Best Practices in Environmental Health Research with Tribal communities


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. – US EPA, 2004
- Sovereign tribal governments – Tribal Institutional Review Board is a governing body.
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

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/xvnybwejmx32/Navajo-Genetics-Group-Panel-_FINAL.mp4?dl=0

Upcoming Events

STRAINS 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)

NNHRB MONTHLY MEETING

July 10, 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

2019 Summer Food Service Program
Free Meals for ages 16 & Under at participating schools
a message from Navajo DOH

Click here for more information

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 NNHRBB application/protocol and ten (10) copies due to NNHRBB 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.

<table>
<thead>
<tr>
<th>Traditional</th>
<th>Western</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body &amp; spirit an integral whole</td>
<td>Scientific &gt; personal value</td>
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</table>
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
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

**Breach of Privacy**

- Data from Navajo Nation children and families
  - University of New Mexico
  - NBCS participant address stays at UNM

- Johns Hopkins/RTI ECHO Data Analysis Center (DAC)

- DAC stores NBCS data separate from other ECHO cohorts

- Only DAC, not ECHO cohort researcher, does analyses with individual-level NBCS data

**Breach of Privacy and Unfair Labeling**

- Only selected ECHO researchers (cohort principal investigators) can submit analysis proposals

- Publications Committee reviews, approves (or not) analysis proposal
  - Includes Navajo Nation members

- ECHO cohort researcher or representative (e.g., NBCS researcher) presents findings to NNHRRB

- NNHRRB pre-reviews, approves (or not) submissions

- At close of program, Data Analysis Center returns individuals’ data to Navajo Nation

Agreement signed 3/8/19 by Navajo Nation, Johns Hopkins, RTI
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.
Navajo Birth Cohort Study Cooperating Organizations

**DiNEH Project Team**
- UNM CEHP
- UNM Pediatrics
- UNM Center for Development and Disability
- Southwest Research and Information Center (SRIC)
- Tribal Consultants

**Navajo Birth Cohort**
Mothers, fathers & babies
community members;
chapters

**With Help From**

Growing in Beauty
(developmental disabilities services provider)

**Other Navajo Nation Agencies**
- NN EPA, WIC, Health Education,
  Office of Uranium Workers

**Navajo Area Indian Health Service**
- PL93-638 Facilities
  (Tséhootsooí, Tuba City)

**USEPA Region 9**

**Navajo Nation Department of Health**
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

<table>
<thead>
<tr>
<th></th>
<th>Blood</th>
<th>Urine</th>
<th>Meconium</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mother</strong></td>
<td>Enrollment, Delivery</td>
<td>Enrollment, Delivery</td>
<td></td>
</tr>
<tr>
<td><strong>Father</strong></td>
<td>Enrollment</td>
<td>Enrollment</td>
<td></td>
</tr>
<tr>
<td><strong>Baby</strong></td>
<td>Birth (cord blood), 2-6 months of age, 12 months of age</td>
<td>Birth, 2-6 months of age, 12 months of age</td>
<td>Birth</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Metric of context</th>
<th>Year value</th>
<th>NHANES (50th - 95th percentile range)</th>
<th>Note: Unavailable currency for fewer than 100 participant samples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Arsenic - Urine</td>
<td>5.82</td>
<td>8.18 - 56.80</td>
<td></td>
</tr>
<tr>
<td>Lead - Blood</td>
<td>2.3</td>
<td>4.00 - 10.00</td>
<td></td>
</tr>
<tr>
<td>Mercury - Urine</td>
<td>0.077</td>
<td>0.01 - 0.04</td>
<td></td>
</tr>
<tr>
<td>Total Mercury - Blood</td>
<td>&lt; 1.00</td>
<td>0.35 - 1.30</td>
<td></td>
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</tbody>
</table>
Participan 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

Dear [Name],

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] on [July 8, 2013] at your home in [town], 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 exposure in your home.

In summary, the HEA 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 used 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 microCuries per hour, abbreviated μCi/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 7.6 μCi/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 6.5 μCi/hr is slightly lower than 7.0 μCi/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 calcul...
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 Dootl’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, Ph.D., Sarah Henio-Adeky

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

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

1 University of New Mexico, College of Pharmacy
2 Southwest Research and Information Center
Thinking Zinc —

*Beesh Dootł’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.

INTERESTED?

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

0
Start of study

3 months later
(3rd to 4th month)

3 months later
(6th to 7th month)

3 months later
(9th to 10th month)

Baseline
- Education
- Eligibility screening
- Consent
- Collection of blood (1 tbs) & urine (3 tbs)
- gift card

Baseline/Zinc
- Education
- Continued eligibility
- Food frequency questionnaire
- Collection of blood (1 tbs) & urine (3 tbs)
- 3-month supply of 15 mg Zn tablets provided
- gift card

Zinc
- Education
- Continued eligibility
- Collection of blood (1 tbs) & urine (3 tbs)
- 3-month supply of 15 mg Zn tablets provided
- gift card

Last visit
- Education
- Continued eligibility
- Food frequency questionnaire
- Collection of blood (1 tbs) & urine (3 tbs)
- gift card

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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 1986

The Homestake Mine in 1889

The Homestake Mine in 1986
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
Questions?