

BIOSPECIMENS AND DATA SHARING CONSIDERATIONS FOR NATIVE PEOPLES

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NCAI Tribal Leader/Scholar Forum

June 28, 2015
St. Paul, MN

OVERVIEW

- Blood and DNA in Research
- Issues Raised with New Guidelines
- Potential Impact of Data Sharing on Tribes



WHAT ARE BIOSPECIMENS?

- Biospecimens are
 - Tissue, blood, urine, or other human-derived material
 - Includes a biopsy of bone, tissue, muscle, or skin
- What does blood contain?
 - Information about your blood group, cholesterol levels, whether you have a virus or bacterial infection, could tell us about cancers of the blood, about your DNA.
- What can blood tell us? What can we learn about a person through their blood?

RESEARCH WITH BIOSPECIMENS

- Biomedical research can be conducted using biospecimens
 - Study diseases (like cancer)
 - Understand drug interactions
 - Learn about human ancestry
 - To advance human health

THE SACREDNESS OF DNA



“To us, any part of ourselves is sacred. Scientists say it's just DNA. For an Indian, it is not just DNA, it's part of a person, it is sacred, with deep religious significance. It is part of the essence of a person.”

- Frank Dukepoo, Ph.D. (Hopi geneticist)

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FEDERAL GUIDELINES

- Broad Informed Consent
 - The informed consent process must comply with requirements: voluntary, understandable, risks/benefits, able to withdraw
 - <http://www.hhs.gov/ohrp/policy/ictips.html>
 - Shift to provide broad consent to allow greater research uses

- Requirements for Data Sharing
 - Investigators are urged to share *de-identified data*
 - Deposit genetic data into NIH database (dbGaP) for other researchers to access
 - Data Access Committee reviews requests
 - <https://federalregister.gov/a/2014-20385>

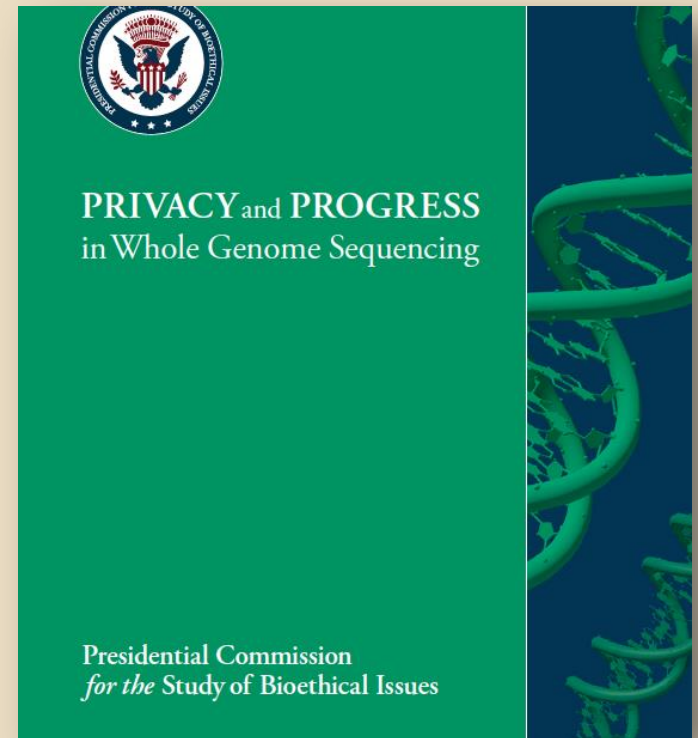
CONCERNS AND ISSUES

- Connection to the Samples
 - Spiritual connection to Blood / Saliva / DNA samples
 - Views around Personhood and Ownership
 - Return of Samples
 - Data-Sharing policies

PRIVACY IN GENOMICS

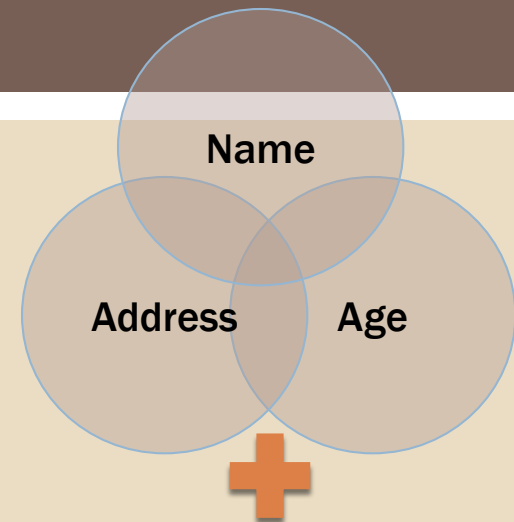
“Without trust in the confidentiality and security of the data, individuals could be less likely to participate in research.”

(Report, pg 21)

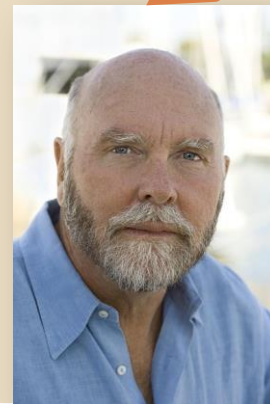


RE-IDENTIFYING PEOPLE FROM DNA

- *De-identifying* removes personal information (such as name, age, and address)
 - No longer “human subjects”
 - Allows for data-sharing
- Research participants were *re-identified* in a database
- Matched *free online database* (last names, age, and state of residency) with *DNA information*



DNA information



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NATIVE AMERICANS IN THE U.S.



- 566 federally-recognized Tribes in the US
 - *Diversity* of views, opinions, and attitudes
 - Differences in reception to genetic research

IMPACT ON TRIBES

- Tribal Sovereignty
 - Tribes with Research Review Boards must think about how to address Data Sharing
 - Need discussions on Data Ownership
- Limitations on Research:
 - Funding of research may be dependent on Data Sharing Agreements
 - May hinder research progress

CHALLENGES

- Building trust and respect for others
 - Transparency about sample use
 - Reporting results back to participants
- Challenges:
 - How do we deal with de-identified Native American samples when one wishes to withdraw and wants samples returned?
 - How do we address withdrawal when notions of ownership and spiritual connections remain?

FUTURE DISCUSSIONS

- Begin and maintain discussions with Tribes
 - Allow for *complete* collaboration with tribes
 - Community-based discussions, project to engage leaders in discussions
- Some tribes are interested, but hesitant
 - Increased regulation by Tribal IRB's
- Pipeline for Training Opportunities:
 - Indigenous Students, Scientists, and Physicians
 - Summer Internship for Native Americans in Genomics (SING), <http://conferences.igb.illinois.edu/sing/>

AHÉ'HEE!

Thanks to:

- Vanderbilt University, Center for Biomedical Ethics and Society
- Stanford University, Center for Biomedical Ethics, Department of Genetics
- National Congress of American Indians (NCAI)
- National Human Genome Research Institute (NHGRI)
- Summer Internship for Native Americans in Genomics (SING)

