Data-Sharing in Research: Maximizing Benefits and Minimizing Risks for Alaska Native and American Indian Populations

5th Alaska Native Health Research Conference

R. Brian Woodbury
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65,000 voices
Vision
A Native Community that enjoys physical, mental, emotional and spiritual wellness

Mission
Working together with the Native Community to achieve wellness through health and related services
Goals

Shared Responsibility
Commitment to Quality
Family Wellness
Customer-Ownership
Operational Principles

Relationships between customer-owner, family and provider must be fostered and supported

Emphasis on wellness of the whole person, family and community (physical, mental, emotional and spiritual wellness)

Locations convenient for customer-owners with minimal stops to get all their needs addressed

Access optimized and waiting times limited

Together with the customer-owner as an active partner

Intentional whole-system design to maximize coordination and minimize duplication

Outcome and process measures continuously evaluated and improved

Not complicated but simple and easy to use

Services financially sustainable and viable

Hub of the system is the family

Interests of customer-owners drive the system to determine what we do and how we do it

Population-Based systems and services

Services and systems build on the strengths of Alaska Native cultures
Work together in relationship to learn and grow
Encourage understanding
Listen with an open mind
Laugh and enjoy humor throughout the day
Notice the dignity and value of ourselves and others
Engage others with compassion
Share our stories and our hearts
Strive to honor and respect ourselves and others
Leadership Principles

Operate from the strength of Alaska Native cultures and traditions of leadership.

Will stand in the gap to align and achieve the mission and vision.

Nurture an environment of trust that encourages buy-in, systematic growth and change.

Encourage ownership of responsible, calculated risk taking.

Expect and grow the skills of future generations to drive initiatives and improvements.

Share and listen to personal life stories in order to be transparent and accountable.

Hedge people in by creating a safe environment where spiritual, ethical and personal beliefs are honored.

Improve for the future by learning from the past, giving away credit and celebrating achievements.

Practice and encourage self-improvement believing there is good in every person.
Data Sharing: Presentation Overview

- Data sharing Review: Terminology and Process
- Increasing Interest in Data Sharing: Research Trends, Programs, Policies, and the Private Market
- Benefits and Harms of Data Sharing: Determining the Value of Data Sharing in Different Contexts
- Data Sharing Policy: Comparing NIH and Tribal Policy
- Data Sharing Research Project: Methods and Preliminary Findings
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Data Sharing: The sharing of data to enable validation of original research and to inform secondary research.

De-identification: The process of removing unique identifiers from private health information, in order to protect the privacy of research participants and patients.

Data Repository/Biobank: A physical or virtual database used to store and manage data or biospecimens collected for, or produced in the conduct of, research.

Data Access Committee: A committee in charge of reviewing requests to access information held in a data repository or biobank and granting access as appropriate.

Secondary Research: Research conducted using data accessed through a data repository or via other data sharing methods.
Data Sharing: Components and Process

Participant → Scientist
Data Sharing: Components and Process

Original Research
Data Sharing: Components and Process

Data Repository
Data Sharing: Components and Process
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Data Sharing: Components and Process

Secondary Research
Data Sharing: A Growing Issue

Data Sharing Articles (2000-2017)
Data Sharing: A Growing Issue

The All of Us Research Program will collect and share genetic, lifestyle, and environmental data from 1,000,000 or more research participants.

Enhanced data sharing is a scientific priority for the Cancer Moonshot program, which aims to accelerate progress in cancer research, improve prevention and early diagnosis, and ensure access to cancer treatment and clinical trials for all patients.
“We may share aggregate information with third-parties, which is any information that has been stripped of your Registration Information (e.g., your name and contact information) and aggregated with information of others so that you cannot reasonably be identified as an individual ("Aggregate Information").... We may provide such Aggregate Information in commercial arrangements with our business partners.”  [23andMe Full Privacy Statement.]
Data Sharing: A Growing Issue
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National Institutes of Health: “Data should be made as widely and freely available as possible while safeguarding the privacy of participants, and protecting confidential and proprietary data.” [NIH Data Sharing Policy and Implementation Guidance]

National Academy of Medicine: “Stakeholders in clinical trials should foster a culture in which data sharing is the expected norm, and should commit to responsible strategies aimed at maximizing the benefits, minimizing the risks, and overcoming the challenges of sharing clinical trial data for all parties. [IOM, 2015. Sharing clinical trial data: maximizing benefits, minimizing risk.]”
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**International Committee of Medical Journal Editors:** “As of 1 July 2018 manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement....Clinical trials that begin enrolling participants on or after 1 January 2019 must include a data sharing plan in the trial's registration.” [Taichman, D.B., Sahni, P., Pinborg, A., Peiperl, L., Laine, C., James, A., Hong, S.T., Haileamlak, A., Gollogly, L., Godlee, F. and Frizelle, F.A., 2017. Data Sharing Statements for Clinical Trials—A Requirement of the International Committee of Medical Journal Editors.]

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- The Electronic Medical Records and Genomics (eMERGE) Database combines genetic and medical records data from over 100,000 participants and has contributed to over 500 publications. [https://emerge.mc.vanderbilt.edu/about-emerge/]
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- Among genetic variants submitted to the ClinVar database by four clinical laboratories, 11.7% (n=724) were discordant and 3.5% (216) were medically significant discordances. **Among 100 initially discordant variants subsequently resolved through reassessment, data-sharing was identified as the key factor in resolving 33% (n=33).**

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- A systematic review of 40 empirical studies assessing stakeholder perspectives on data-sharing and related issues found that a majority of patients and members of the general public were “willing to donate their biological samples to research for altruistic reasons” and recognized data sharing in the context of genomic research as “providing benefits for future generations, science and health”.
  
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“**We demonstrate experimentally the identification of the presence of genomic DNA of individuals within a series of highly complex genomic mixtures... There is a considerable push to make experimental data publicly available so that the data can be combined with other studies. Our findings show that such an approach does not completely conceal identity, since it is straightforward to assess the probability that a person or relative participated in a GWA study.**”

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“There is some doubt as to whether [broad consent] enables individuals to fully exercise their autonomy, as they cannot choose whether to be involved in specific research projects using different biorepositories, determine what kind of research they participate in, or properly assess the privacy risks of involvement.” [See: Kaye, J., 2012. The tension between data sharing and the protection of privacy in genomics research. Annual review of genomics and human genetics, 13, pp.415-431.]
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“Special data access committees have been established...in addition to the normal research ethics committees...These special data access committees develop a new tier of oversight in addition to research ethics committee approval, but there is some doubt as to whether they are the right model to enable effective supranational data sharing.” [Kaye, J., 2012. The tension between data sharing and the protection of privacy in genomics research. Annual review of genomics and human genetics, 13, pp.415-431.]
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- Among surgical cancer trials funded by the National Cancer Institute and conducted between 2000-2002, AN/AI individuals accounted for only 0.25% of 13,991 total participants. [Stewart JH, Bertoni AG, Staten JL, Levine EA, Gross CP. Participation in surgical oncology clinical trials: gender-, race/ethnicity-, and age-based disparities. Ann Surg Oncol. 2007; 14(12):3328–3334.]
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*Havasupai Case Highlights Risks in DNA Research*
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**Misalliances in the Barrow Alcohol Study.**

**Subjects in Radiation Experiment Were Not Informed, Panel Says**

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- Compared with majority populations, AN/AI people have both more to potentially gain and more to potentially lose from participation in data sharing.
- Data sharing in the context of genetic research creates new, and exacerbates existing, benefits and drawbacks.
- There is need for policies that maximize the benefits and minimize the risks of data sharing for AN/AI individuals and communities.
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NIH Genomic data-sharing policy (2015): “The National Institutes of Health (NIH) Genomic Data Sharing (GDS) Policy sets forth expectations that ensure the broad and responsible sharing of genomic research data.”

▪ The policy applies to “all NIH-funded research that generates large-scale human or nonhuman genomic data as well as the use of these data for subsequent research.”
▪ The policy applies “irrespective of funding level and funding mechanism (e.g., grant, contract, cooperative agreement, or intramural support).”

NIH Policy Proposal (Sept. 2017): NIH is proposing to allow broader access to genomic summary results from most studies subject to the NIH GDS Policy. Institutions submitting genomic data to NIH-designated data repositories will be expected to notify NIH of any studies for which there are particular sensitivities...Access to genomic summary results from such datasets will remain under controlled access.
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Data Sharing: Proposed GDS Update

- Unrestricted Access
- Rapid Access
- Controlled Access
Data Sharing: Tribal Policy

▪ **Southcentral Foundation Research Agreement:** All specimens collected from SCF patients or from SCF tissue or data banks during the research project shall be the property of SCF, and shall be returned to SCF when the research is complete...SCF shall retain ownership of the specimens of human biological material collected from SCF patients or SCF data or tissue banks during the Research Project. [SCF Research Agreement. 2012.]

▪ **Turtle Mountain Band of Chippewa Indians Research Protection Act:** Upon completion of the research project...the biological samples must be completely and fully returned to the Tribe...No biological samples from this study may be released to, or used by, any other researcher(s), research institution, or any other entity, whether public or private, without the prior and fully-informed written approval of the Tribe. [Turtle Mountain Band of Chippewa Indians Research Protection Act. 2014. Section 10: Regulation of Biological Samples.]

▪ **Navajo Nation Moratorium on Genetic Research:** “The Health and Social Services Committee on the Navajo Nation Council hereby approves a moratorium on genetic investigations, research or studies that are conducted within the Navajo Nation until such time that a Navajo Nation Health Research Code has been amended and approved by the Navajo Nation Council.” [HSSCAP-20-02. 2002. Resolution of the Health and Services Committee of the Navajo Nation Council.]
Data Sharing: Tribal Policy

- **Southcentral Foundation Research Agreement**: All specimens collected from SCF patients or from SCF tissue or data banks during the research project shall be the property of SCF, and shall be returned to SCF when the research is complete...SCF shall retain ownership of the specimens of human biological material collected from SCF patients or SCF data or tissue banks during the Research Project. [SCF Research Agreement. 2012.]

- **Turtle Mountain Band of Chippewa Indians Research Protection Act**: Upon completion of the research project...the biological samples must be completely and fully returned to the Tribe...No biological samples from this study may be released to, or used by, any other researcher(s), research institution, or any other entity, whether public or private, without the prior and fully-informed written approval of the Tribe. [Turtle Mountain Band of Chippewa Indians Research Protection Act. 2014. Section 10: Regulation of Biological Samples.]

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Data Sharing: Joint Policy?

Research Community Values and Goals
- Objectivity
- Academic Freedom
- Open Access
- Advance Knowledge
- Benefit Society

AN/AI Community Values and Goals
- Cultural Heritage
- Tribal Sovereignty
- Benefit Community
- Traditional Knowledge
- Self-Determination
Data Sharing: Joint Policy?

Shared Goals and Values

Objectivity
Academic Freedom
Open Access
Advance Knowledge
Benefit Society

Cultural Heritage
Tribal Sovereignty
Benefit Community
Traditional Knowledge
Self-Determination

Benefit Society

Academic Freedom

Open Access
Advance Knowledge

Objectivity

Cultural Heritage
Tribal Sovereignty
Benefit Community
Traditional Knowledge
Self-Determination
Data Sharing: Research Questions

Within the context of ANAI communities:

▪ What is the state of current and emerging policies, protocols, and practices on data sharing in general, and genetic data-sharing in particular?

▪ What common ground exists between the data sharing policies adopted by tribal governments and the data sharing policies adopted by stakeholders within the research community?

▪ What does an ethical, effective, and culturally appropriate model for genetic data sharing look like?
## How are scoping and systematic reviews different?

<table>
<thead>
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<th>Scoping Review</th>
<th>Systematic Review</th>
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</tr>
</tbody>
</table>
Data Sharing: Research Methods

Search Strategy

**Concept MeSH Terms:** information storage and retrieval; computer security; data anonymization; databases as topic; information dissemination; confidentiality; privacy; personally identifiable information; informed consent; informed consent by minors; consent forms; freedom; incidental findings; pharmacogenetics; genetic research; genetics, medical; genetics; genetic privacy; databases, genetic; guidelines [publication type]; guidelines as topic; practice guidelines as topic; clinical protocols; guideline adherence; records as topic; policymaking; decision-making, organizational; program development; program evaluation; constitution and bylaws; organizational policy; trust

**Population MeSH Terms:** Indians, North American; Inuits; Alaska Natives

**Concept Keywords [All Fields]:**

- **Data-Related:** data sharing; data stewardship; data control; data ownership; data harmonization; data governance; data access; data release; data management; data use; data repository; biobank
- **Privacy:** Reidentification; deidentification; identifiable
- **Informed Consent:** withdrawal; consent*; reconsent
- **Return of Results:** return of results; secondary research; secondary use; results management
- **Programs:** Wisewoman; special diabetes program; cervical cancer early detection program; colorectal cancer screening
- **Documents:** policy; practice; guideline; principle; recommendation; standard; process; document; record
- **Ethics:** stigma; harm; research ethics
Data Sharing: Research Methods

Study Selection

484 Articles (PubMed) + 27 Articles (Consultants)

511 Total Initial Articles

Title and Abstract Review

78 Relevant Articles

18 Background Articles

415 Non-Relevant Articles
Data Sharing: Research Methods

78 Relevant Articles

Article Sorting Protocol

Article Type
- Empirical Research
- Conceptual/Theoretical Studies
- Reviews
- Commentary, Editorials, Letters
- Guidelines and Recommendations

Article Topic
- ELSI Research
- Genetic Data Sharing
- Participatory Research (TPR, CBPR)
- Data Sharing Program of Interest
- Research Regulation
Data Sharing: Preliminary Findings

- Research efforts equally distributed over theoretical and empirical research
- Minimal synthesis of existing literature
- Limited number of published descriptions/evaluation of program documents
- Data sharing guidelines/recommendations exist, but are limited
Emphasis on data sharing in the context of genetic research and on the Ethical, Legal, and Social Implications (ELSI) of data sharing

Research regulation is a focus of research

Publications on participatory research methodology and programs of interest as they relate to data sharing are limited
Data Sharing: Preliminary Findings

- Tribes have access to a broad range of mechanisms for regulating research. Mechanisms include: Tribal IRBs, Research agreements, Research codes, Community Advisory Boards, Tribal Resolutions, Memoranda of Understanding/Agreement, and Data Sharing Agreements.

- Participatory research methods are seen as a tool for promoting tribal control over data sharing. Methods include: Community-Based Participatory Research, Tribal Participatory Research, and Indigenous Methodologies.

- ELSI Research has identified data sharing as a key ethical concern for genetic research in particular. Related ethical concerns include: Return of results, Broad consent, Inherent identifiability of genetic information, Culturally grounded approaches to data/biospecimen management, and Attribution of original research activity.
Thank You!

- Hák’aa – Haida
- Mahsi’ – Gwich’in Athabascan
- Quyana – Yup’ik
- Tsin’aen – Ahtna Athabascan
- Qaɣaasakung – Aleut
- Quyanaa – Alutiiq
- Igamsiqanaghalek – Siberian Yupik
- Gunalchéesh – Tlingit
- Gwich’in Athabascan
- Tsimshian
- Quyanaq – Inupiaq
- T’oyaxsm – Eyak
- Hák’aa – Haida
- Qaɣaasakung
- Alutiiq
- Inupiaq
- Tlingit
- Dena’ina Athabascan

Thank You!