



Best Practices in Environmental Health Research with Tribal communities

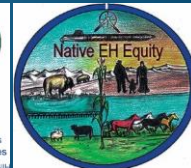
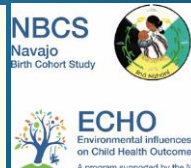
Deb MacKenzie PhD & Esther Erdei, PhD, MPH, M.Sc.Hons.

University of New Mexico Health Sciences Center

College of Pharmacy - Community Environmental Health Program

FUNDING ACKNOWLEDGEMENTS

- NIH/OD UG3 OD023344 (NBCS/ECHO) (Lewis/MacKenzie)
- CDC U01 TS000135 (NBCS) (Lewis/MacKenzie)
- NIEHS & NIMHD P50ES026102 (Native EH Equity) (Lewis/Gonzalez)
- USEPA 83615701 (Native EH Equity Center)
- NIH/NIEHS P42 ES025589-UNM METALS Superfund Center



“unique need for tribal-focused research to identify impacts of pollution, dietary exposure, cumulative risk and climate change as well as to inform decisions to reduce health risks...” – US EPA, 2004

- Land-based cultures
 - Contact with their environment
 - Historical and current presence of mining, oil and gas industry
 - Reliance on natural resources for traditional diets, customs and languages.
- Lack of culturally-centered primary research
 - Limited understanding about environmental contamination on public health.
- Sovereign tribal governments – Tribal Institutional Review Board is a governing body.

US EPA, 2004

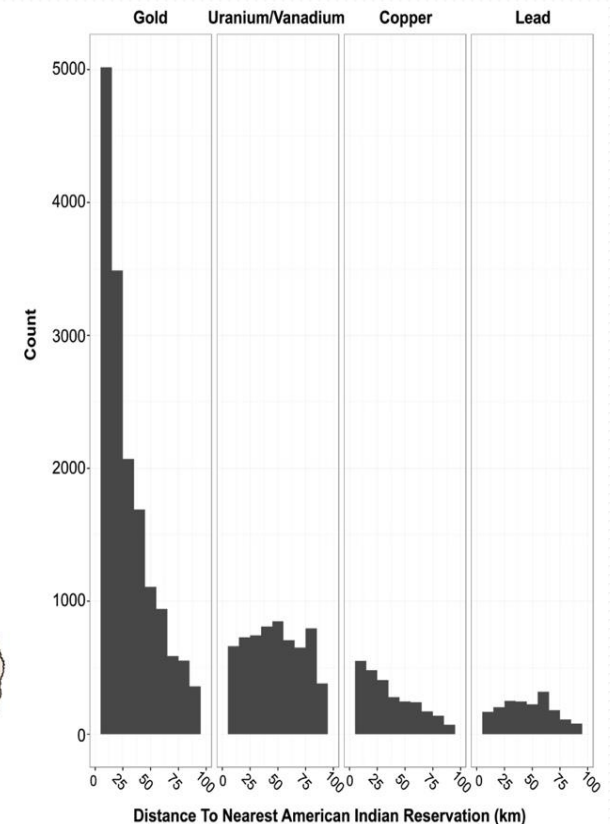
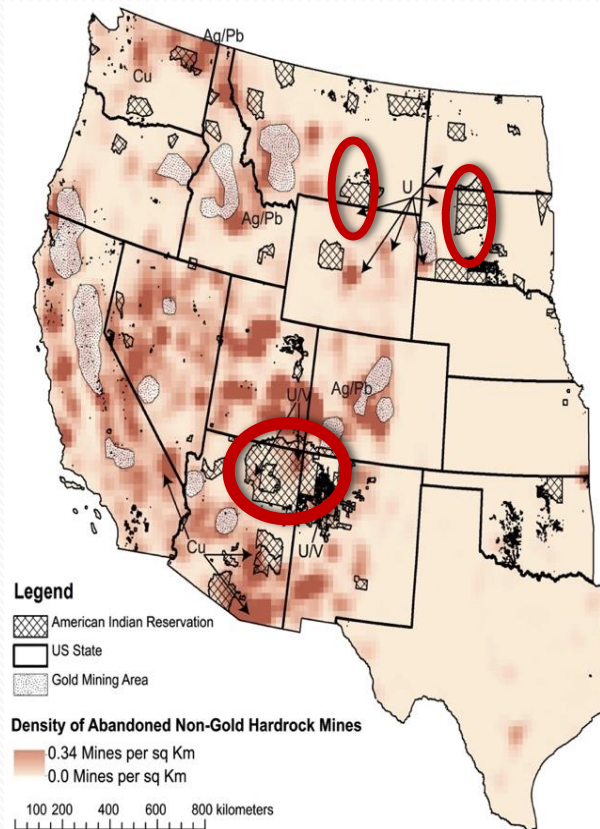
The Need

>1/2 of US Indigenous population lives in 13 western states where 161,000 abandoned hard rock mines also located (500,000 sites)

40% of watershed headwaters in West thought to be contaminated from these mines (USEPA)

>600,000 Native Americans live within 10 km of abandoned mines

Greater reliance on local resources creates increased concern over potentially greater exposure and resultant impacts

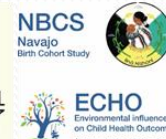


Examples of different ways working with Tribal oversight and solving environmental health problems with Tribal stakeholders and communities

- **Navajo Nation** – largest Tribe of the USA, Southwestern US, in 4 states; > 300,000 enrolled Tribal members in 2010 Census, from those 187,600 live on the land surface area of the size of the State of West Virginia map
- **Cheyenne River Sioux Tribe** – 4th largest Tribes of the USA, more than 19,900 people enrolled, land is located in South Dakota, spans across the geographic area of the State of Connecticut

Tribal environmental health research with Tribal stakeholders and communities

- **Navajo Nation** – health and child developmental effects of abandoned uranium mining and milling (532 sites across the Nation)
 - Navajo Nation Human Research Review Board (NNHRRB) -structured Tribal Council oversight on ALL studies done in the Navajo Nation- more than 270 active studies are ongoing
 - NNHRRB has elected 9 members of the Board representing Tribal educational, community, health/medical and cultural/anthropologic research interest and review



Navajo Nation Human Research Review Board

[HOME](#) | [ABOUT NNHRB](#) | [RESOURCES](#) | [CONFERENCE](#) | [CONTACT](#)



welcome

"Indigenous people and researchers: building collaborative partnerships and the importance of responsibilities, ethics, and values of research on the Navajo Nation"

The mission of the Navajo Nation Research Program is to support research that promotes and enhances the interests and the visions of the Navajo people: to encourage a mutual and beneficial partnership between the Navajo people and researchers; and to create an interface where different cultures, lifestyles, disciplines, and ideologies can come together in a way that improves, promotes, and strengthens the health of the Navajo people.

The Navajo Nation Human Research Review Board (NNHRB) was developed in March 1996 to guarantee ethical research for the Diné people.

Press Releases



Past Events

NOV 26-Navajo Genetic Policy Development Work Group: Genetic Panel Session at Flagstaff, AZ (NAU)



Click here for video of panel discussion.

[https://www.dropbox.com/s/vrvbwgnlromxv32/Navajo Genetics Group Panel - FINAL.mp4?dl=0](https://www.dropbox.com/s/vrvbwgnlromxv32/Navajo%20Genetics%20Group%20Panel%20-%20FINAL.mp4?dl=0)

Upcoming Events

STRANDS OF LIFE

Genetic Research and Efforts to Develop A Genetic Research Policy for the Navajo Nation

MARCH 7, 2019

6-8 MST

AM 660 and FM 101.5

**** AUDIO MP3 RECAP - 2 HOURS, 3 SECONDS ****



[CLICK HERE](#) (225 MB'S)

2019 Summer Food Service Program

Free Meals for ages 18 & Under
at participating schools
a message from Navajo DOH

[Click here for more information](#)

NNHRB MONTHLY MEETING

July 16, 2019
From 9:00 am – 5:00 pm
NN Administration Bldg. #2,
NDOH Conference Room
Window Rock, AZ

07-16-2019 Meeting Agenda
[Click to Download](#)

On August 20, 2019
From 9:00 am – 5:00 pm
NN Administration Bldg. #2,
NDOH Conference Room
Window Rock, AZ

NNHRB 2019 Meeting Schedule



Meetings held every 3rd Tuesday of each month
at Navajo Department of Health East Conference
Room (NDOH)
(Schedule subject to change without advance
notice)

**** One (1) complete original NNHRB
application/protocol and ten (10) copies** due to
NNHRB office by 5:00PM on submission date.

Navajo Nation

Human Research Review Board

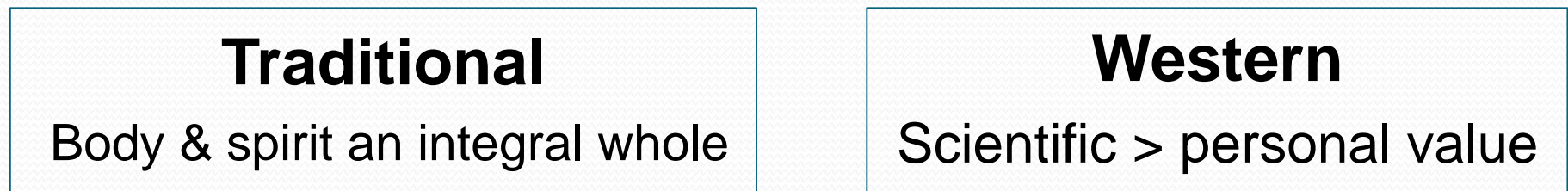
Study Protocol Approval Requirements

- Quarterly Reports
- Annual Report & Continuation Request
- Directly address community benefits of research
- Reports on abstracts, presentations, planned/invited lectures
- Reporting of adverse events, unexpected changes to protocol
- Manuscripts submitted before publication
- Agreement on Material Transfers to other universities, collaborators
- Data evaluation agreement – ASQs to establish Tribal-specific pediatric screening
- Data sharing



Informed consent from the tribal governance as well as individual participants

- Provide community-specific research-related information needed to make an informed decision
- Assure community of prior endorsement, wider dissemination of the study objectives, methods and results.





NORTHERN NAVAJO AGENCY COUNCIL RESOLUTION

NNAC-19-031916A

Recommending and Supporting proposal by the University of New Mexico to the National Institutes of Health for inclusion in the Environmental influences on Child Health Outcomes (ECHO) Program in collaboration with Navajo Nation Department of Health, Navajo Area Indian Health Service and other governmental and nongovernmental organizations including the Southwest Research and Information Center involved in the Navajo Birth Cohort Study.

WHEREAS:

1. The Northern Navajo Agency Council is a recognized political subdivision of the Navajo Nation and has the authority to advocate and make appropriate recommendations on behalf of the 20 Northern Navajo Agency chapters to the Navajo Nation Government, Federal, State, and local entities for appropriate action; and
2. In August 2010, CDC-ATSDR awarded the research lead for the Navajo Birth Cohort Study to a team assembled by the University of New Mexico (UNM) that includes the UNM Community Environmental Health Program (CEHP), Johnnye L. Lewis, Ph.D., principal investigator; UNM Center for Development and Disability; Southwest Research and Information Center (SRIC); and experts in epidemiology and uranium mining impacts on the Navajo Nation; and
3. The Navajo Department of Health CHR/Outreach Program also received funding from ATSDR for the Navajo Birth Cohort Study and has staff working with the UNM team to administer the Ages and Stages Questionnaires, a developmental screening instrument directly related to the ECHO goals; and
4. The current funding for the Navajo Birth Cohort Study allows only for follow-up of children through age 1 year, potentially missing influences of exposure that would not be apparent until later in life; and

NOW, THEREFORE BE IT RESOLVED THAT:

1. The Northern Navajo Agency Council Recommends and Supports the University of New Mexico Environmental influences on Child Health Outcomes (ECHO) proposal in Collaboration with the Navajo Nation CHR/Outreach Program, Navajo Area Indian Health Service and other governmental and nongovernmental organizations including Southwest Research and Information Center and the University of California San Francisco.
2. The Northern Navajo Agency Council supports the proposed inclusion of the Navajo Birth Cohort Study in the ECHO Program through negotiation of data sharing and genetic analyses conditions with the Navajo Nation Human Research Review Board, subject to satisfaction of all applicable rules and regulations of the Navajo Nation related to the conduct of health studies among the Navajo people.

CERTIFICATION

We hereby certify that the foregoing resolution was duly considered by the Northern Navajo Agency Council at a duly called meeting San Juan Chapter, San Juan, New Mexico at which a quorum was present. A motion was made and a seconded and the same passed by a vote of 40 in favor 00 oppose 01 abstained, this 19th day of March 2016.

Motion by: Lovena B. Lee

Seconded by: Sally Ann Joe

David John, Chairperson

Supporting Resolutions come from Agency Councils (5 on Navajo Nation). Also sometimes requires community approval at the Chapter level (110 Local Chapters)



NBCS
Navajo
Birth Cohort Study



Tuesday, May 7, 2019

NIH facilitates first Tribal data-sharing agreement with Navajo Nation

Navajo Birth Cohort Study will share participant data as part of major NIH research initiative.



The National Institutes of Health has facilitated a data-sharing and use agreement between the Navajo Nation and NIH grantees of the [Environmental influences on Child Health Outcomes \(ECHO\)](#) Program, which was ratified today in a ceremony at the Navajo Nation Head Start Center in Leupp, Arizona. The agreement was signed by the Navajo Nation, Johns Hopkins University (JHU), Baltimore, and RTI International, Research Triangle Park, North Carolina. It enables the Navajo Birth Cohort Study (NBCS) to continue as part of the ECHO program and NBCS individual participant data to be shared with ECHO consortium members, but does not cover genetic data or sharing of biospecimens. The agreement was created to respect Navajo Nation cultural beliefs, Tribal sovereignty and community values. It is the first Tribal data-sharing agreement for a nationwide research consortium creating a large-scale database, and lays the groundwork for discussion with other Tribal Nations considering participation in biomedical research programs.

“HHS is pleased that this collaboration has resulted in a data-sharing and use agreement that respects the traditions and culture of the Navajo people and we hope will build trust in research,” said U.S. Deputy Secretary for Health and Human Services Eric Hargan, who participated in the event. “It is exciting that the Navajo Nation will contribute to a major nationwide research program in child health that is poised to benefit Navajo mothers and children as well as moms and kids across the United States.”

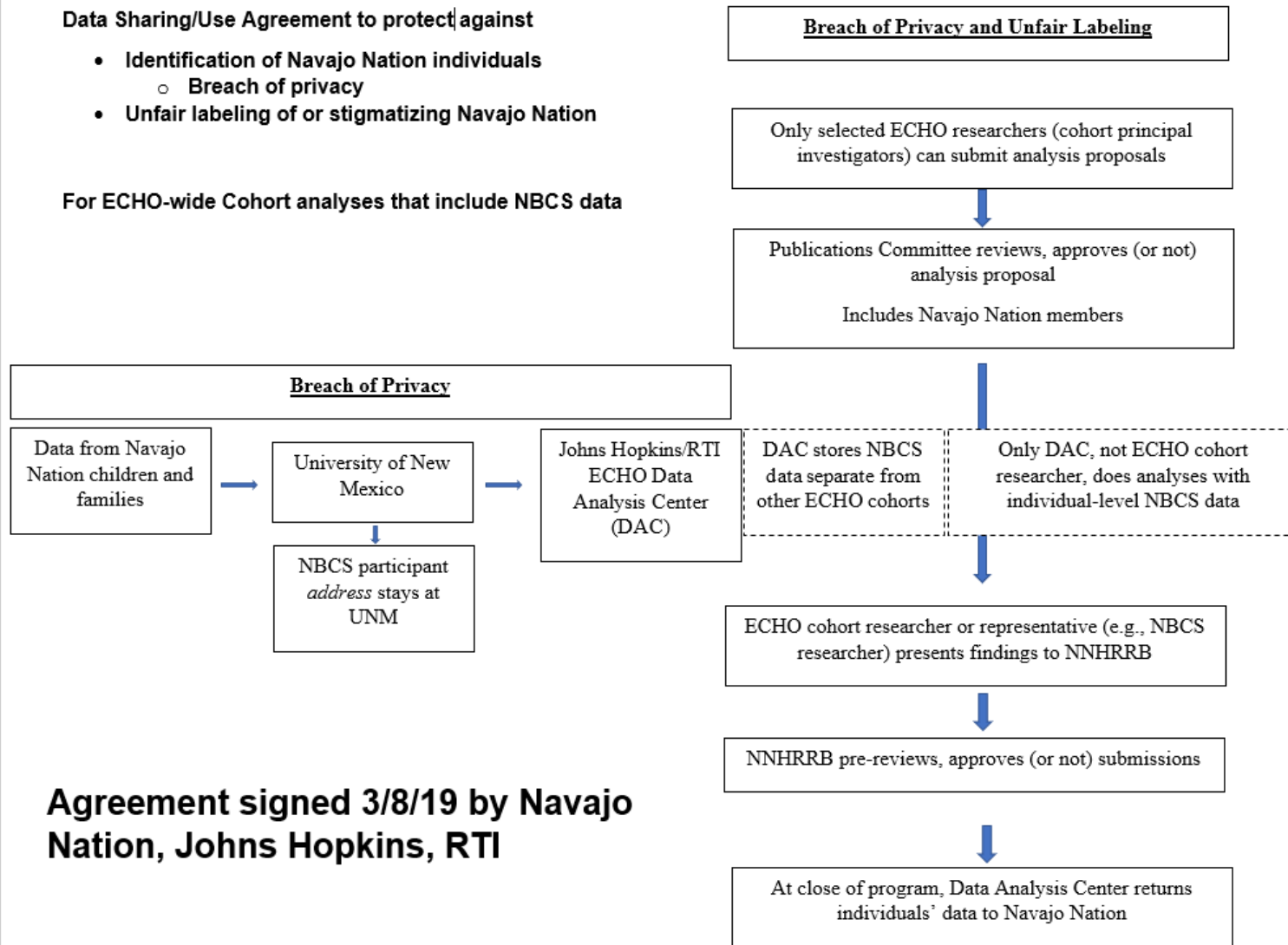
Navajo Nation leadership, and representatives from ECHO’s Data Analysis Center at JHU and RTI International were present at the event. Officials from HHS and NIH, including Mr. Hargan and NIH Principal Deputy Director Lawrence Tabak, D.D.S., Ph.D., were also in attendance. This agreement is the culmination of two years of discussion facilitated by NIH.

“Through this agreement I am confident that data sharing will benefit our Navajo people and allow us to further understand the relationship between uranium exposure, birth effects and childhood development,” said Navajo Nation President Jonathan Nez. “I am optimistic that through this partnership, the Navajo Birth Cohort Study will continue to progress and clarify the environmental impacts on our children’s health.”

Data Sharing/Use Agreement to protect against

- Identification of Navajo Nation individuals
 - Breach of privacy
- Unfair labeling of or stigmatizing Navajo Nation

For ECHO-wide Cohort analyses that include NBCS data



Research Responds to the Navajo Uranium Legacy



Blighted Homeland

(Gail Fisher / LAT)

They took shelter amid the poison
During the Cold War, uranium mines littered the Navajo Nation with contaminated waste. People developed cancer. And the U.S. did little to help.



Congressional committee outraged over Navajo uranium legacy

By Kathy Helms, Dine Bureau, Gallup Independent, Oct. 24, 2007

WINDOW ROCK – A picture may be worth a thousand words, but the sound of an instrument used to detect radioactive contamination, clicking away over a soil sample from Tuba City, set a federal oversight committee on its ear Wednesday during a hearing in Washington.

Chairman Henry Waxman's Committee on Oversight and Government Reform heard from a Navajo Nation delegation about the health and environmental impacts of uranium contamination during a four-hour hearing.

Several congressional leaders expressed outrage at the federal government for allowing such conditions to remain unchecked on Navajoland for so many years, saying they were "ashamed" and "embarrassed." They offered apologies to the Navajo people.

DiNEH Project

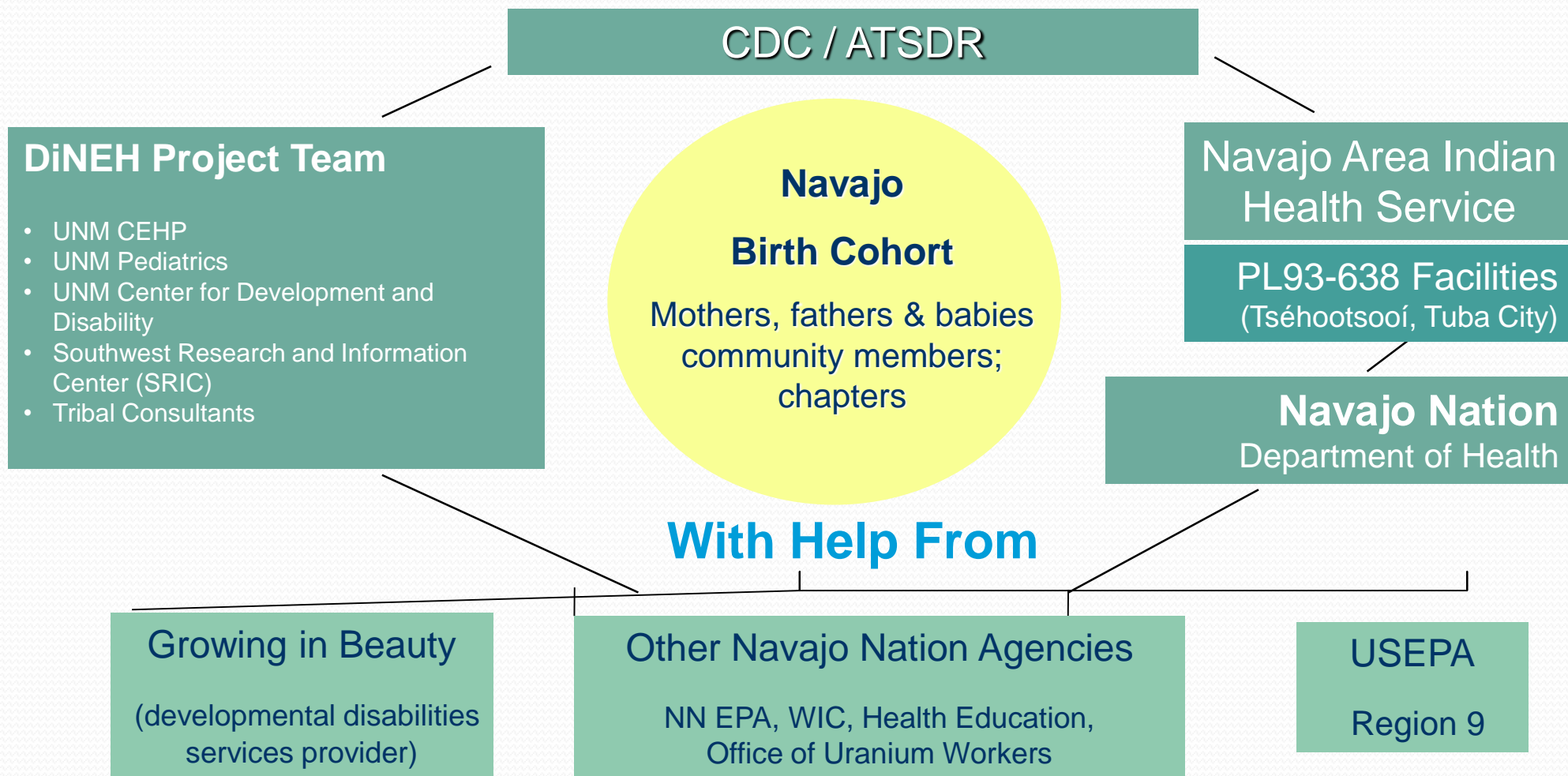


Navajo Birth Cohort Study





Navajo Birth Cohort Study Cooperating Organizations



NBCS Cohort Members



- 781 Mothers (27 years, range 14 - 45 yrs)
- 764 Babies
- 227 Dads (29 years, range 17 – 51 yrs)
- Younger generation of Navajos with no occupational U mining exposure






Our first participants, a couple living in Sheep Springs, NM, were enrolled through the Chinle Hospital in 2013.

Traditional Beliefs

- Giving away some personal samples may be contrary to traditional norms.
- To avoid such unintended conflicts, the collection of these biosamples **should only be undertaken with honest and transparent risk/benefit evaluation conducted in collaboration with the tribal community.**
- Agreements made to co-monitor and openly communicate about study procedures.
- Develop best practices for ethical exposure assessment in environmental health research.
- Capacity building and environmental health education & improvement in health literacy.

Biological sample collection in NBCS



	Blood 	Urine 	Meconium 
Mother	<ul style="list-style-type: none"> ➤ Enrollment ➤ Delivery 	<ul style="list-style-type: none"> ➤ Enrollment ➤ Delivery 	
Father	<ul style="list-style-type: none"> ➤ Enrollment 	<ul style="list-style-type: none"> ➤ Enrollment 	
Baby	<ul style="list-style-type: none"> ➤ Birth (cord blood) ➤ 2-6 months of age ➤ 12 months of age 	<ul style="list-style-type: none"> ➤ Birth ➤ 2-6 months of age ➤ 12 months of age 	<ul style="list-style-type: none"> ➤ Birth

Participant Report Back Letters

Biomonitoring and micronutrients results of all 36 metals (CDC)

- Mother (Enrollment)
- Mother and baby (Delivery)
- Baby (Birth to 12 months)
- Father's letter (Enrollment)
- Include
 - Emphasis on 4 reportable metals (U, As, Hg & Pb)
 - Participant's results
 - Cohort ranges
 - National range
 - 50- 95% range of NHANES concentrations (2011-2012) – CDC Fourth Report



Helping Your Child to
Grow in Beauty

College of Pharmacy
Community Environmental Health Program
MSC 09 5360
University of New Mexico
Albuquerque, New Mexico 87131-0001
905 Vassar NE
Telephone 505.272.4087/ Fax 505.272.4186

<Date>

<Salutation> <FirstName> <LastName>
<Address1>
<Address2>

RE: Results of Navajo Birth Cohort Study Biomonitoring – Metals in Blood and Urine

Dear <Salutation> <LastName>,

The research team from the Navajo Birth Cohort Study (NBCS) wants to thank you for participating in the study. As you know, the NBCS is studying if uranium on the Navajo Nation affects child birth and development. To fully understand uranium exposures and health, we have also analyzed other environmental chemicals that may occur on Navajo.

Recently, you gave us a sample of blood and urine to analyze to see if you might be exposed to metals in your environment. Below are your results for the four metals of most concern on Navajo Nation that are also reportable to state departments of health. Attached at the end of this letter are also results for all metals for which your blood and urine were tested. If you asked us to put the results in your medical record, the full report will be sent to the medical facility you indicated at enrollment.

Your results are within the normal range for arsenic, lead, uranium and mercury.

In the table below, your results are listed in the second column. To help you compare your results to what we see around the United States, the upper half of the ranges found in the National Health and Nutrition Examination Survey (NHANES) conducted by our partners at the Centers for Disease Control and Prevention (CDC) are listed in the second column. NHANES establishes ranges for these chemicals as they are typically found in people all across the United States. (When we have metals information for more than 100 participants in the NBCS, a column showing the range of levels we see on Navajo Nation will also be presented to help you understand your results relative to your community.)

Mother's Enrollment Sample Data

Metal of concern	Your value	NHANES (50 th – 95 th percentile range)	Note: Unavailable; currently fewer than 100 participant samples NBCS (Range: n =)
(Total Arsenic - Urine)	3.82	8.18 - 85.60	
(Lead - Blood)	2.3	<LOD - 50.00	
(Uranium - Urine)	0.0077	0.01 - 0.04	
(Total Mercury - Blood)	< LOD	0.33 - 1.30	

Participant Report Back Letters

Home Environmental Assessment

- Gamma radiation, indoor Rn
- 22 metals in dust
- Quality information of drinking water sources used in the home
- Used in mapping of environmental exposures across Navajo Nation
- Attachment of Letter - developed w/ field staff - FAQs about biomonitoring and metal exposure avoidance, list of abbreviation used in letters



Navajo Birth Cohort Study
c/o Southwest Research and Information Center
P.O. Box 4524
Albuquerque, NM 87196
505-262-1862; fax: 505-262-1864
src.chris@earthlink.net

December 27, 2013

Name
Address
City, State, Zip

Re: Results of Home Environmental Assessment Conducted July 8, 2013

Dear _____,

Thank you for participating in the Navajo Birth Cohort Study (NBCS). This letter provides results of the Home Environmental Assessment (HEA) conducted by Ms. Cora Phillips and myself on July 8, 2013 at your home in Tonalea, AZ in accordance with our approved research protocol.

The HEA is a one-time snapshot of environmental conditions in and around your home. The results indicate whether and how you have been exposed to environmental contaminants; they do not mean you or your family will have any health effects from your exposures. You can use these results to look for ways to reduce exposures in your home.

In summary, the HEA we conducted showed that maximum gamma radiation levels exceeded one of two "Investigation Levels" for your home and property, but for the reasons given later in this letter, we do not believe a referral to the Navajo Nation Environmental Protection Agency (NNEPA) is necessary. The maximum levels are very low and much lower than in other places on the Navajo Nation. We explain how to interpret these results in more detail below.

Our assessment found no contamination from indoor radon gas or metals in dust, and the water that is piped into your house met all federal and tribal safe drinking water standards in 2010 and 2011. We have not located water quality data for a windmill you said you drank from in the recent past, and therefore will have to collect samples from this well for testing in the coming months.

Gamma Radiation Assessment

Results of the gamma radiation surveys we conducted in and around your home are shown in the table below. The results are expressed in units of microrentgens per hour, abbreviated $\mu\text{R/hr}$. Please consult the attached Frequently Asked Questions (FAQ) for an explanation of how "background" radiation levels were determined for your area and how "Investigation Levels" (ILs) are used to determine if a referral to NNEPA is needed.

As shown in the table, the maximum indoor and outdoor gamma radiation level of 7.0 $\mu\text{R/hr}$ is greater than the second of two Investigation Levels calculated for your property, based on local background radiation levels. While the IL-2 level of 6.9 $\mu\text{R/hr}$ is slightly lower than 7.0 $\mu\text{R/hr}$, there is virtually no difference between these two readings given the normal fluctuations of gamma radiation on the surface of the Earth and the limitations of our meters at these low levels. Furthermore, you will notice that the maximum indoor and outdoor levels are less than IL-1, which was calcu

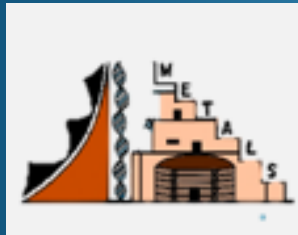
Supporting participant, community and Navajo Area IHS involvement – structured communication

- Navajo Area Indian Health Service medical providers (primary care physicians, midwives, nurses, surgery) receive regular updates and education
- Navajo HIS health technicians and laboratory personnel also receive updates - increase their assistance in enrollment and follow-up of babies
- Participants can ask questions from local, Indian Health Service Clinical Cohort Liaisons
 - almost all of them speak Navajo,
 - CEHP trained our field team and clinical sites in several occasions on possible exposures to mine waste
 - 1-800 phone line at CEHP Office is implemented to answer community/family members' questions in Navajo

Metals Exposure and Toxicity Assessment on Tribal Lands in the Southwest

Thinking Zinc — Béésh Doot'izh Bantsáhákees

A study to assess how taking the recommended daily amount of zinc may help repair damage from harmful metals among Navajo Nation residents



Presentation to the Navajo Nation Human Research Review Board

Presenters: Laurie Hudson,¹ Ph.D., Sarah Henio-Adeky²

Contributors: David Begay,¹ Ph.D., Debra MacKenzie,¹ Ph.D., Chris Shuey,² MPH, Esther Erdei,¹ Ph.D., Mallery Quetawki,¹ BS, Paul Robinson,² MCRP, Johnnye L. Lewis,¹ Ph.D., UNM METALS Director

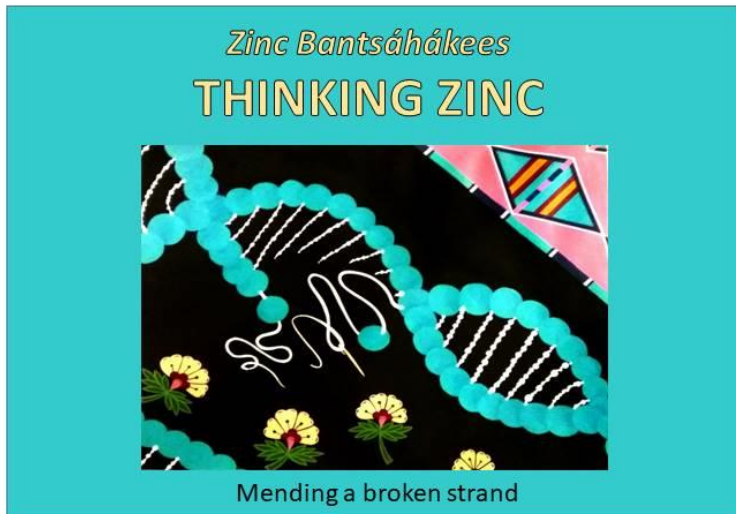
¹University of New Mexico, College of Pharmacy

²Southwest Research and Information Center

NIH/NIEHS P42 ES025589-UNM METALS
Superfund Center

UNM-HSC Office of Research
UNM College of Pharmacy
UNM Comprehensive Cancer Center
UNM COP Department of Pharmaceutical Sciences

January 9, 2019



Research volunteers needed

We are conducting research to understand if taking the daily recommended level of zinc protects our bodies from the effects of heavy metals in the environment.

To participate you are:

- 21-45 years of age
- Not dia 21-64 years
- Not allergic to zinc
- Not pregnant or nursing

You will:

- Have 4 study visits over 9 months
- Take a zinc supplement tablet
- Provide blood and urine samples
- Receive a gift card each visit

INTERESTED?

For more information or to participate, send email to zinc@src.org, call 877-545-6775, or visit www.src.org/Zinc



Thinking Zinc —

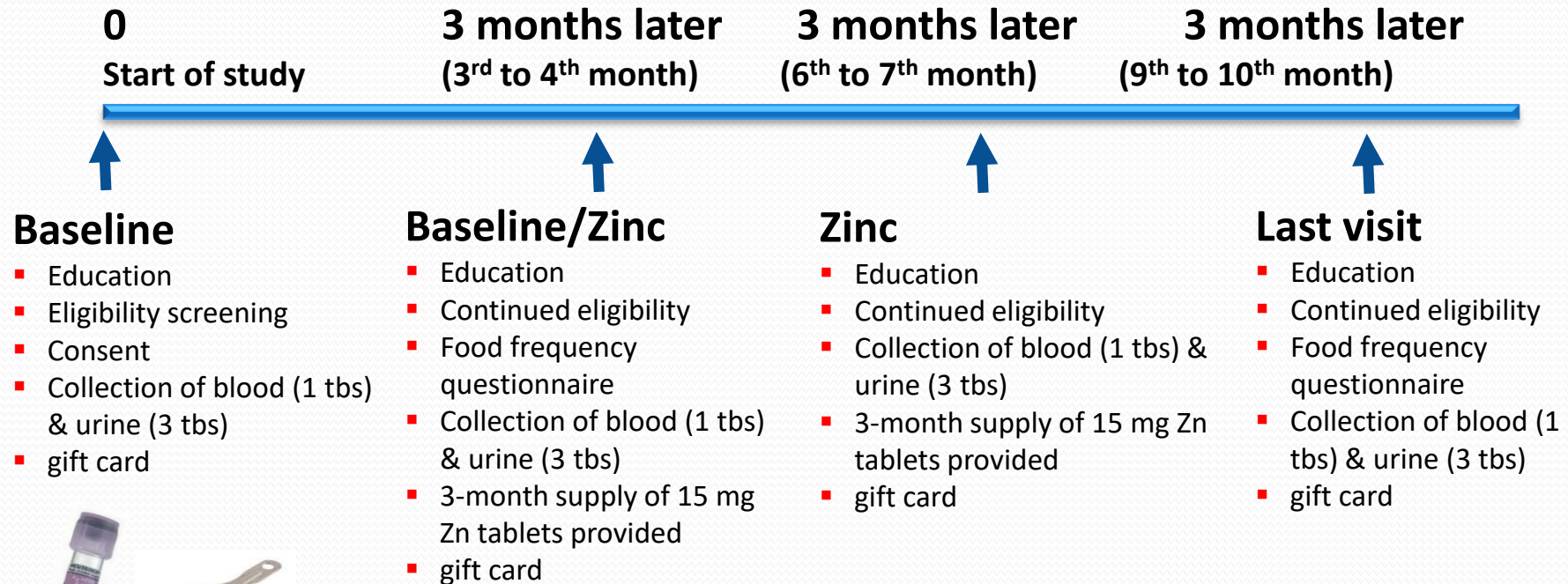
Beesh Doot'izh Bantsáhákees*

[metal + blue (the one that is) + thinking about it]

- This study will be conducted in the Blue Gap-Tachee Chapter and Red Water Pond Road area of the Navajo Nation, 2019-2021
- Blue Gap-Tachee Chapter adopted resolutions supporting its participation in Thinking Zinc in October 2017 and November 2018
- Red Water Pond Road Community supported UNM METALS Center in 2014 and 2016, adopted a resolution of support in May 2018
- Support resolutions from six other chapters and Eastern Agency Council

*From "Code Talker" by Chester Nez and Judith Schiess Avila, 2011.

Thinking Zinc Study Timeline



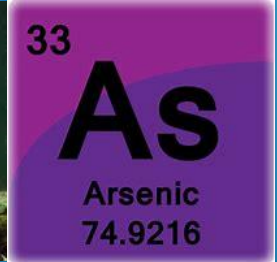
1 tablespoon (tbs)

Our staff will contact you during the study to remind you to keep taking your zinc tablets and to attend the next visit.



The Homestake Mine in 1889

The Homestake Mine in 1886



Tribal environmental health research with Tribal stakeholders and communities

- Cheyenne River Sioux Tribe – mercury contamination related to more than 900 gold and silver mines of the Black Hills
- 9 Lakota Nations are located in South and North Dakota
- Collaborating with the federal Indian Health Service's Great Plains Institutional Review Board (Aberdeen, SD)

CRST was one of the FIRST Native Tribes to receive Environmental Justice grant from NIEHS

(Lewis/ Henderson/Ducheneaux) in 2002;

- participatory and community-based, empowered research approach - Local Research Team: Missouri Breaks Industries Research Inc. (MBIRI)
- more organic development of ideas
- Tribal Health Committee, 9 members, reporting and presentations

- Apply and receive supportive CRST EXECUTIVE RESOLUTIONS
NO. E-302-08-CR, E-134-2014-CR. –No per se IRB Board on CRST
- Agreements to laboratory examinations, transport of materials involving third party labs, state entities

Future Plans - Tribally-driven environmental health research agenda

- Identify critical pathways of environmental exposures – occupational and recreational activities – necessary step for Tribal land development, new town building, medical school on Navajo and to support the creation of new Tribal businesses
- Public health concerns of metal exposures - Traditional practices, outdoor activities, land use, re-vegetation?
- Addressing these problems w/ current and future grant applications



CRAZY-FRANKENSTEIN.COM



Questions?