NIH Policies, Protections, and Implications for the Ethical Conduct of Research with Tribal Communities, including Genetic Research

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Office of Science Policy, NIH

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Tribal Health Research Office, NIH (Detail)

November 7, 2022

NIH National Institutes of Health
Tribal Health Research Office
Building research partnerships for healthy Tribal Nations

Overview

- Historical Review of Research Protections and Current Policies
- Contemporary Research Protection Insights and Practices
- Consent and Genomic Data Sharing
- Data Management and Sharing
- Importance of Inclusion and Diversity

Research Protections

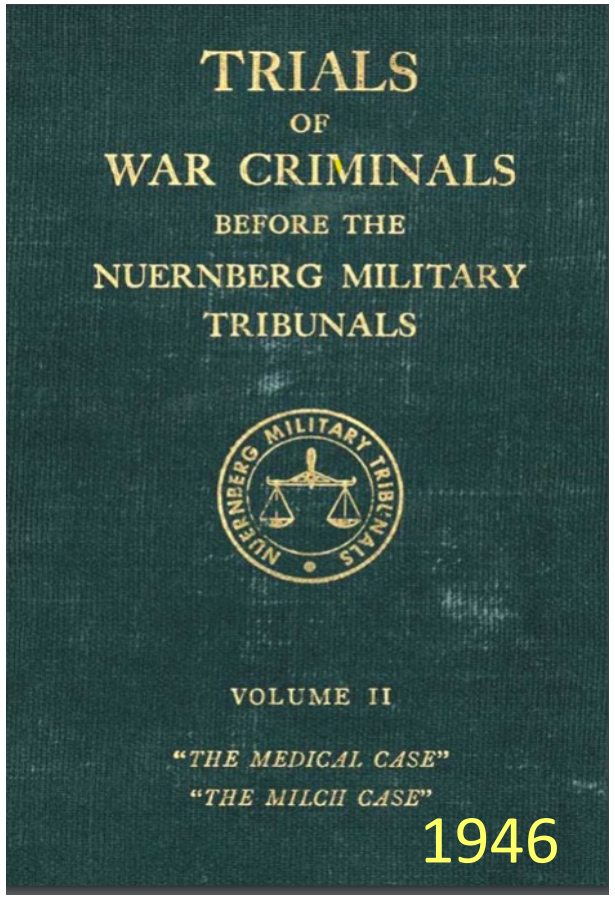
- Why are they necessary?
- Developing an ethical enterprise

1937 – Sulfanilamide Elixir

Those who cannot remember the past are condemned to repeat it.

George Santayana

Nuremberg Trials and Code

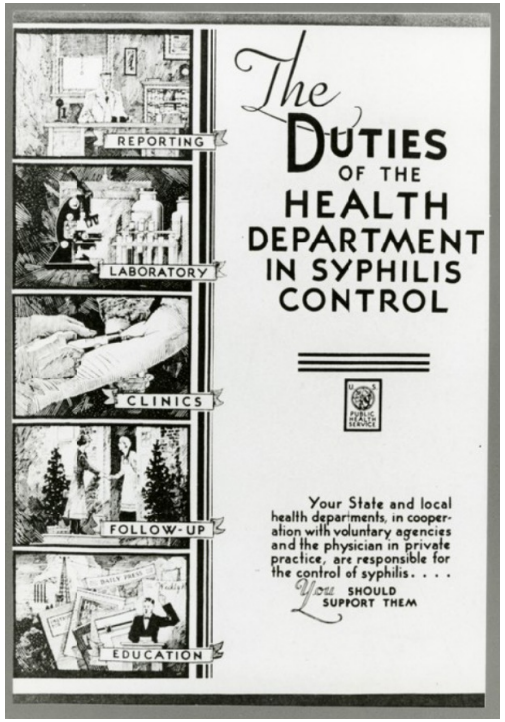


Nuremberg Code (1948)

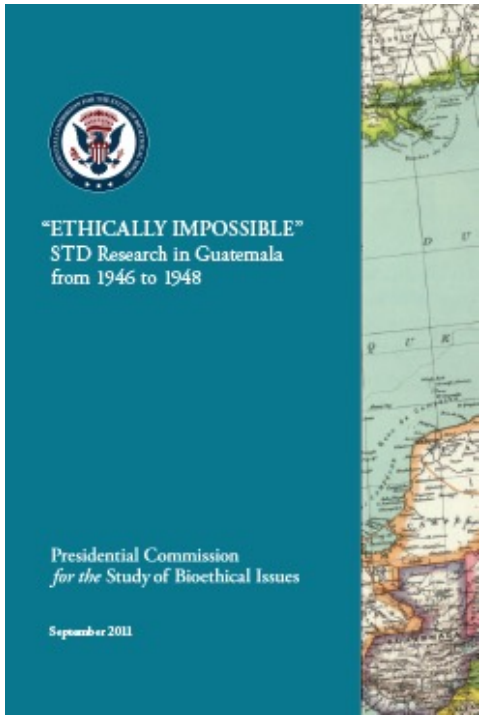
1. The **voluntary consent** of the human subject is absolutely essential.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study, that the **anticipated results will justify the performance of the experiment.**
4. The experiment should be so conducted as to **avoid all unnecessary physical and mental suffering and injury.**
5. No experiment should be conducted, where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to **protect** the **experimental subject against even remote possibilities of injury, disability, or death.**
8. The experiment should be **conducted only by scientifically qualified persons.** The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment, the human subject should be at liberty to bring the experiment to an end, if he has reached the physical or mental state, where continuation of the experiment seemed to him to be impossible.
10. During the course of the experiment, the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgement required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject

Significant Failures to Protect Research Participants and the Public

1932-1972 Tuskegee



1946-1948 Guatemala



1953-1962 - Thalidomide

Declaration of Helsinki (1964)

Basic principles for physician involvement in research

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964
and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added)
55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)
59th WMA General Assembly, Seoul, Republic of Korea, October 2008
64th WMA General Assembly, Fortaleza, Brazil, October 2013

- Based on animal experimentation first;
- Research protocols reviewed by independent body
- Conducted by scientifically qualified individuals and take responsibility for participants welfare
- Weigh benefit-risk
- Respect for participant privacy
- Voluntariness; use of informed consent

Further Developments

Surgeon General Policy (1966)

SURGEON GENERAL'S DIRECTIVES ON HUMAN EXPERIMENTATION

THE Surgeon General, Public Health Service, United States Department of Health, Education,
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Health Service in the support of research, training, or demonstration projects, including the projects supported through general research support and those of fellows and trainees. The policy is not

grantee institutions to assist the Service in the conduct of its study.

No new, renewal, or continuation research or research training grant in support of clinical research and investigation involving human beings shall be awarded by the Public Health Service unless the grantee has indicated in the application the manner in which the grantee institution will provide prior review of the judgment of the principal investigator or program director by a committee of his institutional associates. This review should assure an independent determination: (1) of the rights and welfare of the individual or individuals involved, (2) of the appropriateness of the methods used to secure informed consent, and (3) of the risks and potential medical benefits of the investigation. A description of the committee of the associates who will provide the review shall be included in the application.

SUPERSEDES: PPO #129, February 8, 1966
PPO #129 Supplement, April 7, 1966

1. BACKGROUND

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VART, M.D.

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National Research Act (1974)

342 PUBLIC LAW 93-348—JULY 12, 1974 [88 STAT.

Public Law 93-348

July 12, 1974
[H. R. 7724]

AN ACT

To amend the Public Health Service Act to establish a program of National Research Service Awards to assure the continued excellence of biomedical and behavioral research and to provide for the protection of human subjects involved in biomedical and behavioral research and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

National Research Act.
42 USC 289l-1 note.

SECTION 1. This Act may be cited as the "National Research Act".

TITLE II—PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

PART A—NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

ESTABLISHMENT OF COMMISSION

42 USC 289l-1 note.

SEC. 201. (a) There is established a Commission to be known as the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (hereinafter in this title referred to as the "Commission").

Belmont Report (1979)

NIH National Institutes of Health
Office of Science Policy

Belmont Principles and Application

Principles

- **Respect for persons**
  - Individuals should be treated as autonomous agents
  - Persons with diminished autonomy are entitled to protection
- **Beneficence**
  - Do no harm
  - Maximize possible benefits and minimize possible harms
- **Justice**
  - Research benefits and risks need to be fairly distributed

Application

- **Informed consent**
  - Research participants should be given the opportunity to choose what happens to them
  - Participation in research should be voluntary and free from undue influence/coercion
  - Informed consent has 3 elements: information, comprehension, and voluntariness
- **Risks and benefits must be systematically assessed**
  - Determine validity of the presuppositions of the research
  - Distinguish nature, probability, and magnitude of risks (risks should be reduced to those necessary to achieve the research objective)
- **Selection** of participants
  - Should be **fair** procedures and outcomes in the selection of research participants

“Common Rule” (1981-present)

- HEW and FDA revise human subjects regulations taking into account foundation laid by Belmont
- President’s Commission calls for all federal agencies to adopt HHS human subjects regulations
- 1991 – 15 depts and agencies adopt Common Rule
- Today – 20 departments and agencies
- Outlines basic provisions for IRBs (membership, function, operations, review, record keeping), informed consent (required elements, obtainment, documentation), and assurance of compliance

Revised Common Rule

- § 46.101 To what does this policy apply?
  - (f) This policy does not affect any state or local laws or regulations (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) that may otherwise be applicable and that provide additional protections for human subjects.
- § 46.114 Cooperative research.
  - (2) The following research is not subject to this provision:
    - (i)Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe);
- § 46.116 General requirements for informed consent.
  - (i) Preemption. The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective.

HHS and FDA Harmonization

- 2018- Harmonization where possible FDA/ Common Rule
- 2022 Institutional Review Boards: Cooperative Research
- 2022 Protection of Human Subjects and Institutional Review Boards

> "FDA requests comment on whether it is appropriate to include an exception for cooperative research for which use of a single IRB is unable to meet the needs of specific populations"

Benefits of Single IRB

- Enhance and streamline the IRB review process for multi-site trials to allow research to proceed expeditiously without compromising protections
- Eliminate unnecessarily duplicative IRB review
- Reduce administrative burden and systemic inefficiencies for investigators, institutions, IRBs, and NIH staff

Development of the NIH Single IRB Policy

- Draft NIH Single IRB Policy published in December 2014
  - 167 public comments received from a range of stakeholders including researchers, institutions, IRBs, patient advocates, scientific societies, Tribal Nation representatives, and others
- Final NIH Single IRB Policy published June 2016; effective date delayed until January 25, 2018
  - Applies to all competing grant applications for due dates on or after January 25, 2018
  - Applies to all R&D contract solicitations issued on or after January 25, 2018
  - Applies to intramural research studies submitted for initial review after January 25, 2018

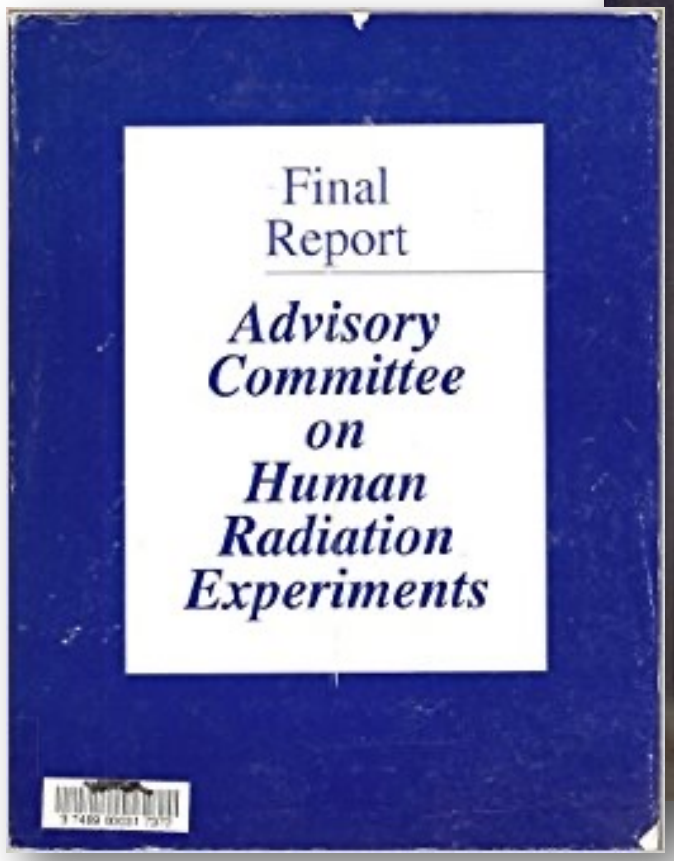
NIH Single IRB Policy and Tribes

Exceptions to this policy will be made **where review by the proposed sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy.**

NOT-OD-16-094: Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research

Contemporary Research Protection Insights and Practices

October 3, 1995



Los Angeles Times

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Clinton Apologizes for Radiation Tests : Experiments: Cabinet will study compensation for some victims and their families. About 4,000 secret studies through 1974 were disclosed.

October 04, 1995 | MARLENE CIMONS | TIMES STAFF WRITER

WASHINGTON — President Clinton apologized Tuesday to the survivors and families of those whc unknowingly were subjects of government-sponsored radiation experiments, and ordered his Cabi devise a system of relief--including financial compensation.

"When the government does wrong, we have a moral responsibility to admit it," Clinton said. "The we owe to one another to tell the truth and to protect our fellow citizens from excesses like these is we can never walk away from."

Saying "our government failed in that duty," he apologized "to all the American people who must b to rely upon the United States to keep its word to tell the truth and to do the right thing."

White House apology ceremony, 16 May 1997. Participants and survivors of the study (first row): Herman Shaw, Fred Simmons, Charles Pollard, Frederick Moss, Carter Howard. White House officials (back row): U.S. Surgeon General David Satcher, President William J. Clinton, Vice-President Albert Gore.

National Institutes of Health
Turning Discovery Into Health

NIH Tribal Consultation Advisory Committee Meeting
February 25-26, 2016

National Institutes of Health
Building 31, Conference Room 10
31 Center Drive
Bethesda, MD 20892

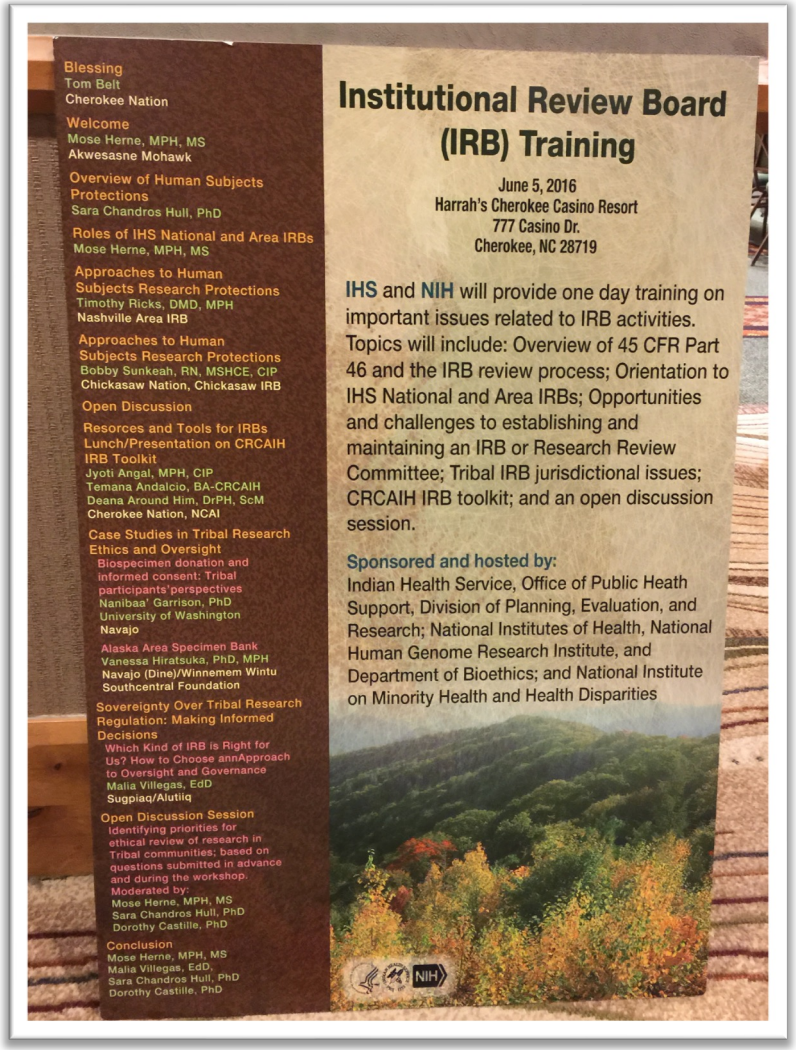
ETHICAL REVIEW OF RESEARCH WITH TRIBAL COMMUNIITES:
NIH Training Opportunities

Sara Chandros Hull, PhD
Chair, NHGRI Institutional Review Board
Faculty, Department of Bioethics
Director, NHGRI Bioethics Core

titutes of Health

BIOETHICS AT THE NIH

Native Research Network Pre-Conference Workshop (2016)



Capacity Building: Partnering with PRIM&R (2016-present)

- Ongoing webinars and workshops on topics of relevance to Tribal research
  - e.g., NIH DMS Policy (2/23)
- Customized “On Demand” programs
- Additional scholarships/ networking for AI/AN IRB professionals
- Online portal of Tribal IRB resources
  - Ethics case studies
  - Model data sharing agreements

Current Landscape of Research Oversight in AI/AN Communities

PRIM&R
@primrconnect

Follow

Some of research's most important questions regard Native sovereignty. See these questions explored at #AER17
primr.org/aer17

Panel II: Sovereignty in Research

The history of research with Indigenous populations in America includes important advances with respect to specific topics (e.g., vaccines, diabetes) and research approaches (e.g., community-based participatory research). Instances of egregious ethics violations, however, tend to dominate the narratives about tribal research both within and outside of tribal communities. For example, the Nutritional Studies in Residential Schools in Canada during the 1940s, the Study of Alcohol Abuse in a Northern Alaska community during the 1980s, and studies of Havasupai biospecimens in Arizona during the early 2000s, are three frequently cited examples of research harms that often drive present-day conversations about tribal research to start from a place of fear. The sovereign status of American Indian and Alaska Native nations, however, provides an opportunity for tribes to steward research in a way that reflects cultural values and that both benefits and protects their citizens and communities. In the context of changing federal and institutional research policies, it is increasingly important to move narratives about tribal research beyond fear toward conversations that acknowledge points of tension and possible benefit, respect tribal sovereignty, and identify the practical needs necessary to support tribal research oversight. This session will provide an overview of historical experiences of tribal research, convey the importance tribal sovereignty in guiding research for the benefit of tribal peoples, and review implementation needs associated with rapidly evolving research technology and interest in research oversight among tribal nations.

Grappling with "Classic" Research Ethics Cases: An Exercise in Humility and Course Correction

Sara Chandros Hull, PhD
Mose Herne, MPH, MS
Senior Advisors, NIH Tribal Health Research Office

NHGRI Short Course in Genomics
August 2, 2022

What Are The Lessons?
History of Insufficient Respect for Tribal Sovereignty

- "Existing federal legal and regulatory protections for human subjects fail to shield the cultural interests of Indian nations."

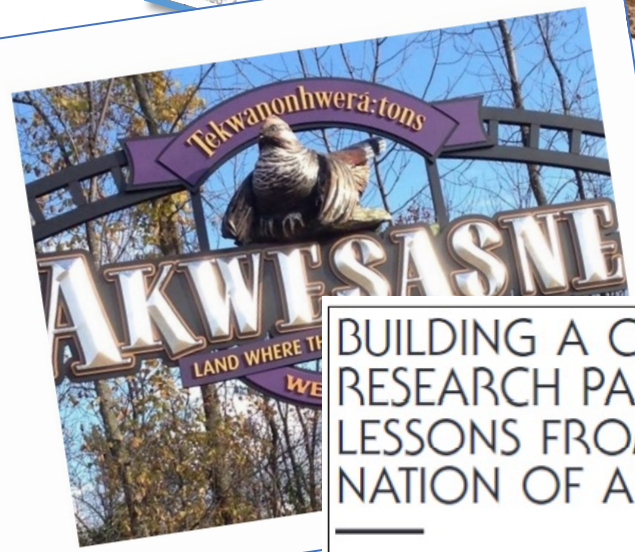
  James, Tsosie, Sahota *et al* (2014) *GiM*

- "[A] profound disconnect exists between common academic research practices and legitimate community expectations, and justice requires that this gap be bridged."
- "[A]ddressing their [research] needs may require precisely that we address their history of trauma, stigma, and exclusion."

  Goering, Holland, and Fryer-Edwards (2008) *HCR*

Example of equitable Tribal-State-academic partnership: Akwesasne

- Akwesasne – "Land where the partridge drums" is in the St. Lawrence River Valley and used by Mohawks for thousands of years to fish, hunt, and trade
- Akwesasne Mohawks have maintained language, traditions, and ceremonies
- Home to the first and longest running Indigenous newspaper, Akwesasne Notes



BUILDING A COMMUNITY-BASED RESEARCH PARTNERSHIP: LESSONS FROM THE MOHAWK NATION OF AKWESASNE

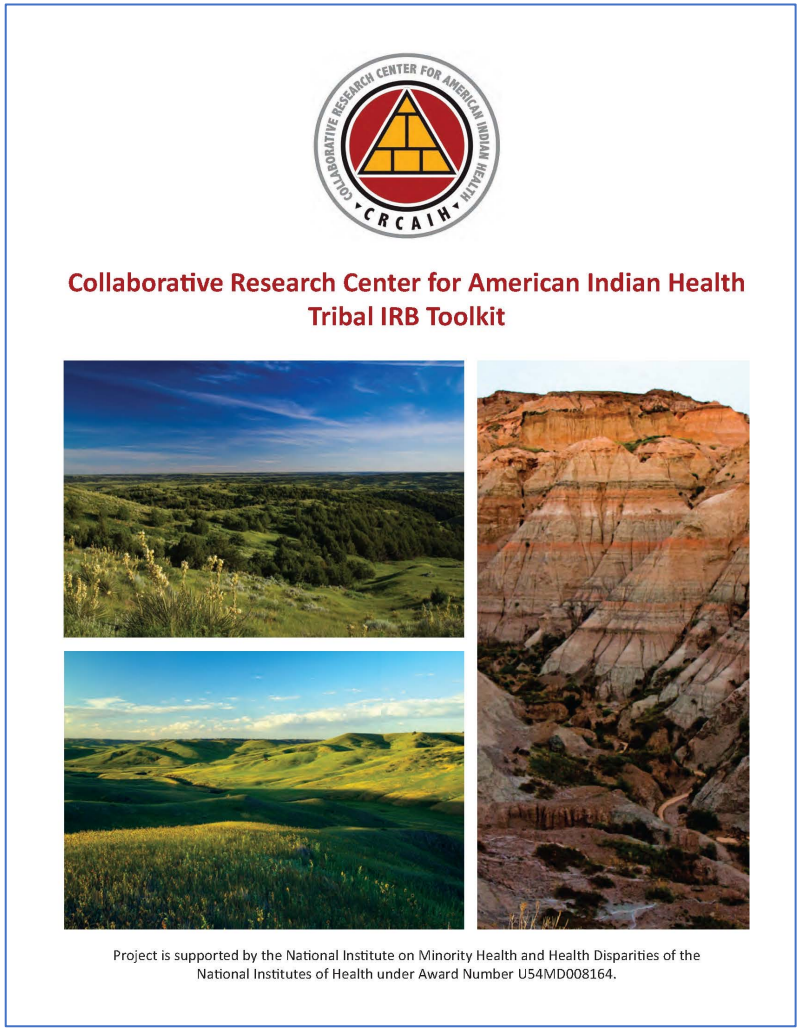
Asara L. Santiago-Rivera, Gayle Skawennio Morse, and Anne Hunt
State University of New York at Albany
Henry Lickers
Akwesasne Task Force on the Environment, Mohawk Council Hogansburg, New York

NIH Support for Tribal IRBs

- NIH Tribal Consultation on the NIGMS Native American Research Centers for Health (NARCH) Program Evaluation (June 2021)

Key Outcome: *Grants to support the establishment or enhancement of Tribal Institutional Review Boards (IRBs).* These grants would support establishing additional Tribal IRBs or enhancing the function of existing ones (e.g., through additional support for staff, systems, and training) to help reduce delays in the IRB approval process and reliance on external IRBs, giving Tribes greater autonomy over their own research processes.

*9/15/2022 NIGMS Council/Concept Clearance



Facilitating the Ethical Conduct of Tribal Research within NIH

- Teaching/mentorship of NIH investigators, trainees, IRB staff, program staff
  - NIH IRB: OHSRP Education Series
  - CC Bioethics Ethical and Regulatory Aspects of Clinical Research Course
    - Conversations with Dr. Katrina Claw, case discussions
  - NINDS Summer Internship - Health Disparities in Tribal Communities

OHSRP Education Series: Ethical Conduct of Research with American Indian and Alaska Native Participants: Extending Protections through Respect for Tribal Sovereignty

Thursday, September 2, 2021

Dr. Sara Hull, NIH and Dr. Dave Wilson, NIH

Read more **248 views** (206 live, 42 VOD) - Runtime: 01:01:08

Facilitating the Ethical Conduct of Tribal Research within NIH

5.2 * Does this study include any of the following:

(select all that apply)

- [ ] Take place on American Indian/Alaska Native (AI/AN) land or territory
- [ ] Take place at an Indian Health Service (IHS) or other tribal AI/AN facility
- [ ] Use IHS resources (staff, funding, space or other support)
- [ ] Access non-research data collected at an IHS facility
- [x] Target enrollment of any AI/AN population
- [ ] Involve specimens or data from American Indian/Alaska Native populations that was initially collected for other purposes
- [ ] None of the above

* Has the protocol been reviewed and approved by an Indian Health Service IRB and/or a tribal IRB?

- (•) Yes
- ( ) No

(attach documentation with the submission form)

Consent and Genomic Data Sharing

Consent Under the Common Rule

§46.116 General Requirements and Basic Elements for Informed Consent

- Prospective participant must be provided with **information "reasonable person would want to have** in order to make an informed decision about whether to participate, and an opportunity to discuss that information"

Broad consent may be obtained in lieu of informed consent only for **storage, maintenance, and secondary research** uses of identifiable private information and identifiable biospecimens

RESPONSIBLE SHARING OF GENOMIC DATA

NIH GENOMIC DATA SHARING (GDS) POLICY *(EFFECTIVE JAN 2015)*

- Applies to all NIH-funded research generating large-scale human or non-human genomic data and secondary research using these data
- Ensures broad, responsible, and timely sharing of genomic data
- Establishes baseline expectation of the importance of consent
- Developed through extensive stakeholder interactions

Informed Consent

- The GDS Policy expects IRBs to review the informed consent materials
  - Purpose of review is to determine whether it is appropriate for data to be shared for secondary research use.
  - Specific considerations may vary with the type of study and whether the data are obtained through prospective or retrospective data collections.

Informed Consent

- NIH expects investigators to obtain participants' consent for their genomic and phenotypic data to be used for future research purposes and to be shared broadly
- Expected even if the cell lines or clinical specimens are de-identified
- Expected IRBs consult with investigators and their institution about the appropriate secondary use of the data

Additional Resources

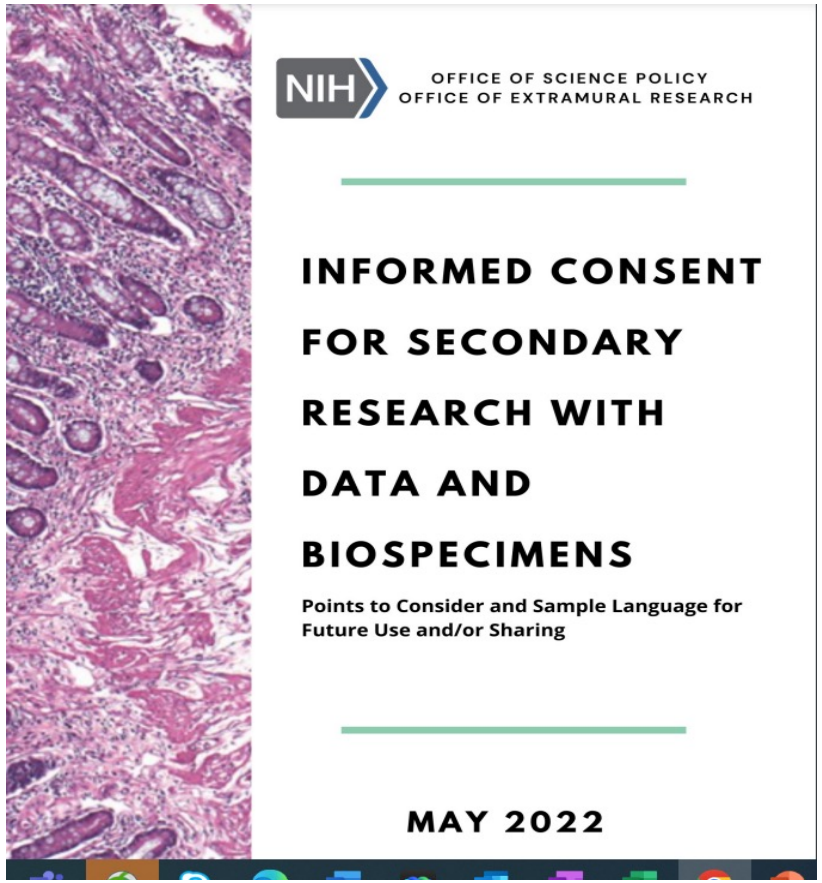
NIH Guidance on Consent for Future Research Use and Broad Sharing of Human Genomic and Phenotypic Data Subject to the NIH Genomic Data Sharing Policy

Background

NIH-funded studies that generate large-scale human genomic data are subject to the NIH Genomic Data Sharing (GDS) Policy.[1] According to the GDS Policy, investigators who intend to use research or clinical specimens collected or cell lines created after January 25, 2015, to generate genomic data may only do so when informed consent processes explicitly discuss future research use and broad data sharing, even if the data are generated from specimens that are de-identified. NIH-designated data repositories will not accept genomic data derived from specimens or cell lines collected or created after January 25, 2015, without this type of consent.[2] NIH strongly encourages the broadest appropriate future use and sharing of genomic and phenotypic data.

NIH also recognizes that in some circumstances broad sharing may not be consistent with the consent of the research participants whose data are included in the dataset.[3] If the research that involves the generation of genomic and phenotypic data is part of a larger study, such as a clinical trial, and a participant declines to consent to future research use and broad sharing of their data, the participant should not be excluded from the larger study on that basis. If future research use and data sharing are intrinsic to the study, investigators may decline to enroll participants who are unwilling to provide consent for future research use and broad data sharing.

NIH_Guidance_on_Elements_of_Consent_under_the_GDS_Policy_07-13-2015.pdf



https://osp.od.nih.gov/wp-content/uploads/Informed-Consent-Resource-for-Secondary-Research-with-Data-and-Biospecimens.pdf

Additional Resources

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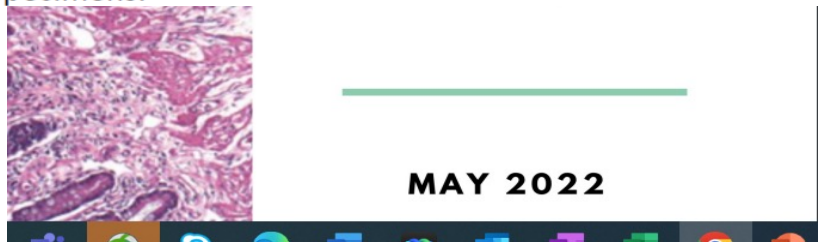
NIH_Guidance_on_Elements_of_Consent_under_the_GDS_Policy_07-13-2015.pdf

Some cultural, donor, and/or sovereign groups may have preferences or requirements regarding how data and biospecimens are handled, including the disposition of biospecimens. For example, sovereign Tribal Nations may have laws, policies, and/or regulations governing research that may impact the storage and sharing of data and biospecimens. It is strongly encouraged to seek consultation with the appropriate contacts to determine applicable regulations, policies, and cultural preferences or Tribal laws that will need to be taken into consideration prior to storage and sharing of data and biospecimens.



https://osp.od.nih.gov/wp-content/uploads/Informed-Consent-Resource-for-Secondary-Research-with-Data-and-Biospecimens.pdf

Consent Contextualized

What Makes Clinical Research Ethical?

- Collaborative partnership
- Social value
- Scientific validity
- Fair selection of study population
- Favorable risk-benefit ratio
- Independent review
- Informed consent
- Respect for recruited participants and study communities


JOURNAL ARTICLE

What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research FREE

Ezekiel J. Emanuel, David Wendler, Jack Killen, Christine Grady

The Journal of Infectious Diseases, Volume 189, Issue 5, 1 March 2004, Pages 930–937, https://doi.org/10.1086/381709

Published: 01 March 2004 **Article history**

Culturally Appropriate Consent Processes (Sample Language)

- *Our recruitment focuses on individuals who are American Indian…because there is a need to confirm genetic findings in these groups*
- *…[M]embers of the same Tribe also share some genetic information. If some of the ir… could po… stigma.*
- *In the fu… learn ab… to recruit … Americ… metabo… tests are not part of standard health care but are for research to find out more about the causes of [disease under study]*

Original Paper

Public Health Genomics

Public Health Genomics 2011;14:135–142
DOI: 10.1159/000317497

Received: November 9, 2009
Accepted after revision: June 21, 2010
Published online: October 8, 2010

Patient Perspectives on Group Benefits and Harms in Genetic Research

A.J. Goldenberg[a, b] S.C. Hull[c, d] B.S. Wilfond[e, f] R.R. Sharp[b, g, h]

Data Management and Sharing

Why does NIH Want Data to be Shared?

- **Advance rigorous and reproducible research**
  - Enable validation of research results
  - Make high-value datasets accessible
  - Accelerate future research directions
  - Increase opportunities for citation and collaboration

- **Promote public trust in research**
  - Foster transparency and accountability
  - Demonstrate stewardship over taxpayer funds
  - Maximize research participants' contributions
  - Support appropriate protections of research participants' data

NIH Policy for Data Management and Sharing

- **Submission of Data Management & Sharing Plan for all NIH-funded research** *(how/where/when)*
- **Compliance with the ICO-approved Plan** *(may affect future funding)*
- **Effective January 25, 2023** *(replaces 2003 Data Sharing Policy)*

Scope and Expectations

- **Scope:** All NIH-supported research generating ***scientific data***
  - **What's in: "**Recorded factual material… of **sufficient quality to validate and replicate research findings**, regardless of whether the data are used to support scholarly publications"—relates to the proposed research questions and findings can include unpublished null results
- **Expectations:** Data sharing should be maximized (with justifiable limitations), responsibly implemented, and prospectively planned for at all stages of the research process

Potential Limitations on Sharing

- **Data Management and Sharing Plans should maximize appropriate sharing:**
  - **Justifiable ethical, legal, and technical factors for limiting sharing of data include:**
    - Informed consent will not permit or limits scope of sharing or use
    - Privacy or safety of research participants would be compromised and available protections insufficient
    - Explicit federal, state, local, or Tribal law, regulation, or policy prohibits disclosure
    - Restrictions imposed by existing or anticipated agreements with other parties
    - Datasets cannot practically be digitized with reasonable efforts
  - **Reasons not generally justifiable to limit sharing include:**
    - Data are considered too small
    - Researchers anticipate data will not be widely used
    - Data are not thought to have a suitable repository
  - **Additional considerations:**
    - NIH respects Tribal sovereignty and supports responsible management/sharing of AI/AN participant data
    - SBIR/STTR Program Policy Directive permits withholding data for 20 years, as stipulated in agreements and consistent with program goals

Supplemental Information: Responsible Management and Sharing of American Indian/ Alaska Native Participant Data

- Information to assist in developing appropriate DMS Plans
- Emphasizes:
  - ✓ Respect for Tribal Sovereignty
  - ✓ Partnerships and mutual agreements
  - ✓ Building trust
- Developed through Tribal Consultation and stakeholder engagement beginning in 2019

NIH National Institutes of Health
Office of Science Policy

NOT-OD-22-214

Best Practices for Responsible Management and Sharing of AI/AN Participant Data

Understand	Understand Tribal sovereignty and laws, regulations, policies, and preferences
Engage	Engage early with Tribes when developing a data management and sharing plan, before research begins, and continue throughout research
Establish	Establish mutually beneficial partnerships
Agree	Agree who will manage data (e.g., Tribe, researcher, trusted 3rd party)
	Consider additional protections, as necessary

What are **FAIR Principles**, and what's all the fuss? In 2016, stakeholders came together to **endorse** "a concise and measurable set of principles" to improve the management and sharing of research data. Findable, Accessible, Interoperable, and Reusable (FAIR) principles are critical elements for making data maximally useful to the research community. Not long after, the **Collective Benefit, Authority to Control, Responsibility, and Ethics (CARE) Principles for Indigenous Data Governance** were developed, which aimed to ensure that data-sharing movements (like FAIR) would also consider Indigenous peoples' goals, values, and rights to self-determination.

Eric Green, MD, PhD, NHGRI Director
The Genomics Landscape

Listening in Albuquerque

UNM HEALTH SCIENCES CENTER
Community Environmental Health Program
Center for Native Environmental Health Equity Research

TRIBAL DATA SHARING & GENETICS
Policy Development Workshop

August 31 - September 1, 2017
UNM Comprehensive Cancer Center
1201 Camino de Salud, NE . ABQ, NM 87131

sites.google.com/view/UNMCEHP17

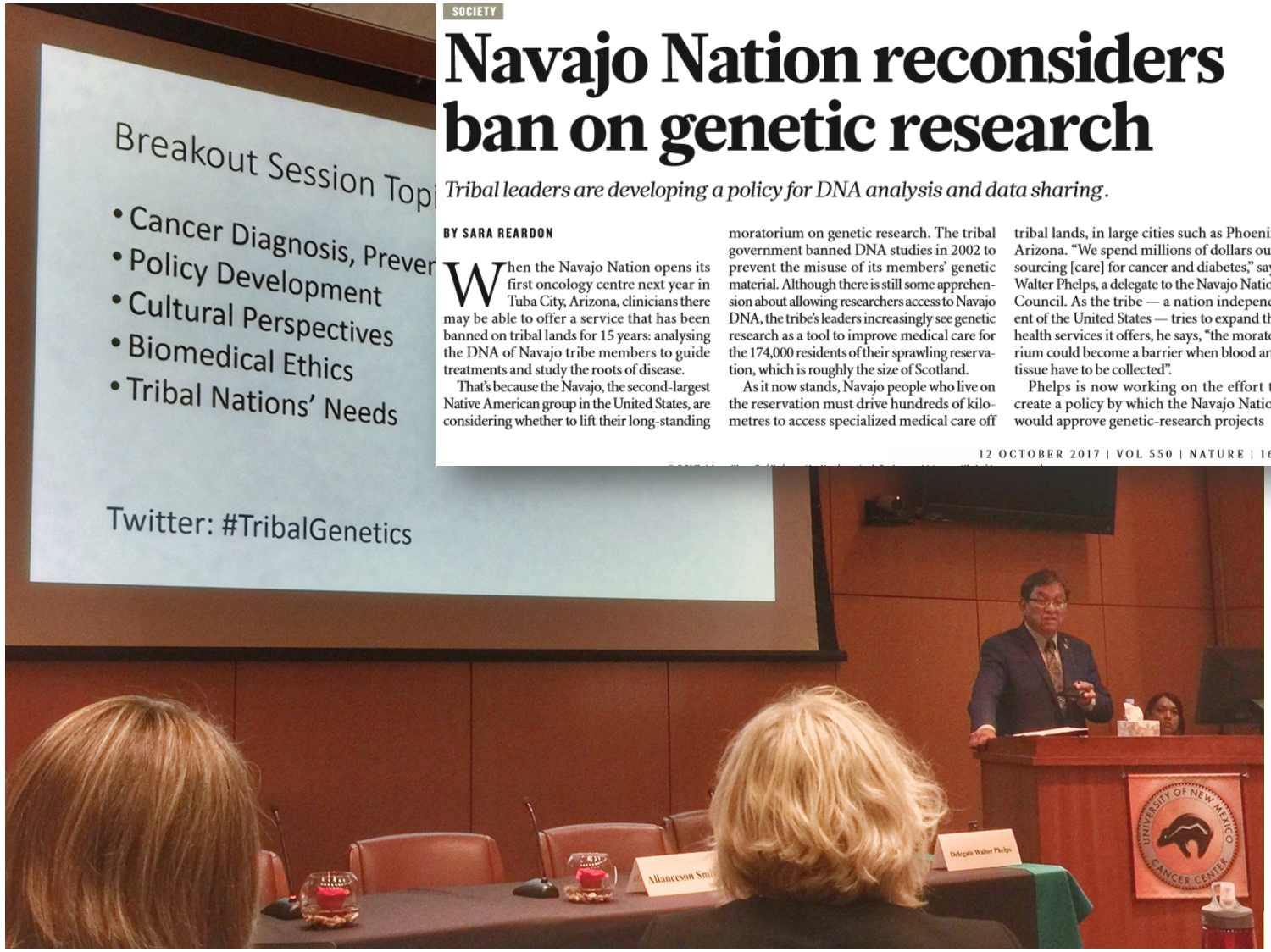
livestream available beginning August 31 at
http://206.192.150.42

Contact: C.J. Laselute | 505.272.7407 | claselute@salud.unm.edu

This workshop will bring together tribal policy and spiritual leaders, health researchers, and community members to discuss and understand the benefits and risks for Native American populations from participating in genetic research studies.

Through open dialogue, the goal will be to develop policy recommendations for genetic studies and sharing of research data.

artwork by Mallery Quetawki, Artist-in-Residence, UNM Center for Native Environmental Health Equity Research



SOCIETY

Navajo Nation reconsiders ban on genetic research

Tribal leaders are developing a policy for DNA analysis and data sharing.

BY SARA REARDON

When the Navajo Nation opens its first oncology centre next year in Tuba City, Arizona, clinicians there may be able to offer a service that has been banned on tribal lands for 15 years: analysing the DNA of Navajo tribe members to guide treatments and study the roots of disease.

That's because the Navajo, the second-largest Native American group in the United States, are considering whether to lift their long-standing moratorium on genetic research. The tribal government banned DNA studies in 2002 to prevent the misuse of its members' genetic material. Although there is still some apprehension about allowing researchers access to Navajo DNA, the tribe's leaders increasingly see genetic research as a tool to improve medical care for the 174,000 residents of their sprawling reservation, which is roughly the size of Scotland.

As it now stands, Navajo people who live on the reservation must drive hundreds of kilometres to access specialized medical care off tribal lands, in large cities such as Phoenix, Arizona. "We spend millions of dollars outsourcing [care] for cancer and diabetes," says Walter Phelps, a delegate to the Navajo Nation Council. As the tribe — a nation independent of the United States — tries to expand the health services it offers, he says, "the moratorium could become a barrier when blood and tissue have to be collected".

Phelps is now working on the effort to create a policy by which the Navajo Nation would approve genetic-research projects ▸


Tribal Data Sharing & Genetics Workshop
August 31 & September 1
University of New Mexico Comprehensive Cancer Center
Education Wing Auditorium and Foyer

NIH Tribal Advisory Committee Meeting (September 2017)

"American Indian and Alaska Native Cultural Wisdom Declaration"
Recommendations

"Modify your requirements to fit the relevant traditional [T]ribal paradigm or allow room for flexibility when evaluating proposals submitted by American Indian and Alaska Native [T]ribal nations."

Genomic Research Workshop, Anchorage Alaska (July 2018)

REVIEW ARTICLE | Genetics in Medicine

Open

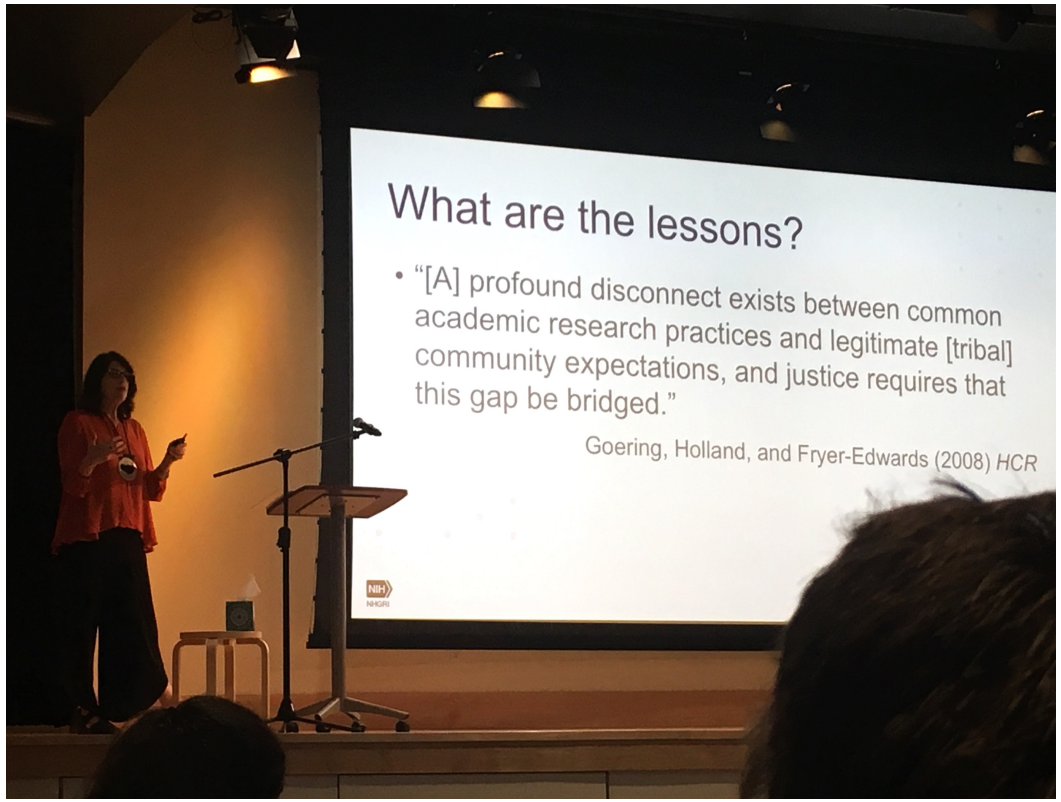
Alaska Native genomic research: perspectives from Alaska Native leaders, federal staff, and biomedical researchers

Vanessa Y. Hiratsuka, PhD, MPH[1], Michael J. Hahn, BA[2], R. Brian Woodbury, BA[1], Sara Chandros Hull, PhD[2], David R. Wilson, PhD[2], Vence L. Bonham, JD[2], Denise A. Dillard, PhD[1], The Alaska Native Genomics Research Workshop Group, Jaedon P. Avey[3], Andrea C. Beckel-Mitchener[4], Juliana Blome[4], Katrina Claw[5], Elizabeth D. Ferucci[6], Francine C. Gachupin[7], Armen Ghazarian[4], Lucia Hindorff[4], Sonya Jooma[4], Susan B. Trinidad[8], Jennifer Troyer[4] and Hina Walajahi[4]

Meaningful engagement of Alaska Native (AN) tribes and tribal health organizations is essential in the conduct of socially responsible and ethical research. As genomics becomes increasingly important to advancements in medicine, there is a risk that populations not meaningfully included in genomic research will not benefit from the outcomes of that research. AN people have historically been underrepresented in biomedical research; AN underrepresentation in genomics research is compounded by mistrust based on past abuses, concerns about privacy and data ownership, and cultural considerations specific to this type of research. Working together, the National Human Genome Research Institute and two Alaska Native health organizations, Southcentral Foundation and the Alaska Native Health Board, cosponsored a workshop in July 2018 to engage key stakeholders in discussion, strengthen relationships, and facilitate partnership and consideration of participation of AN people in community-driven biomedical and genomic research. AN priorities related to translation of genomics research to health and health care, return of genomic results, design of research studies, and data sharing were discussed. This report summarizes the perspectives that emerged from the dialogue and offers considerations for effective and socially responsible genomic research partnerships with AN communities.

Genetics in Medicine (2020) 22:1935–1943; https://doi.org/10.1038/s41436-020-0926-y

Keywords: Alaska Natives, North American; ethics; US National Institutes of Health; social responsibility; trust



Panel Presentation and Discussion: Data Sharing Approaches

- AN leaders not opposed to data sharing
  - Stressed reciprocity, transparency, respect
  - Themes included flexibilities that specific NIH policies have for AN communities
- Researchers must cultivate authentic relationships with AN communities to build trust, develop tailored approaches to consent
- More communication and education about risks, benefits, privacy, how to apply for exceptions

Importance of Inclusion and Diversity

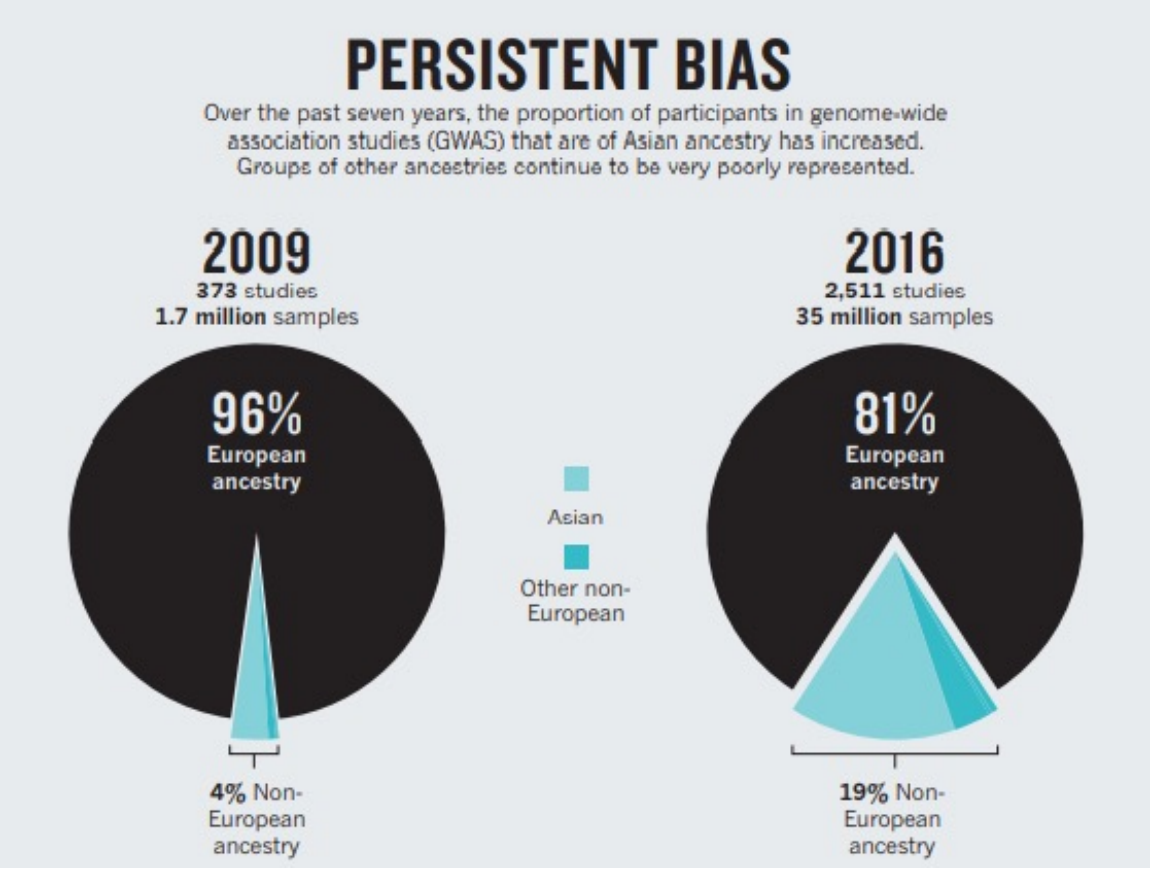
Inclusion/Diversity

NIH Policies

Inclusion of Women and Minorities as Participants in Research

Inclusion of Individuals Across the Lifespan as Participants in Research

Changing the Conversation about Diversity and Inclusion



Popejoy and Fullerton 2016 *Nature*

TRANSLATIONAL GENETICS

SCIENCE AND SOCIETY

Prioritizing diversity in human genomics research

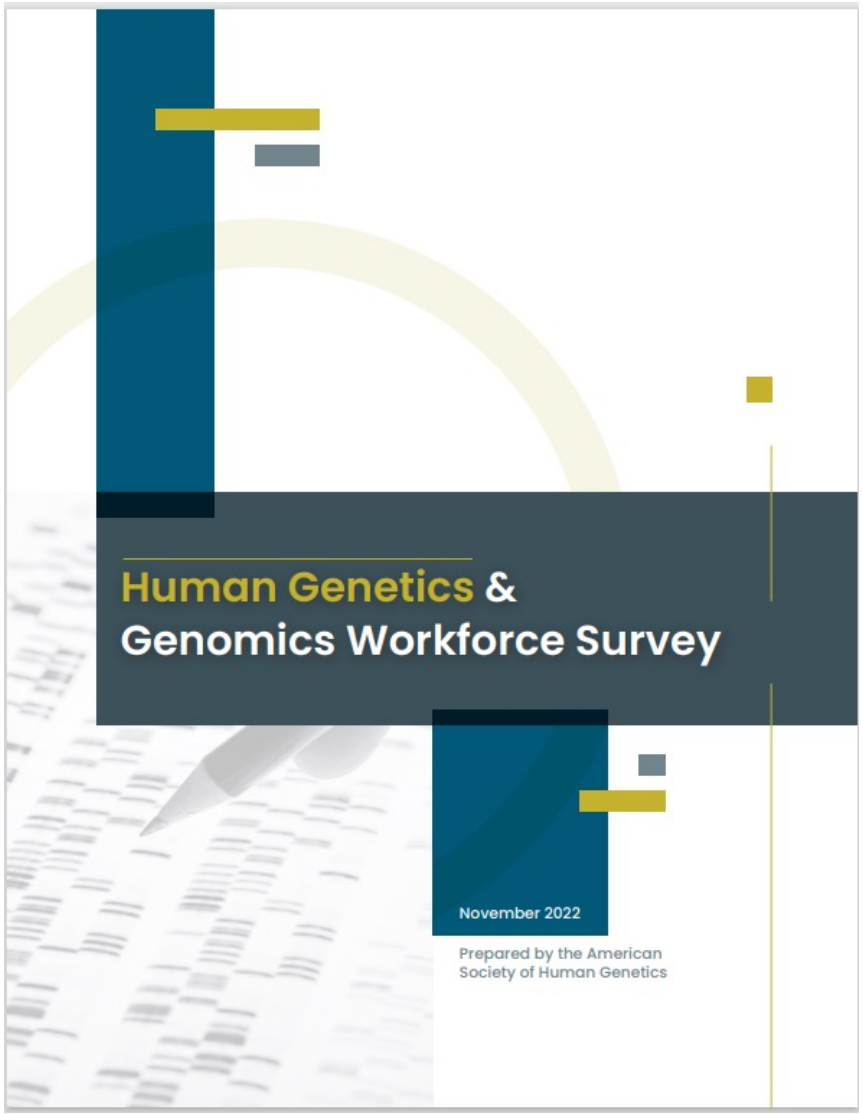
Lucia A. Hindorff, Vence L. Bonham, Lawrence C. Brody, Margaret E. C. Ginoza, Carolyn M. Hutter, Teri A. Manolio and Eric D. Green

Genetics and Health Disparities

- "[I]nequities in the amount and quality of genetic and genomic data generated for various human populations have the potential to exacerbate existing health disparities as genetic discoveries are translated into clinical and public health interventions."

Knerr, Wayman, and Bonham (2011) *JLM&E*

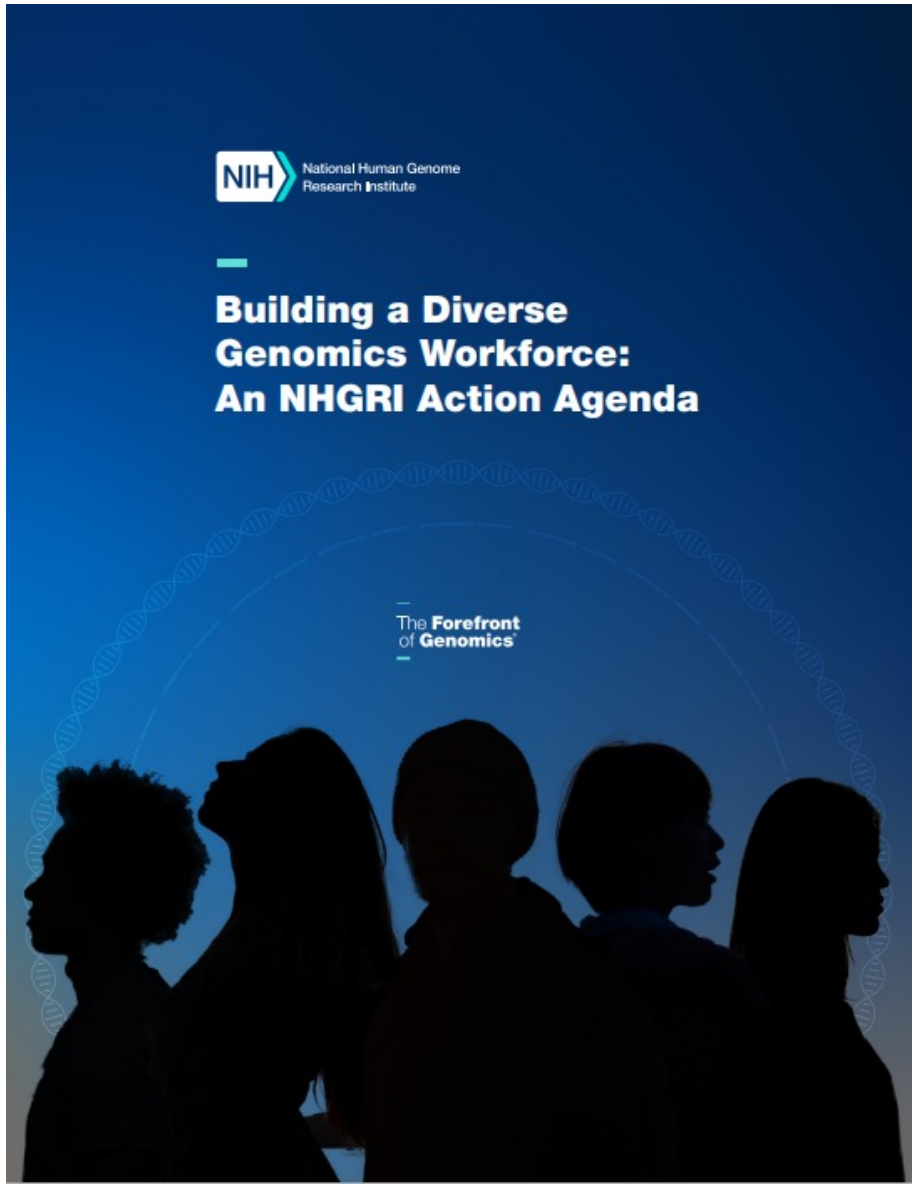
Changing the Conversation about Diversity and Inclusion

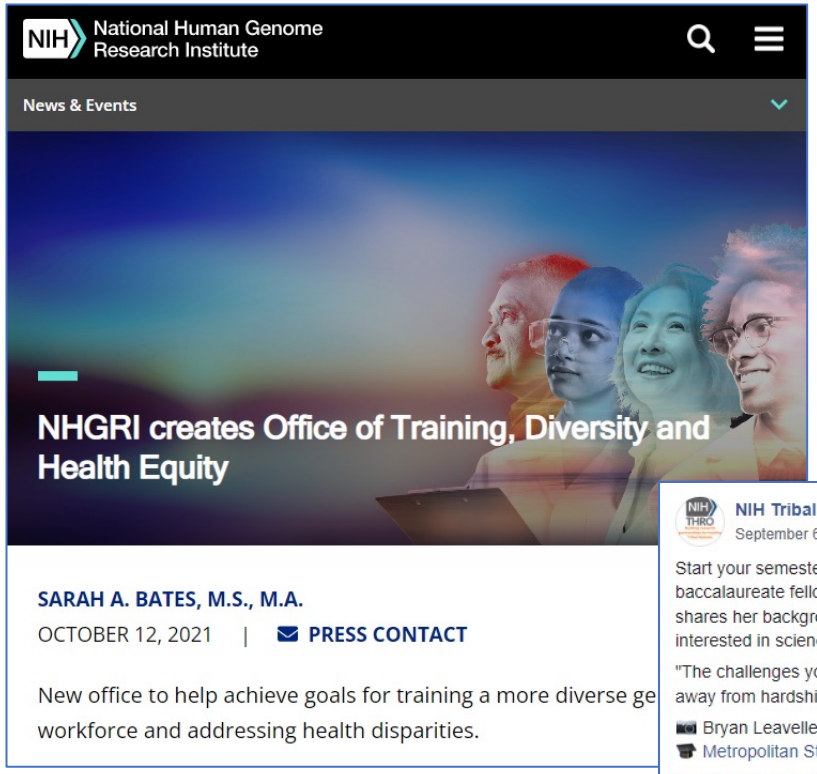

Human Genetics &
Genomics Workforce Survey
November 2022
Prepared by the American
Society of Human Genetics

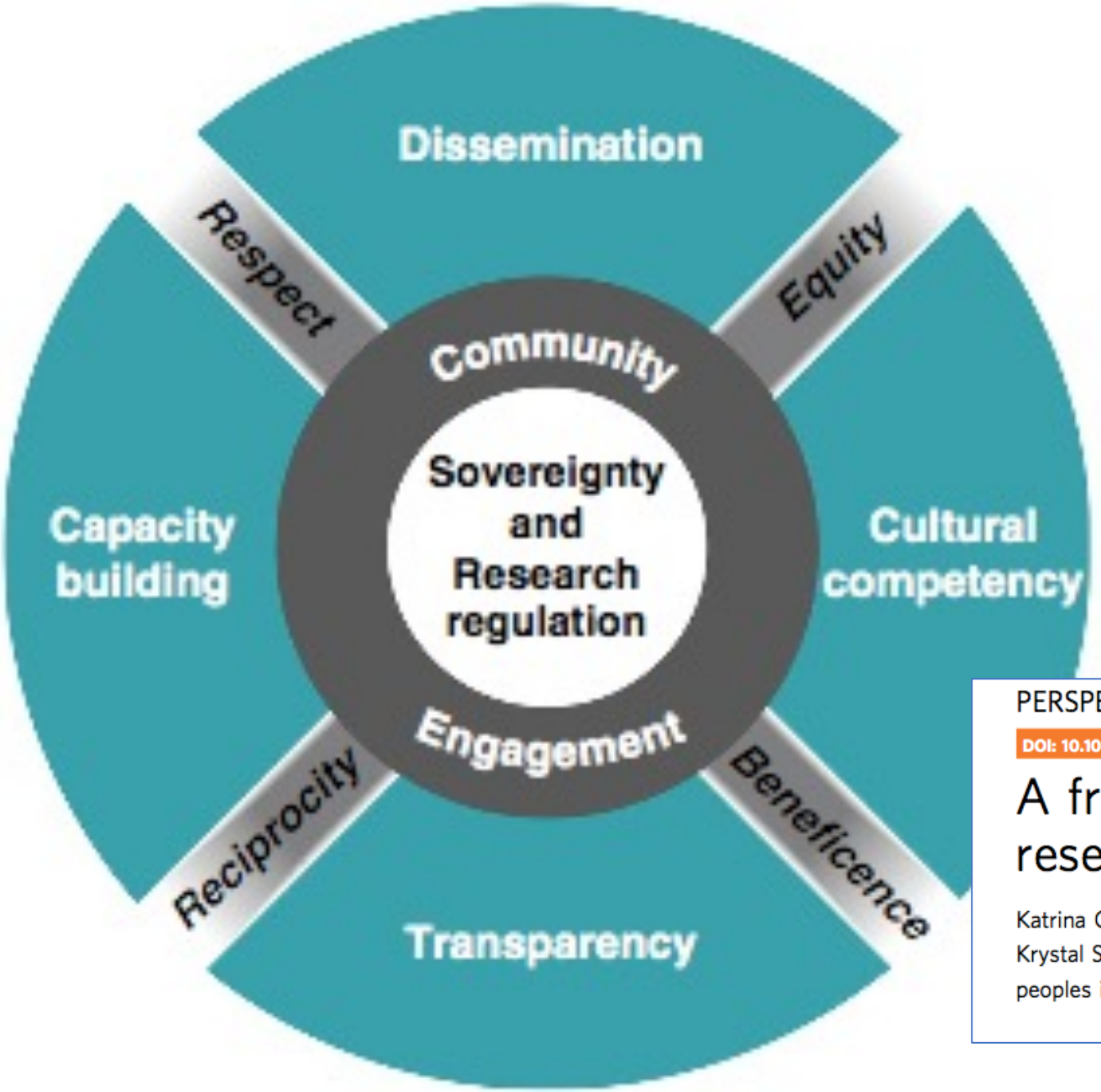

American Indian or Alaska Native
<1%
Native Hawaiian or other Pacific Islander
<1%
Middle Eastern or North African
1.1%
Black, African American, or African
1.5%
Hispanic, Latino, or Spanish
2.0%
Multiracial
4.8%
Asian
7.4%
White
67.0%

(n=2,224)

Applying a Health Equity Lens to Genomics







PERSPECTIVE

DOI: 10.1038/s41467-018-05188-3 OPEN

A framework for enhancing ethical genomic research with Indigenous communities

Katrina G. Claw [1], Matthew Z. Anderson [2,3], Rene L. Begay [4], Krystal S. Tsosie [5,6], Keolu Fox[7], Summer internship for INdigenous peoples in Genomics (SING) Consortium & Nanibaa' A. Garrison [8,9]

Thank you!