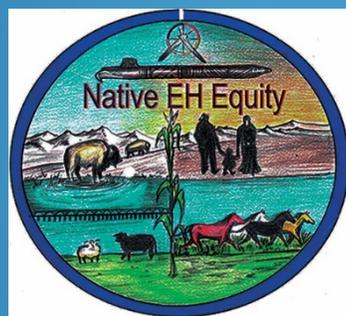




# Tribal IRBs as gateways to open communication in environmental health research

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College of Pharmacy - Community Environmental Health Program*



**Funding:**  
Navajo Birth Cohort Study:  
CDC/NCEH/ATSDR:5U01TS000135-05

*“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.
- Sovereign tribal governments – Tribal Institutional Review Board is a governing body.
- Lack of culturally-centered primary research
  - Limited understanding about environmental contamination on public health.

US EPA, 2004

# 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** – 4<sup>th</sup> 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 – abandoned uranium mining
  - structured Tribal Council oversight on ALL studies done in the Navajo Nation- more than 270 active studies are ongoing
  - Navajo Nation Human Research Review Board, elected 9 members of the Board representing Tribal educational, community, health/medical and cultural/anthropologic research interest and review

# Navajo Nation

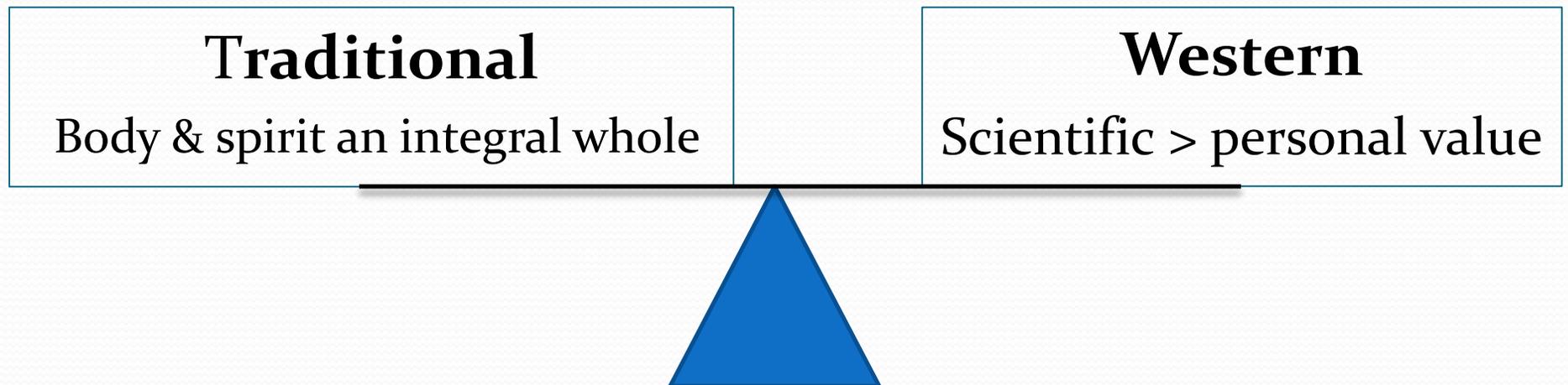
## Human Research Review Board

### 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.



# 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.



## DiNEH Project



## Navajo Birth Cohort Study



## Congressional committee outraged over Navajo uranium legacy

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

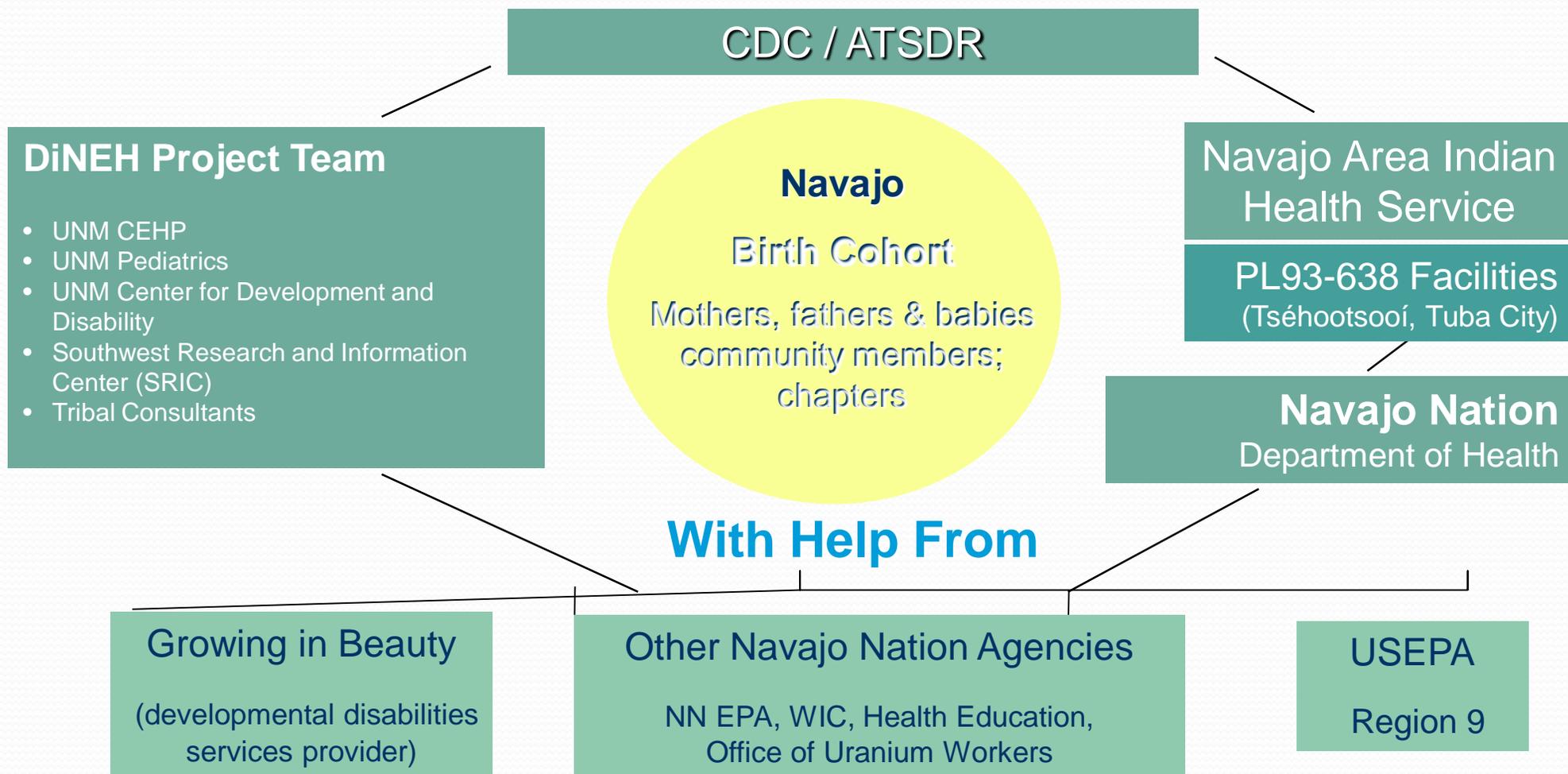
WINDOW ROCK – A picture may be worth a thousand words, but the sound of an instrument used to detect radioactive contamination, clicking away over a soil sample from Tuba City, set a federal oversight committee on its ear Wednesday during a hearing in Washington.

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



# 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"> <li>➤ Enrollment</li> <li>➤ Delivery</li> </ul>	<ul style="list-style-type: none"> <li>➤ Enrollment</li> <li>➤ Delivery</li> </ul>	
Father	<ul style="list-style-type: none"> <li>➤ Enrollment</li> </ul>	<ul style="list-style-type: none"> <li>➤ Enrollment</li> </ul>	
Baby	<ul style="list-style-type: none"> <li>➤ Birth (cord blood)</li> <li>➤ 2-6 months of age</li> <li>➤ 12 months of age</li> </ul>	<ul style="list-style-type: none"> <li>➤ Birth</li> <li>➤ 2-6 months of age</li> <li>➤ 12 months of age</li> </ul>	<ul style="list-style-type: none"> <li>➤ Birth</li> </ul>

# 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 Healthy

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 (NBSC) wants to thank you for participating in the study. As you know, the NBSC 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 NBSC, 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 <sup>th</sup> – 95 <sup>th</sup> percentile range)	Note: Unavailable; currently fewer than 100 participant samples NBSC (Range: n = )
(Total Arsenic - Urine)	3.82	8.18 - 85.80	
(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  
sric.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 microroentgens 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 calculated as  $8.6 \mu\text{R/hr}$ .

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

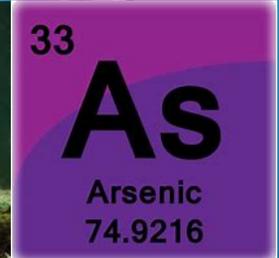
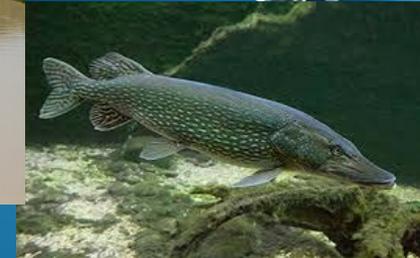
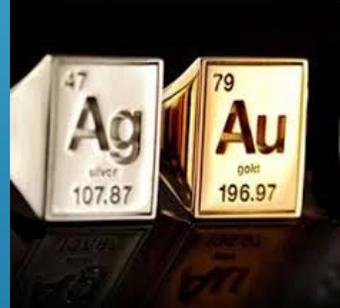
- Navajo Area Indian Health Service medical providers (primary care physicians, midwives, nurses, surgery) receive regular updates and education
- Navajo HIS health technicians and laboratory personnel also receive updates - increase their assistance in enrollment and follow-up of babies
- Participants 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



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 on CRST – 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, to create Tribal businesses
- Farming/ranching, community-level exposures to pesticides
- Public health concerns of very high rates of active cigarette smoking, indoor exposures to chemicals
- Addressing these problems w/ current and future grant applications



CRAZY-FRANKENSTEIN.COM



# Questions?