

When Place Identifies People.

Can Causes of Disparities Be Identified Without Creating New Risks?

Data Sovereignty and Privacy in the Age of Big Data

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UNM METALS Superfund Research Center (METALS)

Center for Native Environmental Health Equity Research (Native EH Equity)

Navajo Birth Cohort Study/Environmental influences on Child Health Outcomes (NBCHS/ECHO)

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NIH National Institute of Environmental Health Sciences
Your Environment. Your Health.

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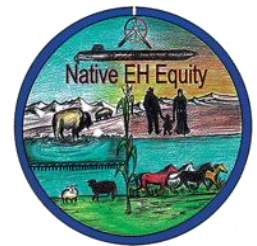
National Institute of Minority Health and Health Disparities
P50 MD015706 – Native EH Equity Research Phase 2



2000



2010



2014



2016



2016

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USEPA 83615701 – Native EH Equity Research Phase 1
CDC U01 TS000135 – Original Navajo Birth Cohort Study



Tribal Sovereignty, Treaties, Research, and Trust

- **Treaty Rights: Entered into by US Government**
 - Historically poorly adhered to by federal government – treaty lands given to resource extraction throughout country

- **Sovereign Nations w/in US borders: Right to self-governance existed prior to colonization/contact, acknowledged through treaty rights**
 - Sovereignty extends to data sovereignty and protection of privacy of individuals and tribe
 - Many tribes now have own research policy, FWA accredited IRBs in addition to academic and IHS review

- **Substantial environmental and economic injustice has resulted from lack of federal adherence to treaties and honor of sovereign rule.**
 - Congressional reversals of treaty obligations to allow for resource exploitation
 - Mining in Black Hills reversed treaty documented ownership of Sioux
 - Cold War Uranium mining throughout Navajo → >500 abandoned mines,
 - Death of generation of Navajo miners



Perceptions of research in Indigenous communities: Generalized distrust of research based on historical abuses

- “Helicopter” Research
 - Scientists enter communities, collect data, leave, publish – mission accomplished
 - No report back, no benefit accrues to communities – scientists enhance reputation
 - Often published results conflicting with tribal culture, origin stories
 - Incriminated behaviors as linked to disease, exacerbating discrimination and racism

- Turning Point: Havasupai law suit against ASU
 - 1989 -- Samples collected under informed consent for Type 2 diabetes research
 - DNA samples distributed to others after consented use
 - Publications on tribal origins, inbreeding, and schizophrenia
 - 2004 lawsuit by Havasupai settled in 2010: return of samples, clinic & school, financial award (\$700,000)
 - No precedent for future research to ensure no recurrence
 - 2013 study of IRB members indicated take-home message was to create broader informed consents! (*Garrison, Sci Technol Human Values. 2013:38(2): 201-223*)



What were the issues of concern to tribes in Havasupai case?

- Research conducted beyond original consent
- Publication of results beyond issues of concern or interest to the tribe
- Stigmatization – migration publications in conflict with culture; increased discrimination; increased historical trauma
- Improper disposal of samples – All parts of people are sacred, right to return of sample
 - Return of the DNA to participants a key of the settlement

IMPACT

Many tribes instituted bans or moratoriums on future genetic research

Tribal IRBs (w/ FWA) or other formal review and approval processes implemented for all research



Problems from moratoriums and bans

- Significant underrepresentation of indigenous populations in environmental health research
- Exacerbated further when considering genomic research: <0.05% globally
 - *(Garrison et al, Annu. Rev. Genom. Hum. Genet. 2019. 20:495–517)*
- Dominant-culture data generalized to develop treatment and prevention strategies
 - May or may not be appropriate – may even be lethal!
 - Environmental exposure limits may or may not protect

*How to bridge the gap and ensure
 respect of culture,
 control of data,
 involvement in planning and implementation, and
 accrual of benefits to indigenous people*

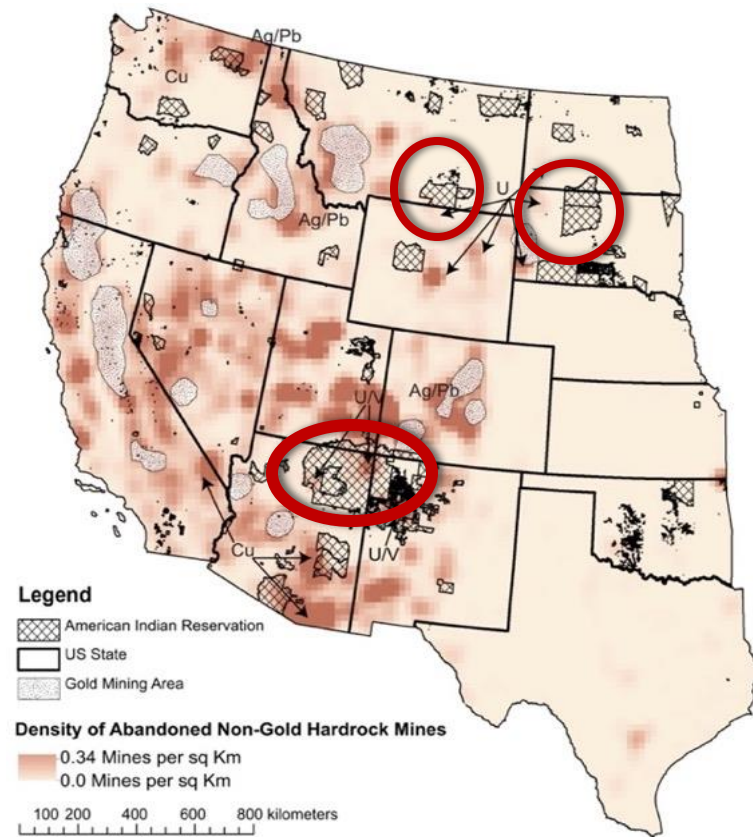
Prevent abuses of past



Uranium and other metal mixtures in mine waste widespread in Indian Country

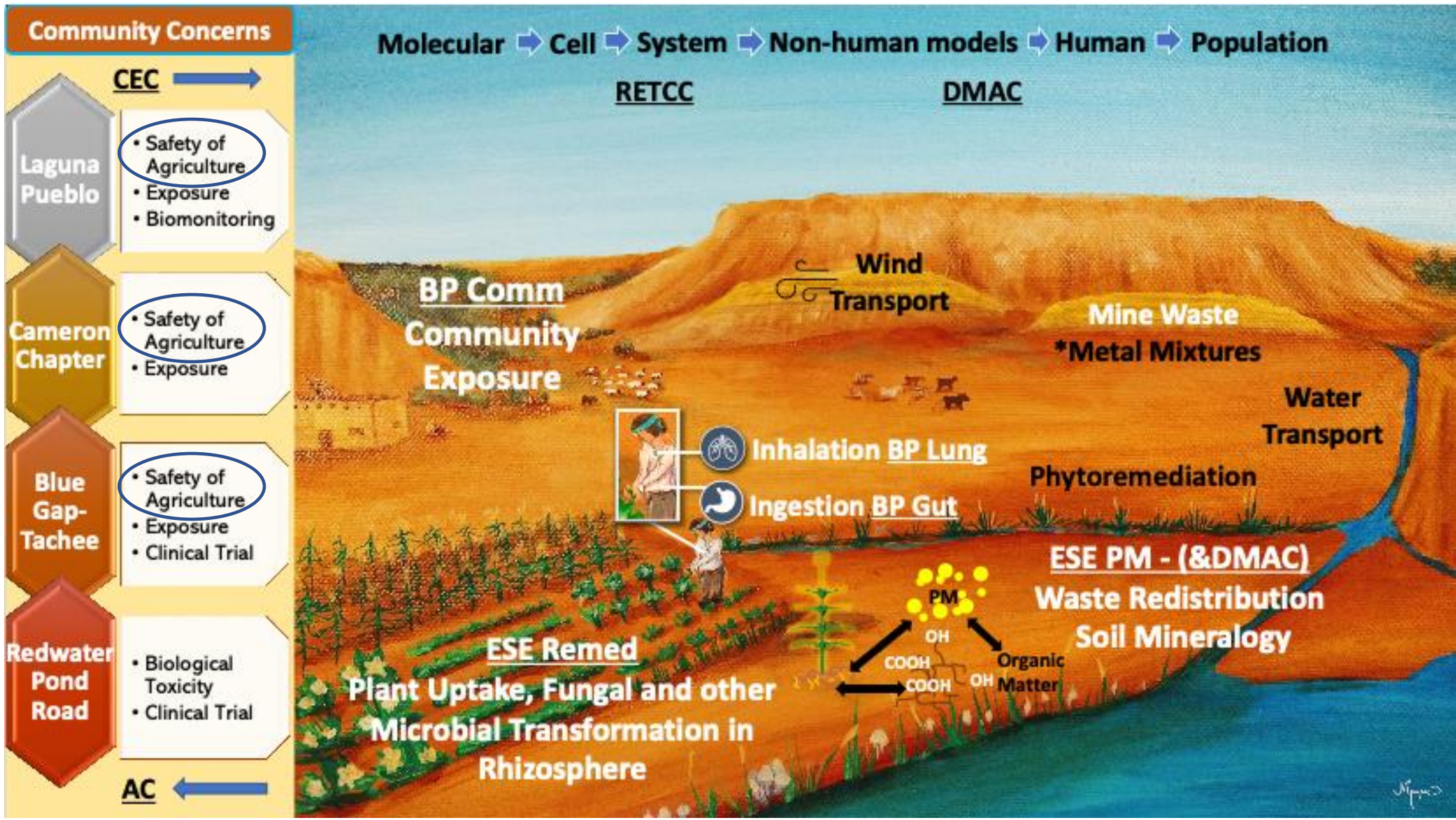
15 Western US States

- Home to >50% US indigenous population
- 161,000 abandoned hard rock mines (GAO)
- 5,000 – 10,000 abandoned *uranium* mines (USEPA – DOE)
- **>600,000 Indigenous peoples w/in 10km of abandoned mine waste (based on 2010 Census)**
- Waste has contaminated 40% of Western US surface waters (USEPA)



Tribal boundaries and history frequently link exposures to tribal members despite geoshifting

METALS Superfund Research Center Conceptual Model



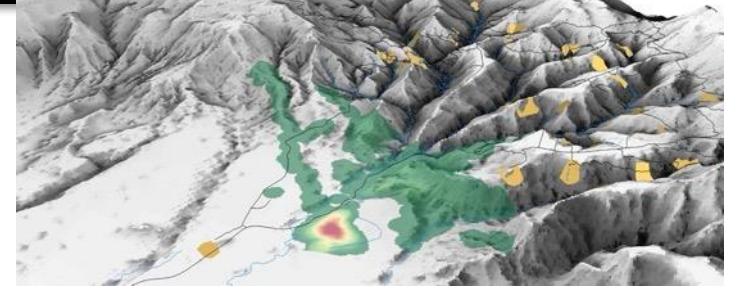
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Assessing Agricultural Pathways

Risks

- Health
 - Toxicity to current & future generations
- Economic
 - Loss of market

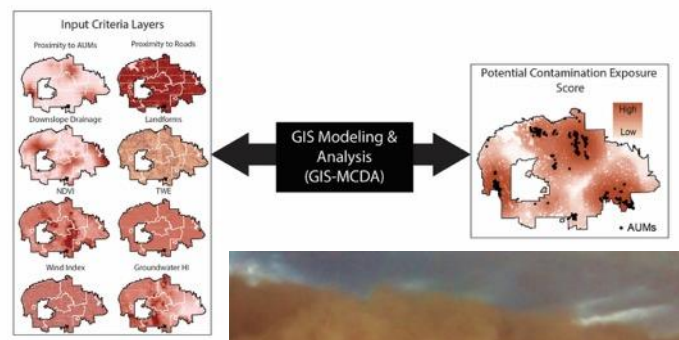
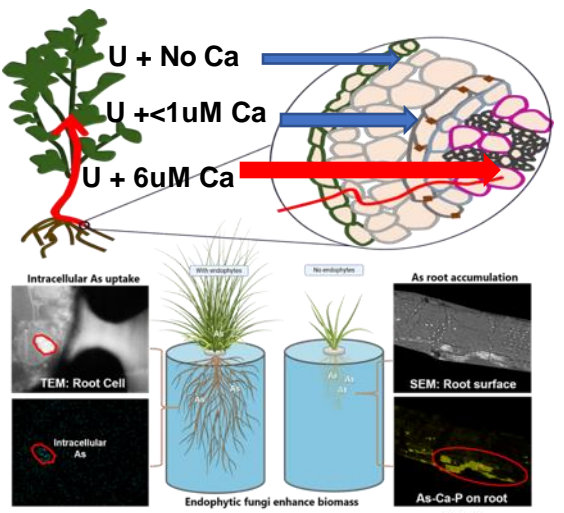


How and where do livestock graze?

Benefits

- Understanding mechanisms can help mitigation/risk reduction
 - w/o data, uncertainty → belief in worst case scenario
 - Understanding uptake controls → soil amendment
 - Understanding grazing patterns → ID of true risk → land use controls

What controls plant uptake?



Does waste redistribute?

Lin et al., 2020. Environmental Science and Pollution Research, 27, 30542-30557.

El Hayek et al., Environ Sci Technol. 2018; 20;52(22):13089-13098.
DeVore et al., ACS Earth Space Chem. 2021 17;5(6):1278-1287.



How can respectful AND valid research be developed?

- Open and repeated discussion with communities (multiple chapters)
- Involvement of tribal agencies (Tribal Environmental Protection Agency, Veterinary Services)
- Sharing of research and cultural needs to find common ground
- Continual sharing of data as the process develops
- Train community members to collect data, be part of research team



Assessment of perspectives



Meeting Summary

Tribal Data Sharing and Genetics Policy Development Workshop

August 30 – September 1, 2017
UNM Comprehensive Cancer Center
Albuquerque, NM

Developed by UNM CEHP with support from

- NIH Tribal Health Research Office
- NHGRI
- NCAI
- UNMCCC

20+ years after Navajo moratorium put in place, panel participants included

- Multiple medicine associations
- Navajo IRB
- Navajo Council Delegates
- Community Members
- Indigenous researchers
- Non-indigenous researchers working with tribes
- NIH OD, THRO, NHGRI

Consensus: Need to move forward with control through policy

Committee struck, policy developed, vote pending

Big Data, Public Datasets



- Navajo Birth Cohort Study – began through request of tribe and communities (2013)
 - Collaborative community design
 - All Navajo field staff
 - Navajo Nation Department of Health and Navajo IHS partners

- Environmental influences on Child Health Outcomes (ECHO)(2016) – opportunity to follow cohort, understanding longer term impacts, developed evidence-based care with Navajo IHS for first time

- BUT!
 - Required sharing of data onto publicly accessible server, combining data with that from non-indigenous cohorts that would be linked to Navajo
 - Reconciliation of risks, benefits, and needs to protect sovereignty

Navajo research oversight under Navajo-ECHO data sharing and use agreement.

	<u>Before the agreement</u>	<u>Under the new agreement</u>
Navajo Birth Cohort Study (NBCS)	Single cohort study	Part of ECHO, a US nationwide consortium of cohort studies
Navajo Nation	Owns data	Owns data—ECHO Data Analysis Center holds a copy of NBCS data, returns them at end of program
	Did not allow data use beyond trusted partners who are doing the research	Allows data use to larger circle, ECHO principal investigators, to propose analyses
Navajo Nation Human Research Review Board (NNHRRB), its Institutional Review Board	Approved every analysis proposal	Has representative to ECHO Publications Committee, who informs NNHRRB of proposals Committee has approved
	Reviewed every manuscript before submission	Reviews only manuscripts that identify Navajo (or Native American) separately
	Required lead investigator to appear before Board for initial proposal and interim reports	Allows proxy to report to Board

ECHO approaches to research oversight under Navajo ECHO data sharing and use agreement. For ECHO-wide Cohort data analyses.

	<u>For all other ECHO cohorts</u>	<u>For the Navajo Birth Cohort Study (NBCS)</u>
Data Sharing	Cohorts must share exact dates onto ECHO-wide Cohort data platform	NBCS may share coded dates
Data Use	Cohorts must share addresses onto ECHO-wide Cohort data platform	University of New Mexico holds addresses. ECHO Data Analysis Center may use them in a distributed data approach.
	All data merged into single database	Data Analysis Center stores NBCS data separately. Analyst merges them with other cohorts per analysis proposals approved by ECHO.
ECHO-wide Cohort data analyses	Any investigator may propose an analysis if no NBCS data	Only ECHO principal investigators may propose an analysis if includes NBCS data
	Cohort investigator/analyst may perform data analysis if no NBCS data	ECHO Data Analysis Center or NBCS analyst must perform data analysis if includes NBCS data

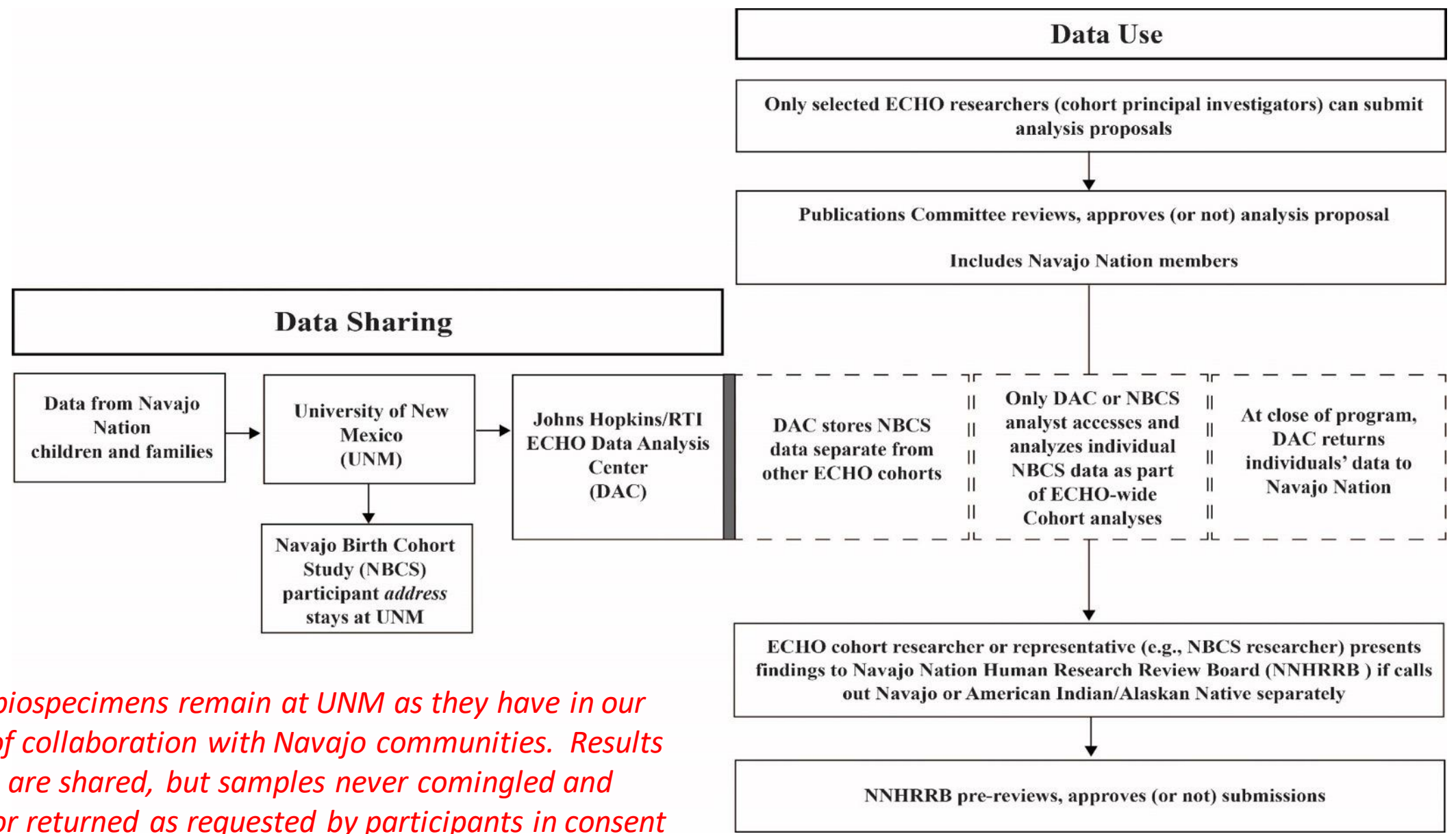
Navajo-ECHO Data Sharing Agreement

- ~ 2 years to negotiate – NIH OD facilitated
 - Many f2f discussions
 - Signed by tribal executive branch and ECHO Data Analysis Center that holds the data
- **Compromise on both sides**
- Built-in process for iterative evaluation and revision

NBCS ECHO & METALS SUPERFUND



Summary of Navajo-ECHO data sharing and use agreement stipulations. Protections throughout pipeline from analysis proposal to manuscript submission.



NOTE: All biospecimens remain at UNM as they have in our >20 years of collaboration with Navajo communities. Results of analyses are shared, but samples never comingled and destroyed or returned as requested by participants in consent



History is long, trust is minimal

Listening, honesty & inclusion essential to success



- Integration of community into planning and implementation to ensure common goals
- Recognize *community* has many levels (members, executive, council, clinicians)
- Involve community members in data collection
- Ensure regular communication of results, plan for benefit
- Ensure security of data, samples, and appropriate return and destruction





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NBCS
Navajo
Birth Cohort Study



ECHO
Environmental influences
on Child Health Outcomes
A program supported by the NIH

The people of the Navajo Nation:

- > 1000 participating Navajo families
- Many supporting chapters
- HEHSC, Tribal and Agency Councils, Executive Branch, NNEPA, GIB
- NAIHS & PL-638 hospital laboratory staff, leadership, and health boards

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