBCS
 - Dr. David Begay
 - Mae-Gilene Begay
- NBCS
 - Dr. Johnnye Lewis
 - Dr. Deb McKenzie
- ECHO Program
 - Dr. Matt Gillman
 - Dr. Juliana Blome
- NIH THRO
 - Dr. Dave Wilson

Group Meeting Dec 2017

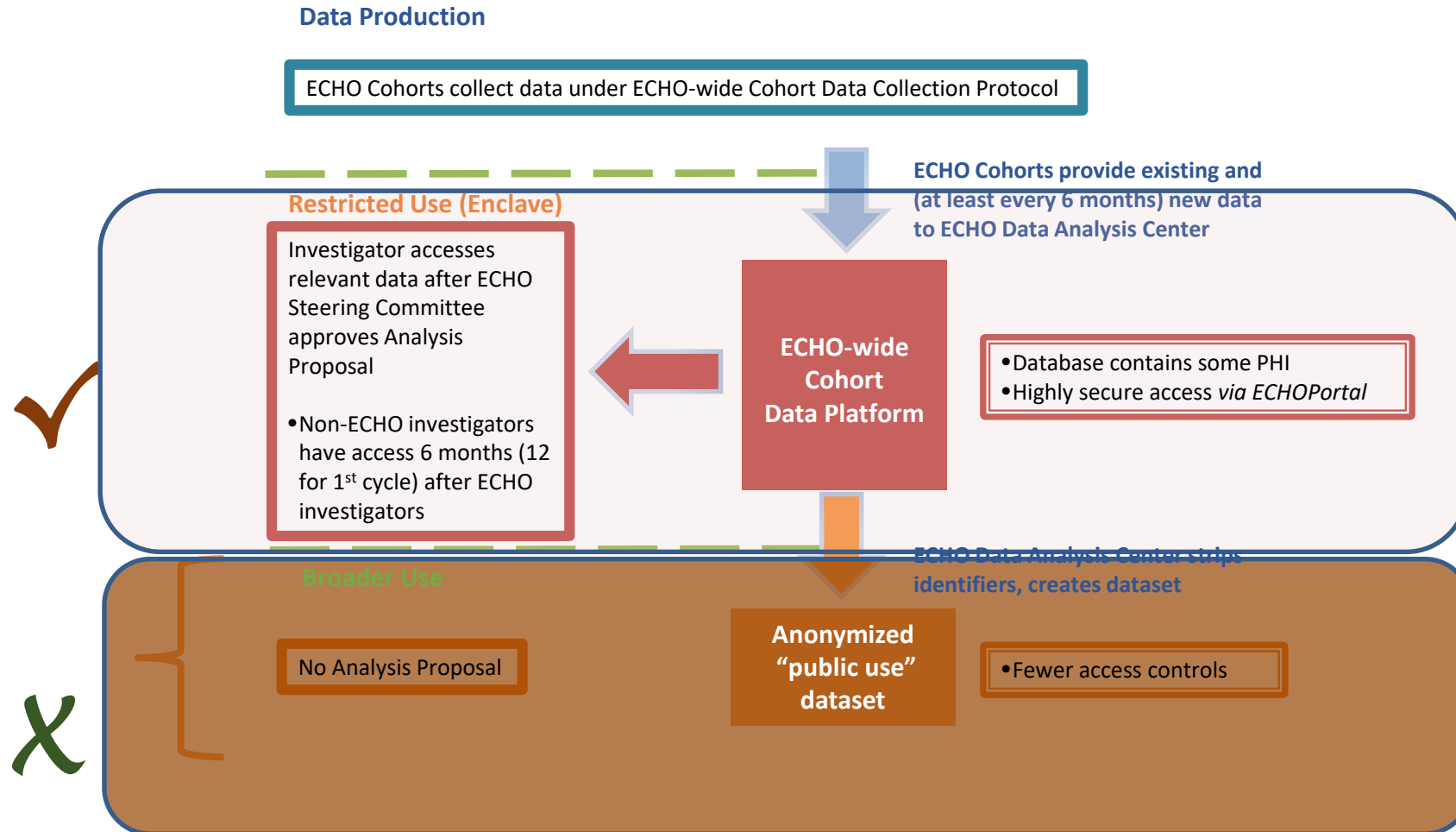
- Started with existing data sharing approach in the ECHO-wide Cohort
 - Current safeguards
 - Data safety & security
 - Multi-step analysis proposal approval process
- Discussed ideas for additional safeguards
 - For individuals and Nation
 - At many steps of the processes

Since Group Meeting Dec 2017

- Presented detailed ideas to Navajo Nation Human Research Review Board (IRB)
- Draft agreement
 - Reviewed/discussed/edited by
 - Navajo Nation
 - NBCS
 - NIH Office of the Director
 - Latest draft to Navajo this week...

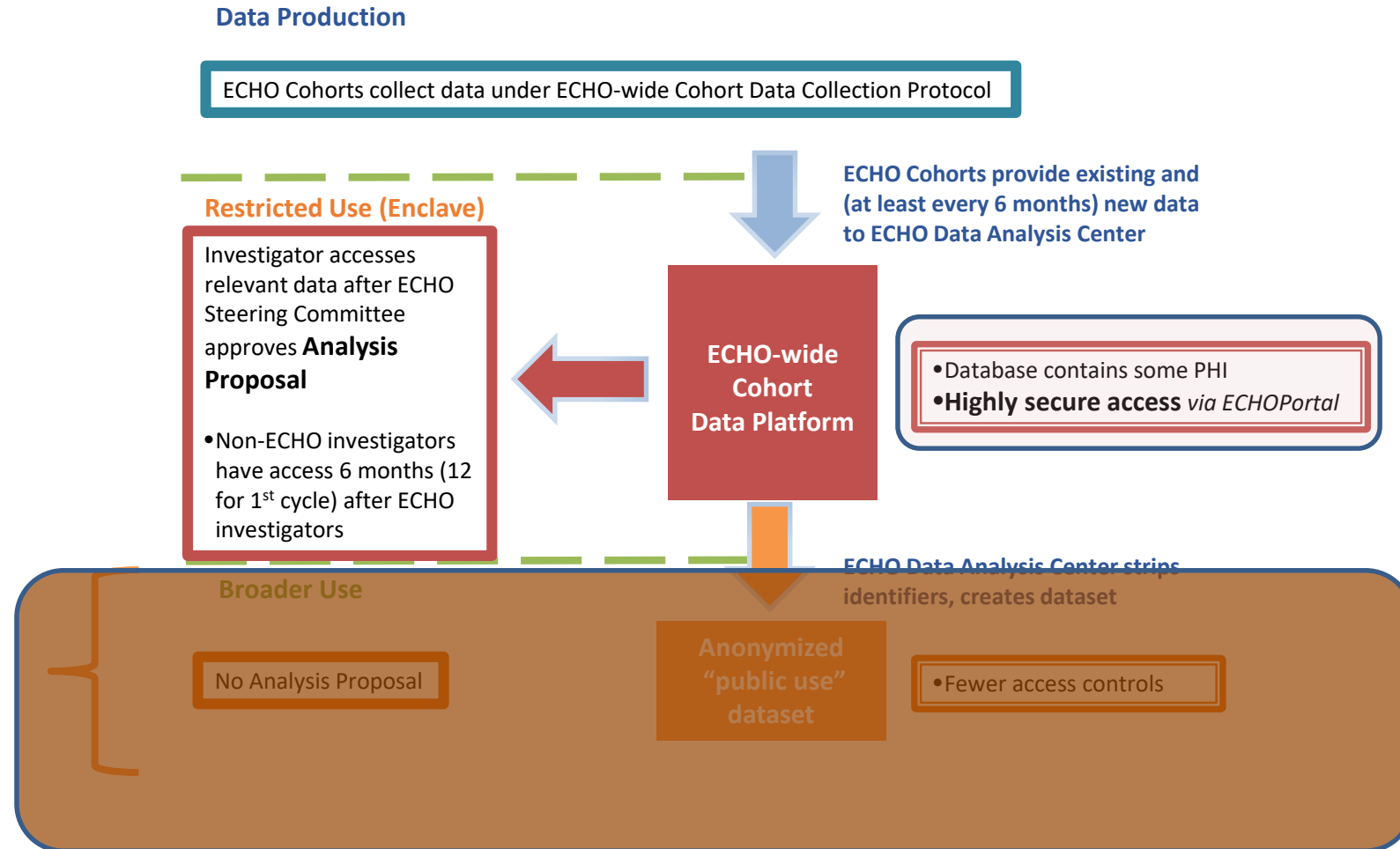
ECHO-wide Cohort Data Sharing

Today—restricted use, not “public use”



ECHO-wide Cohort Data Sharing

Current safeguards



ECHO Data Analysis Center

Johns Hopkins/RTI

Receives, stores, and analyzes data



ECHO Data Analysis Center

Johns Hopkins/RTI

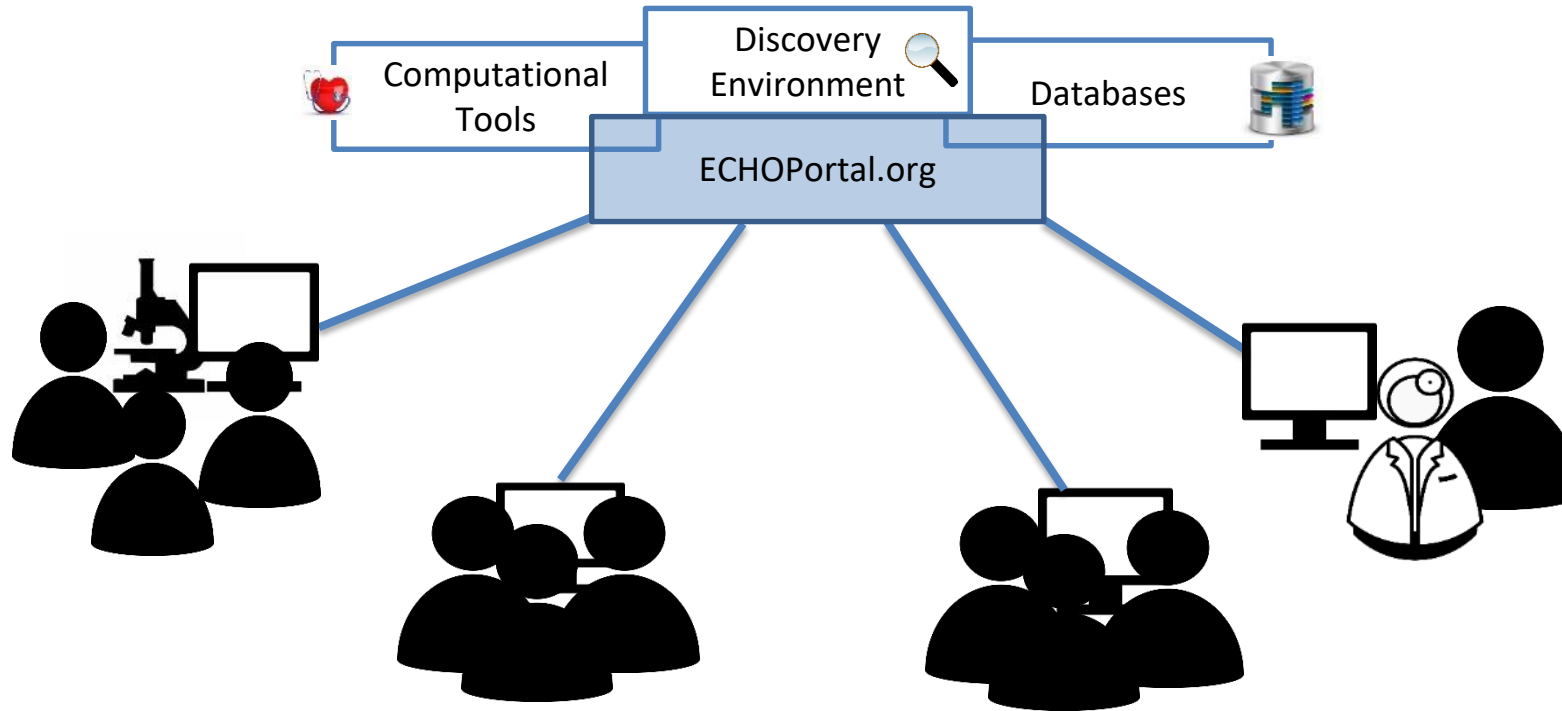
Receives, stores, and analyzes data



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

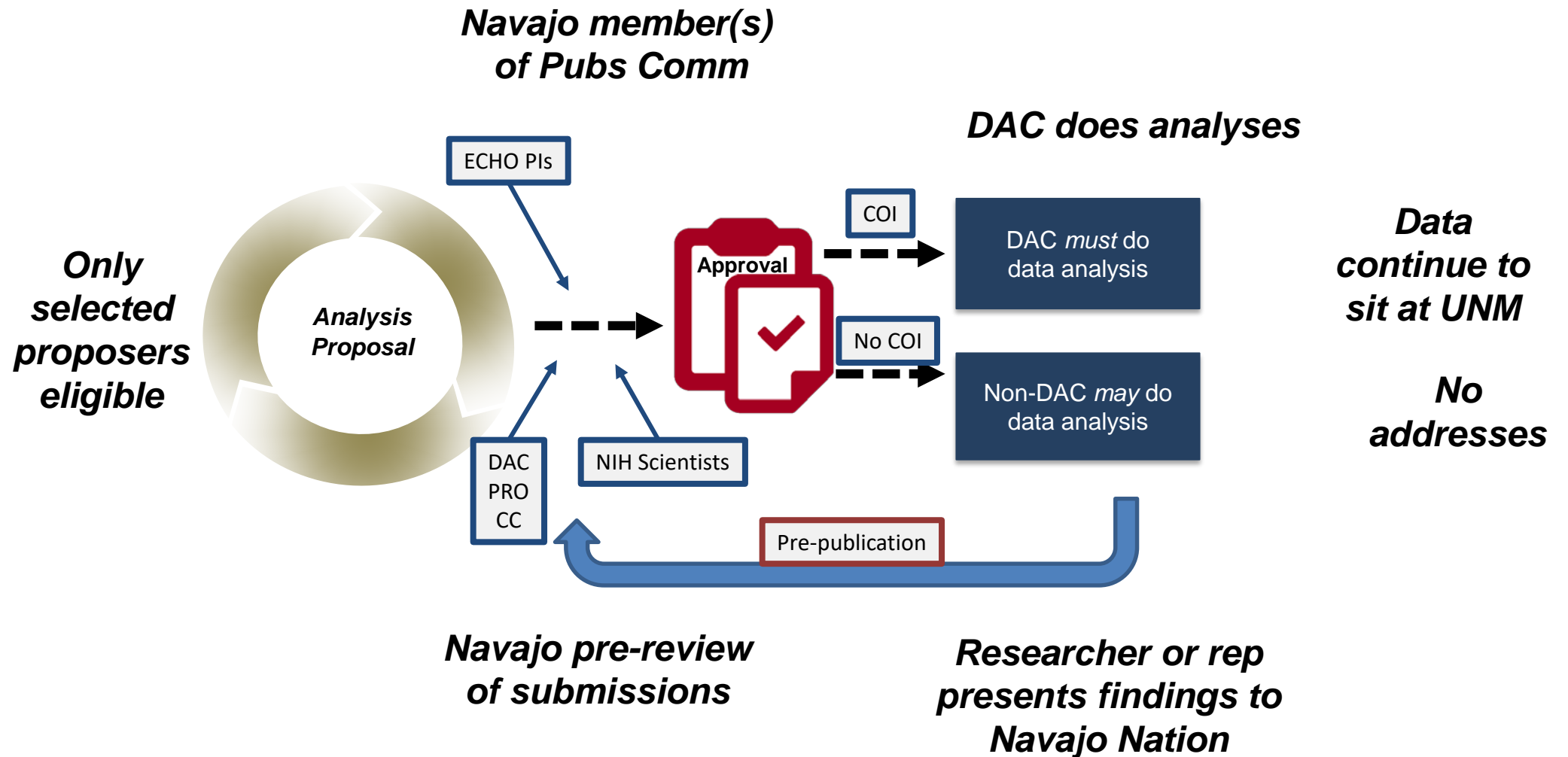
- 2-factor authentication—prove identity twice before logging in

Navajo Birth Cohort Study—draft agreement to add protections



Restricted Use ECHO-wide Cohort Analyses

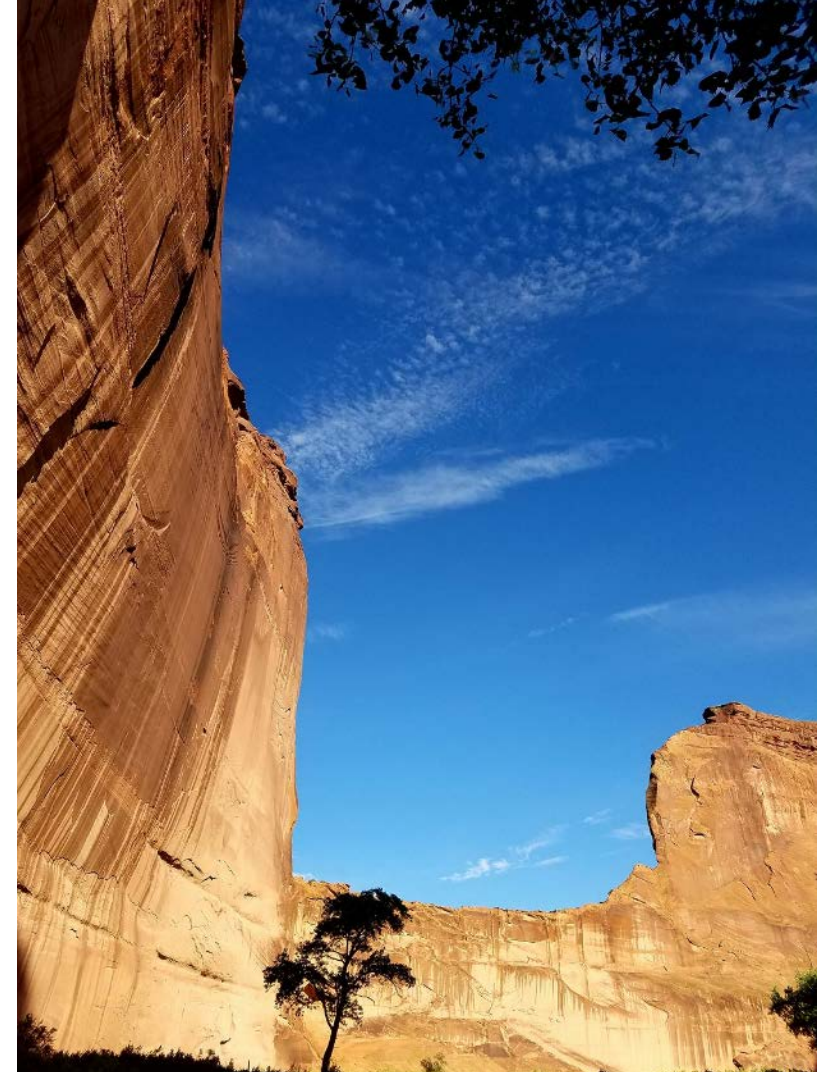
Navajo Birth Cohort Study—draft agreement to add protections



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
 - Process
 - Content



Thank you to TAC

- Started ECHO on this path
- Helped us listen
- Provided contacts
- Offers ongoing sounding board
- Look forward to continued advice as ECHO matures



Extra slides

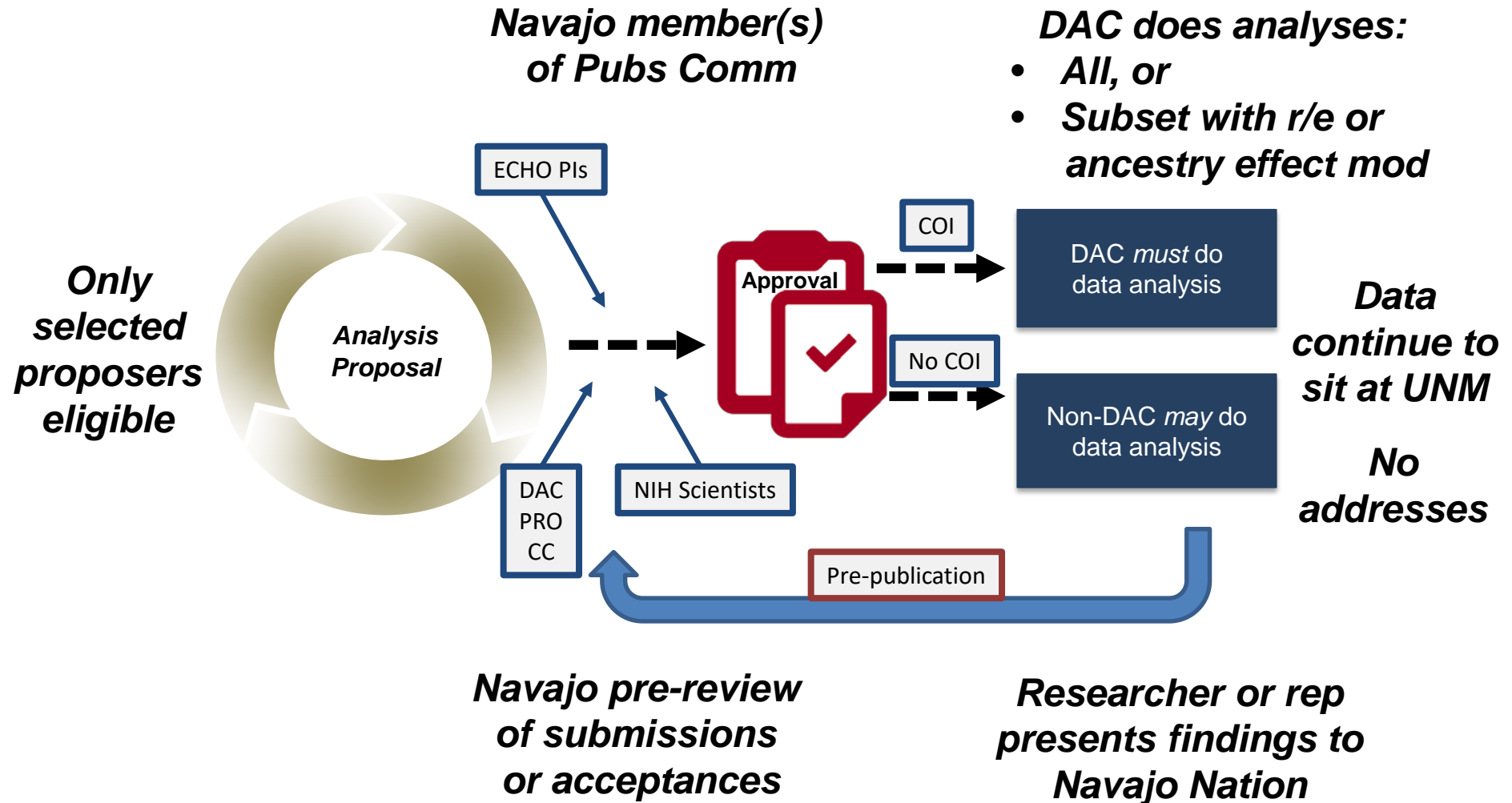
ECHOPortal.org

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
 - Controlled access
 - Particular researchers for particular analyses
- Tracking of all user actions
- Independent security audit, continuous monitoring

Restricted Use ECHO-wide Cohort Analyses

Possibilities for Navajo Birth Cohort Study; others too?



Proposed additional protections for Navajo Birth Cohort Study

For discussion...

- Only selected proposers eligible to start
 - e.g, principal investigators of the 35 grants
 - Expand later if goes well
- Navajo permanent members of Publications Committee
 - To provide more scrutiny for selected analysis proposals
 - Teach investigators what the issues are
 - Co-investigator of NBCS?
 - Johns Hopkins member of NNHRRB?
 - Other tribal representatives in the future?

Proposed additional protections for Navajo Birth Cohort Study

For discussion...

- Ensure DAC itself does analyses for
 - All analyses that involve Navajo?
 - Perhaps not too risky if just mixed with all other participants
 - ~1% of all participants
 - Limited to analyses in which investigator
 - Proposes separate analysis of AI/AN?
 - [No genetic ancestry studies til later]

Proposed additional protections for Navajo Birth Cohort Study

For discussion...

- Data continue to sit at UNM for starters
 - Ultimately could NBCS data be in the platform with the other 82 cohorts if things go well?
 - Set up evaluation metrics
 - Don't need to decide now
- Addresses or geocodes
 - Not in actual database?
 - Statistical approaches at UNM to scramble

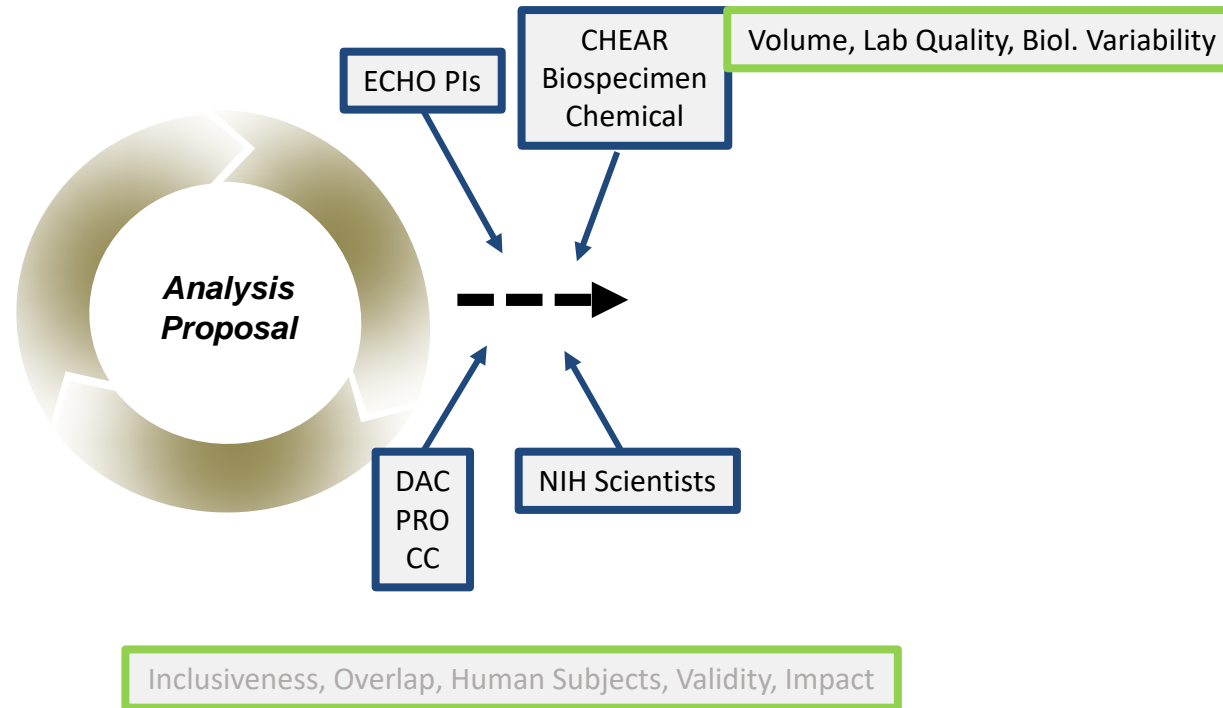
Proposed additional protections for Navajo Birth Cohort Study

For discussion...

- Investigator—or representative from NBCS?—reports findings to Navajo Nation
 - Investigators may not use NBCS data, reducing benefit, if too onerous to travel
 - Benefit-to-risk balance...
- Navajo Nation reviews manuscripts
 - Continue at acceptance stage?
 - At submission stage in future if things go well?
 - Don't need to decide now
 - Only those flagged at analysis proposal stage for more scrutiny
 - E.g., analyses with AI/AN separately vs. all analyses

ECHO-wide Cohort Analyses within Enclave

Ensuring Equity, Quality, Priority (with biospecimens)



The ECHO-wide Cohort

Examples of research questions

- What is the relationship of lower fetal growth to attention problems and cognitive functioning in childhood and adolescence?
 - Does that relationship differ according to ethnicity?

The ECHO-wide Cohort

Examples of research questions

- To what extent is exposure to poor indoor (or outdoor) air quality
 - during pregnancy associated with preterm birth?
 - during pregnancy and childhood associated with incidence of asthma and severe asthma?
 - Is either of these worse in the face of maternal stress?
- Potential benefit for Navajo
 - Better practices for wood-burning stoves
 - E.g., EPA “Burn the right fuel”
 - Specific programs to address stress

The ECHO-wide Cohort

Examples of research questions

- How do combinations of the following factors work together to increase rates of childhood obesity and pre-diabetes?
 - Excess maternal weight coming into pregnancy
 - Gestational weight gain
 - Gestational diabetes
 - Smoking during pregnancy
 - Household
 - Economic conditions
 - Environment for child's sleep, nutrition, and physical activity
- Potential benefit for Navajo
 - Test culturally appropriate interventions to reduce these risk factors

The ECHO-wide Cohort

Examples of research questions

- How much does positive health change when children enter school?
- How much does it matter if these kids have obesity or asthma or attention deficit disorder?
- How much does it differ for girls vs. boys?
- Potential benefit to Navajo
 - Focus on positive aspects of health rather than deficits
 - Are there ways that schools can support positive health?

Question—General

Your advice has been crucial

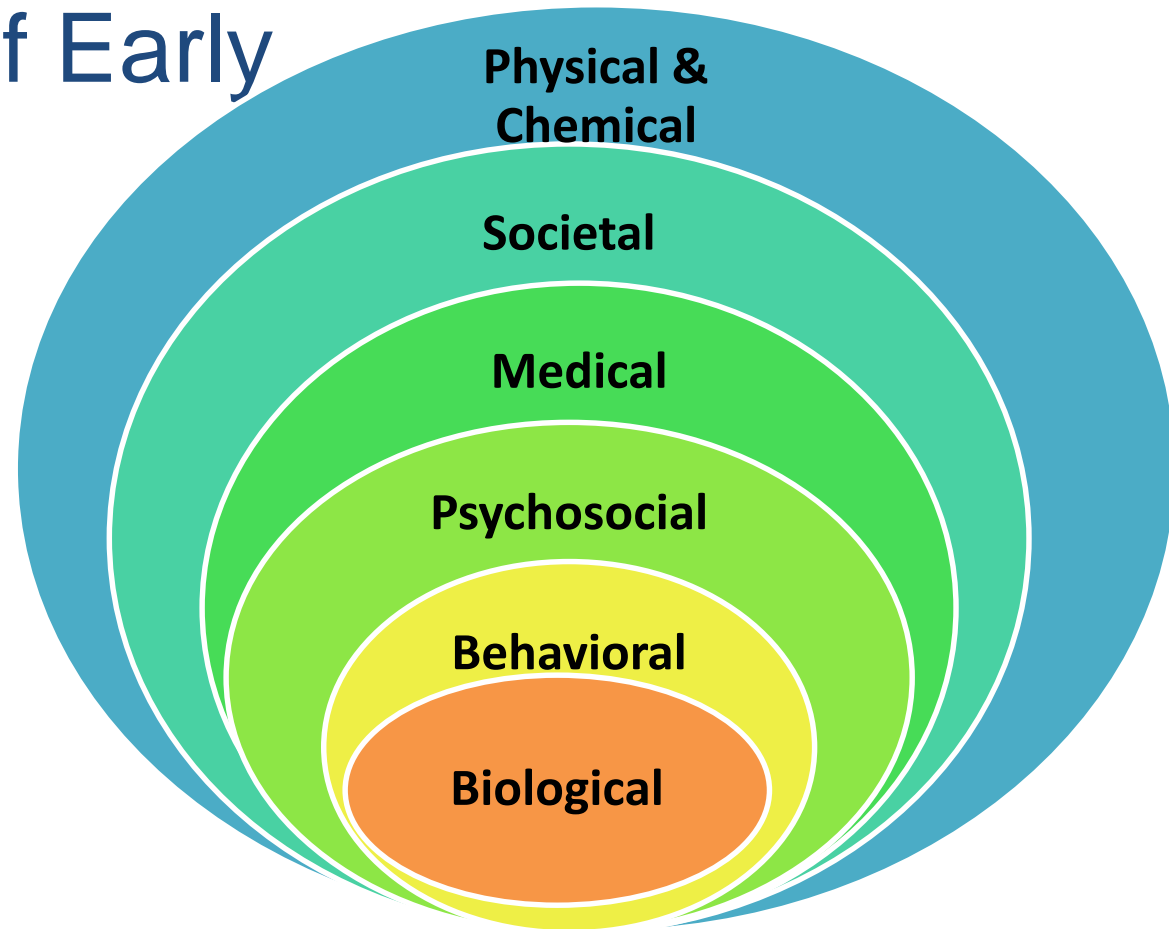
- Best ways for...
 - NIH ECHO Program Office and
 - Investigators...to build relationships with Tribal Nations and collaborate to address concerns

ECHO Overall Scientific Goal

Answer crucial questions about effects
of
broad range of early environmental exposures
on
child health and development

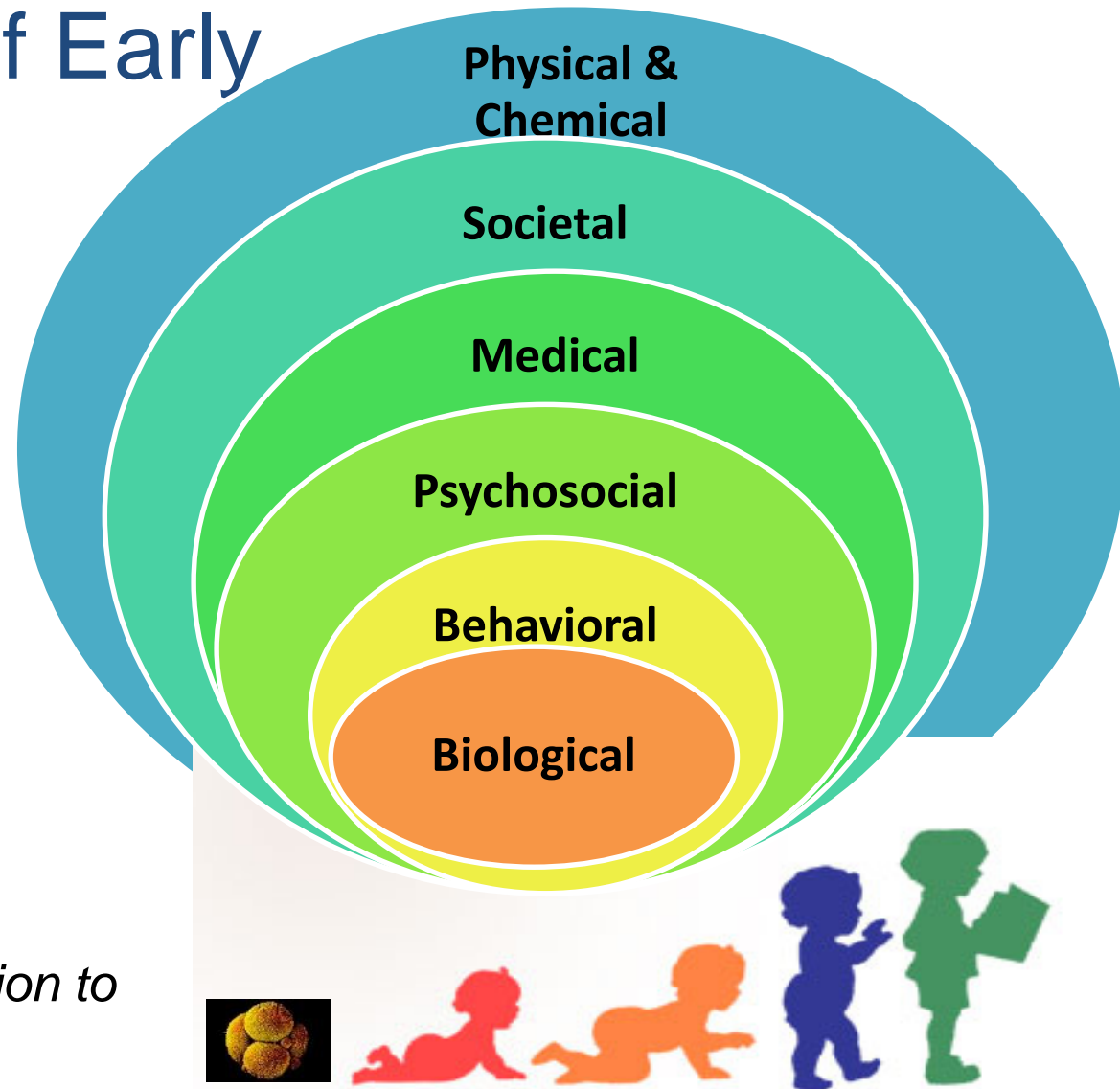
Broad Range of Early Environmental Exposures

From society to biology



Broad Range of Early Environmental Exposures

From society to biology



- *Exposures from conception to age 5 years*

Health Outcomes

Focus on high-impact conditions
throughout childhood and adolescence

PRE-, PERI-
AND POSTNATAL



UPPER AND
LOWER AIRWAY



OBESITY



NEURO-
DEVELOPMENT



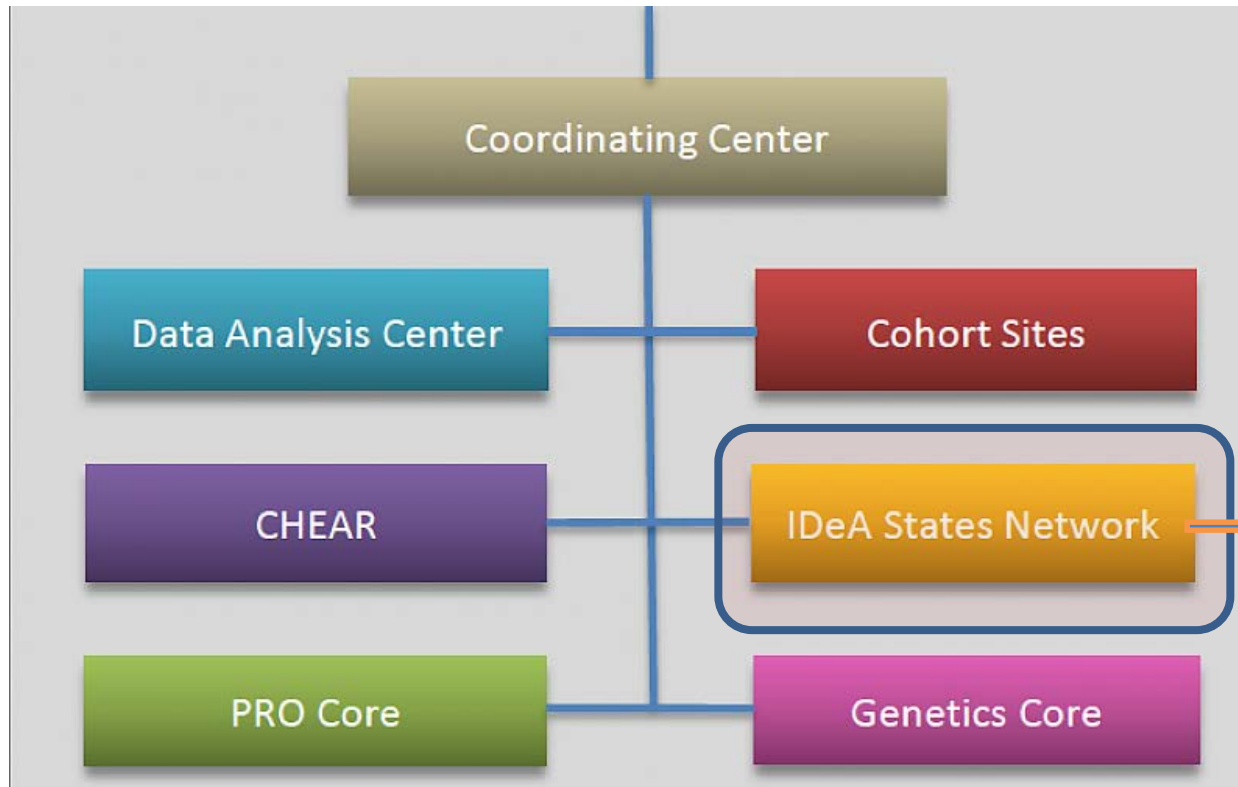
POSITIVE CHILD HEALTH





- Positive health
 - Focuses on assets that enable well-being
- Well-being
 - Happiness
 - Life Satisfaction
 - Meaning & Purpose
 - Relationships
 - Achievement
 - Sleep

ECHO Components



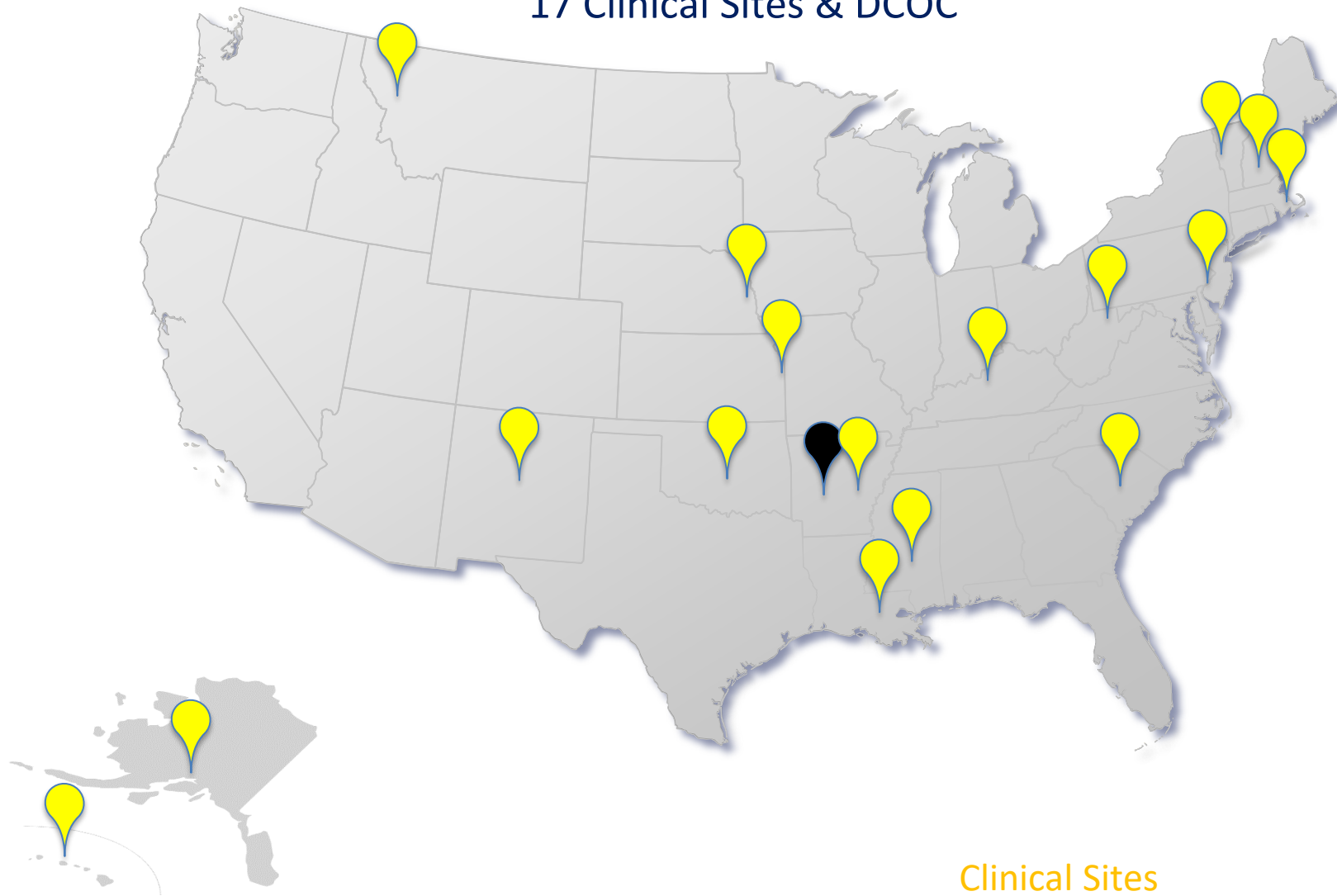
Intervention studies
Clinical trials

IDeA States Pediatric Clinical Trials Network

Overarching Goals

- 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
 - To compete for future funding

IDeA States Pediatric Clinical Trials Network 17 Clinical Sites & DCOC

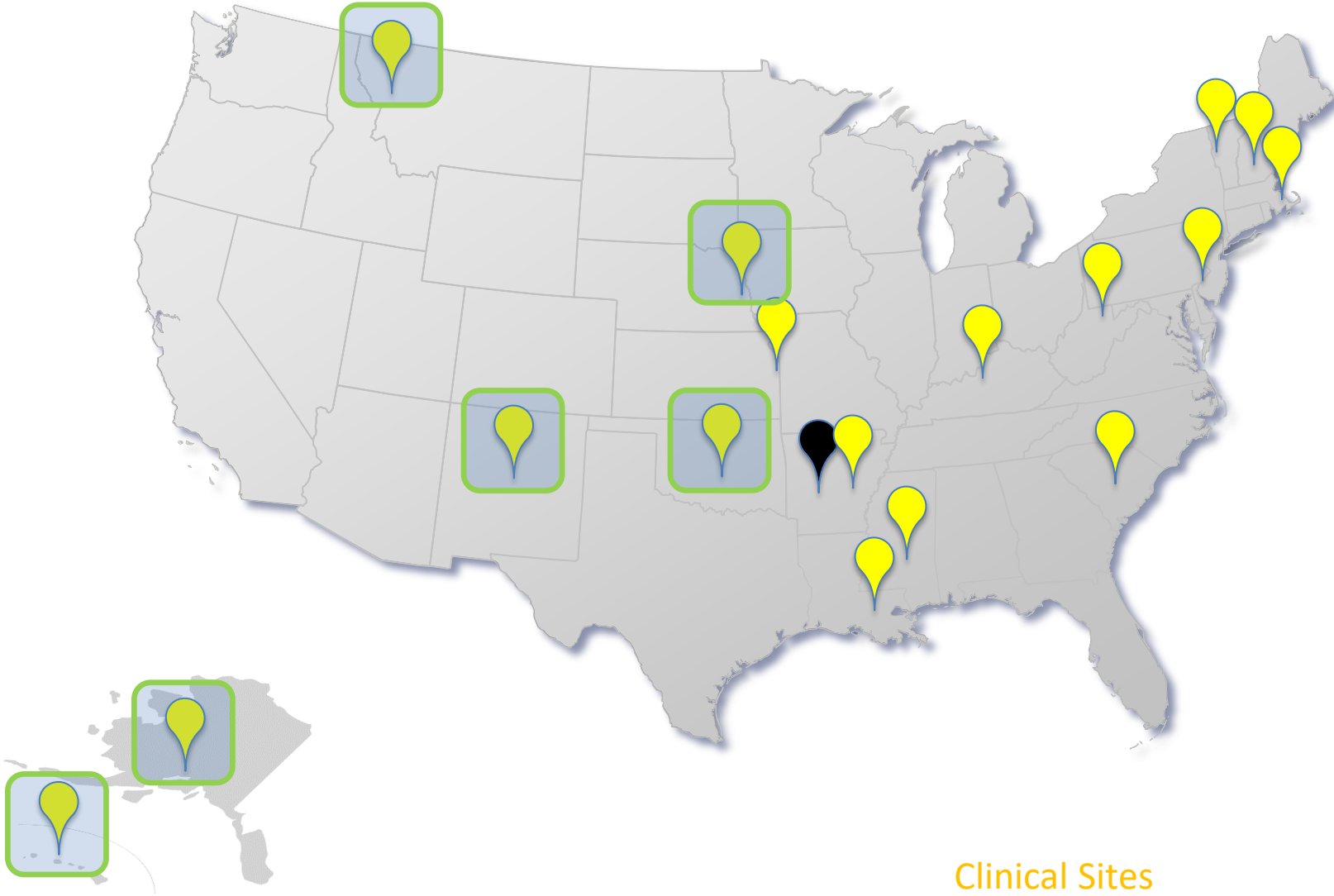


Clinical Sites

Data Coordinating and Operations Center (DCOC)

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

- New network
 - Getting its legs
- Stakeholder group—indigenous populations
 - Working with AI/AN/NH researchers and community members
 - Enumerating principles and policies
 - Future—community-based participatory research strategies

Create The ECHO-wide Cohort

- Start with multiple existing cohorts (longitudinal studies) of moms & kids
 - Continue to recruit new & follow existing participants
- Combine into single data platform so that researchers can ask far-reaching questions
- 50,000+ children and their families

The ECHO-wide Cohort

Tapestry of many people, many layers of data, many stages of life course

