

# DATA SHARING ISSUES

## TRIBAL ADVISORY COMMITTEE

BETHESDA, MD  
9/14/17



# YOUR SPEAKER



- GREW UP IN WAHPETON, ND
- IHS FAMILY DOC, 77-98
- PART TIME, DUNSEITH, ND 99-2012
- BEGAN WORK WITH STRONG HEART STUDY IN 1998
- TAUGHT GENETICS AT TURTLE MOUNTAIN COMMUNITY COLLEGE, 99-2012
- INVOLVED IN VARIOUS RESEARCH STUDIES, 1977-PRESENT

# STRONG HEART STUDY

## Phase I

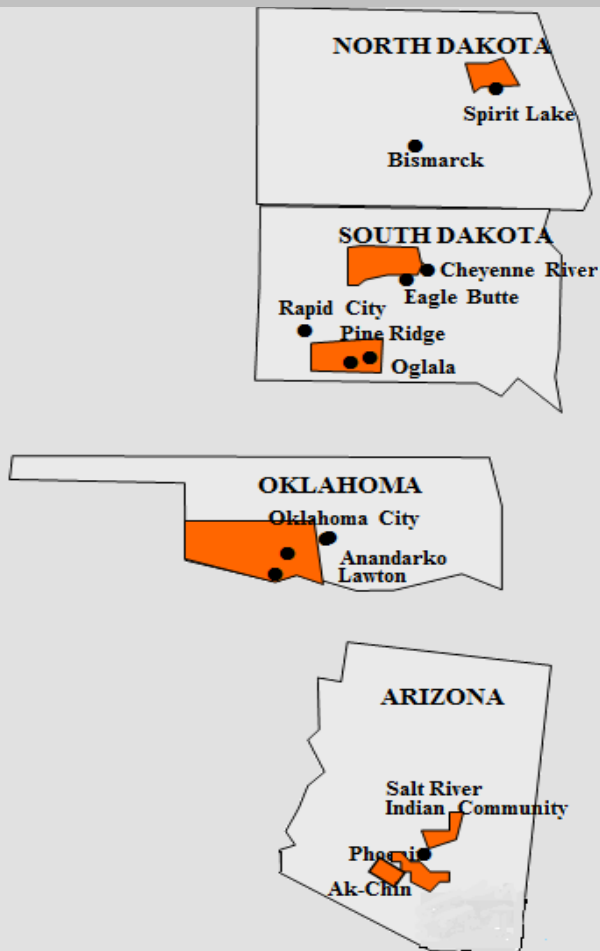
1988

4549 Participants  
ages 45-74 years

Arizona: Pima/Maricopa/Papago in  
the Salt River, and  
Ak-Chin Indian communities

Oklahoma: Apache, Caddo,  
Comanche, Delaware, Fort Sill  
Apache, Kiowa, and Wichita

Dakotas: Oglala Sioux and  
Cheyenne River Sioux and the  
Spirit Lake Nation



# STRONG HEART STUDY

- **SIX PHASES:**
  - Phase I (1988 - 1992)....Original Cohort
  - Phase II (1993 - 1995)....Original Cohort
  - Phase III (1998 - 1999)....Original Cohort
    - plus pilot Family Study
  - Phase IV (2000 - 2005)...Family Study
    - 3,600 total participants, ages 16 and up
    - Large families with original cohort members
  - Phase V (2005 - 2010)...Family Study
  - Phase VI (2013 - 2018)...Surveillance of all

# STRONG HEART STUDY



**Drs. Everett Rhoades, Yvette Robideaux et al**



**Dr Spero Manson**

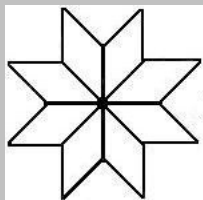


**Dr Rich Fabsitz, NHLBI**

- **Began in 1988**
- **Pioneered community-based participatory research**
  - **Centers in AZ, OK and Dakotas**
  - **Recruited and retained <7,000 over multiple exams**
  - **Assisted >50 American Indian young investigators attain advanced degrees**
  - **Among first to incorporate genetic analysis**



# STRONG HEART STUDY: Dakota Center



Missouri Breaks Industries Research, Inc.



# **STRONG HEART STUDY: Oklahoma Center**



**Dr E Rhoades and Fabsitz  
at OK community mtg**



**Much younger SHS folks  
at OK field health office**

# **STRONG HEART STUDY: Texas Biomedical Institute**



**John Emhoolah Jr blessing  
SHS samples, 7/11/17**

**Visiting the samples and lab  
facilities during SHS community  
meeting, 2016**





# INTO THE FUTURE:



**Dr. Jolly**



**Dr. Henderson**



**Dr. Dorscher**



**Dr. Deen**



**Dr. Verney**



**Dr. Fretts**

- **Dr. Stacey Jolly**
  - Alaska Native (Aleut)
  - Principal Investigator, DK center
- **Dr. Jeff Henderson**
  - Cheyenne River Sioux
  - CEO Black Hills Center AI Health
- **Dr. Joy Dorscher**
  - Turtle Mountain Band, Chippewa
  - Dean, UND Medical School
- **Dr. Jason Deen**
  - Blackfeet Nation
  - Pediatric Cardiologist
- **Dr. Steve Verney**
  - Mi'kmaq
  - Dept Psychology, University of Washington
- **Dr. Amanda Fretts**
  - Mi'kmaq
  - Epidemiology, University of Washington

# FURTHER INTO THE FUTURE



- **Minority Supplement to Strong Heart Study (Dakota Center) for Kaytlin Lawrence**
  - Cheyenne River Sioux tribal member
  - 2<sup>nd</sup> year Medical Lab Tech at University of Mary
  - Previously worked as summer intern for MBIRI
  - Extending recruitment of SHS participants to investigate pre-eclampsia
  - Obtaining additional instrumentation (thermocycler) through SPHERE, Precision Medicine grant at Stanford University

# PUBLIC HEALTH IMPACT



- Confirmed relevance of Framingham risk factors in American Indian population
- Helped establish critical importance of diabetes as a CVD “equivalent”
- Found high prevalence of stroke in American Indians
- Discovered high prevalence of LVH in youth
- Accurate community nutrition and physical activity baseline data

# STANDARDS OF CARE

Get In Step  
with  
NCEP

**NCEP ATP III Guidelines**

Test	Desirable
Total Cholesterol (TC)	< 200 mg/dL
HDL Cholesterol	> 40 mg/dL
LDL Cholesterol	< 130 mg/dL May be modified in the presence of major risk factors.
Triglycerides	< 150 mg/dL
TC/HDL Ratio	4.5 or less
Glucose	Fasting: 60–110 mg/dL Nonfasting: < 160 mg/dL

**SANDS**  
Stop Atherosclerosis in Native Diabetics Study

From the Strong Heart Study

**Calculator: Estimated Risk of Developing CHD in 10 Years**

ong Heart Study (Citation: *Circulation* 2006; 113: 2897–2905) to estimate a person's chance of having CHD (Co  
r. To find your estimated risk, enter your information in the calculator below. [Definitions and descriptions](#) of some

ock this ActiveX control application. When they do, a yellow information bar showing the message "To protect your security..." v  
and select "Allow Blocked Content..."

Prediction using (select one)	<input checked="" type="radio"/> LDL-C and HDL-C	<input type="radio"/> TC and HDL-C
Gender	<input checked="" type="radio"/> Male	<input type="radio"/> Female
Age	<input type="text"/>	
Are you currently taking hypertension medications for high blood pressure?	<input checked="" type="radio"/> No <input type="radio"/> Yes	
Systolic Blood Pressure (SBP)	<input type="text"/>	
LDL-C or TC (mg/dL)	<input type="text"/>	

- Helps to inform NCEP, ATP III guidelines, including diabetes as CVD equivalent
- SANDS (SHS outgrowth) provides important evidence related to effects of aggressive lipid and BP treatment
- Framingham risk scores modified for IHS
- Important evidence of albuminuria as a key predictor of CVD



# **“TRANSLATION”**



**George Starr, Physician Assistant (Wanblee), and Drs. Welty**

# **“TRANSLATION”**



**High School Students taking part in 3<sup>rd</sup> Annual Research Conference, Eagle Butte, 4/11/17**

# “TRANSLATION”



Dr. Ana Navas-Acien



Dr. Christine George



Mr. Joseph Yracheta  
MBIRI, Eagle Butte, SD

- **SOME PRIVATE WELLS IN PINE RIDGE AND SPIRIT LAKE COMMUNITIES**
  - **LEVELS OVER 10 PPB**
- **PUBLIC (“RURAL WATER”) SYSTEMS ALL MEET EPA STANDARD OF <10 PPB**
- **NO WELLS ON CRST TESTED OVER 10 PPB**
- **INTERVENTION FOR PRIVATE WELLS FUNDED AND BEGUN IN 2015**

# **“TRANSLATION”**



**Dr. Lonnie Nelson**  
**Cherokee, U Washington**

**Dr. Dedra Buchwald**  
**Washington State U**



- **FITSMI Study to test the ability of a family based intervention to reduce stroke risk factors**
  - **Motivational interviewing**
  - **Improve blood pressure control, reduce smoking**
  - **Drs. Nelson and Buchwald**
  - **Began in 2014**
- **“Rhythm and Timing”**
  - **Novel physical therapy technique to improve recovery after a stroke**
  - **Dr. Verney**
  - **Began in 2015**



# “TRANSLATION”



Dr. Amanda Fretts,  
Mi'kmaq  
Univ. Washington



- Community nutrition information
  - Many people call both SPAM and hamburger “meat”
  - **SPAM: \$2.29 / oz protein**
  - 77% of daily salt
  - **Hamburger (80/20)**
  - **\$0.85 / oz protein**
  - 4% of daily salt
  - “meats” like SPAM increase risk of diabetes by 60%
- CRCAIH funded pilot data
- Promising evaluation of R01 application

# STRONG HEART STUDY BENEFITS



- **INFORMATION TO TRIBAL LEADERS AND HEALTH DIRECTORS:**
  - **HHS AND COUNCIL MEETINGS**
    - PUBLICATION REVIEW
  - **“DATA BOOK”...EPIDEMIOLOGY OF CVD AND DIABETES IN LAY TERMS**
    - USEFUL FOR LOBBYING EFFORTS
  - **MEETING WITH SHS STEERING COMMITTEE IN ABERDEEN AREA**
  - **DATA CRITICAL FOR OBTAINING SDPI**
    - **FUNDING DECISIONS BASED ON FACTS, NOT ANECDOTES AND HEADLINES**

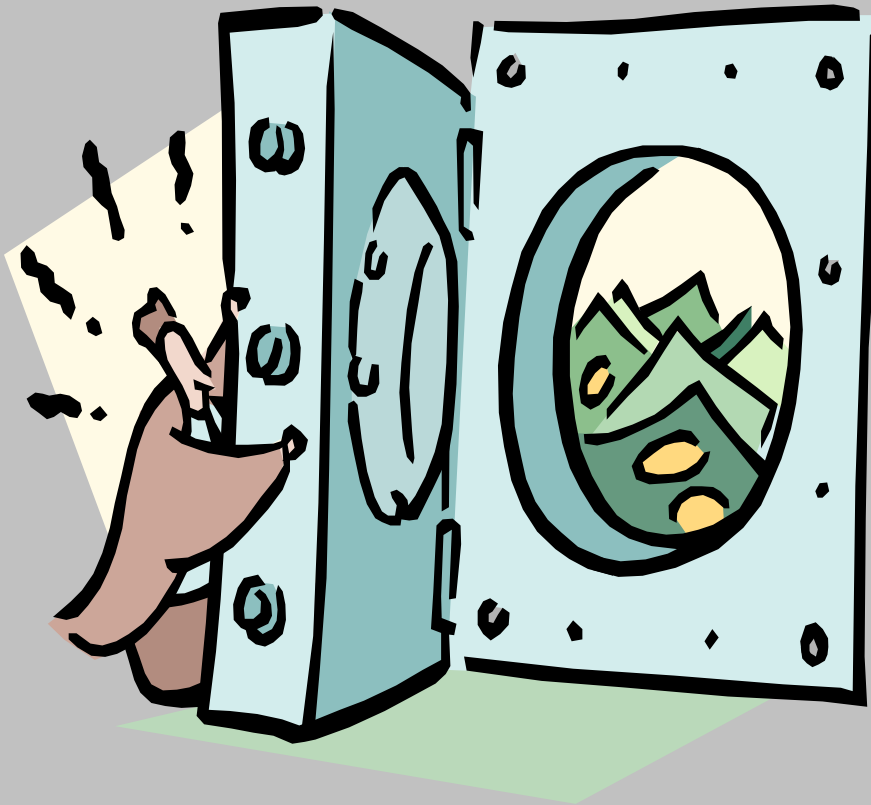
# STRONG HEART STUDY

## BENEFITS

- CAPACITY BUILDING:
  - increased knowledge of research organization, benefit, risks
  - above via publication review, proposal approval process, close collaboration with investigators
  - training of tribal members in research fields
  - public information related to research
  - assistance in developing IRBs, RRBs etc
  - discussion of global issues, eg “**data sharing**”



# **“DATA SHARING”**



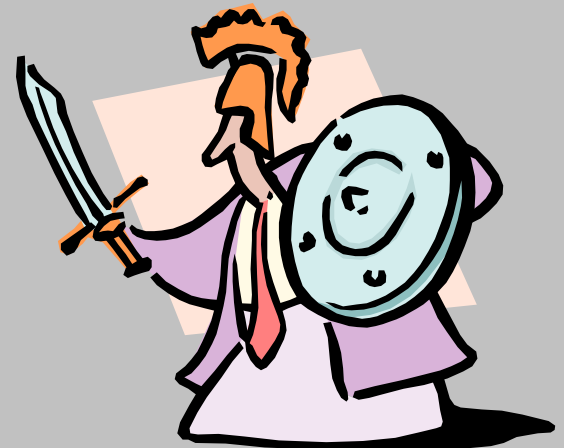
- **“SHARING” DOESN’T ALWAYS COME EASY, EVEN FOR SCIENTISTS!**
- **SOME RESEARCHERS GUILTY OF “HOARDING” DATA**
- **SOME DATA LOST TO THE FUTURE BECAUSE NO PLANS MADE FOR DISTRIBUTION**



# **“DATA SHARING”**



- **IMPORTANT NOT TO REMOVE INCENTIVE FOR COLLECTING DATA**
- **IF OTHERS COULD SIMPLY COME ALONG AND USE WHAT OTHERS HAD GATHERED**



# **“DATA SHARING”**

- **ORGANIZATIONS ENDORSING:**
  - **INSTITUTE OF MEDICINE**
  - **WELLCOME TRUST**
  - **NATIONAL RESEARCH COUNCIL**
  - **BILL / MELINDA GATES FOUNDATION**
  - **AMERICAN HEART ASSOCIATION**
  - **“POLICY” FOR MANY JOURNALS**
- **OFFICIAL NIH POLICY AS OF 2003**
- **INTENT: TO MAXIMIZE THE UTILITY OF RESEARCH DATA COLLECTED**

# “DATA SHARING...HISTORY”



- FEB 13, 2004 NIH WORKBOOK ON “DATA SHARING”
- “An important issue associated with the sharing of all data ...is the **protection of research participants'** identities.”
- “...possibility of **harmful social**, economic, or legal consequences...”
- “What constitutes “sensitive” data varies by context, **population**, and time.”

# **“DATA SHARING...HISTORY”**

- **NIH/NHLBI ASKS ALL FUNDED RESEARCH PROJECTS TO MAKE THE DATA AVAILABLE <1 YEAR AFTER DATA COLLECTION COMPLETE**
- **THOUGHT TO PROVIDE ENOUGH TIME FOR INVESTIGATORS TO COMPLETE INITIAL ANALYSIS AND REPORTING**
- **THE STRONG HEART STUDY HAS DEVELOPED DATA SHARING PLANS IN COLLABORATION WITH THE TRIBES**
- **FIRST PRESENTATION TO DAKOTA TRIBAL COUNCILS ON THIS ISSUE, 2004.**

# “DATA SHARING...HISTORY”



Prairie Knights Casino, 2006





# **“DATA SHARING...HISTORY”**



- **SINCE THEN, MULTIPLE PRESENTATIONS TO:**
  - **TRIBAL COUNCILS**
  - **COMMUNITY GROUPS**
  - **TRIBAL CHAIRMEN'S HEALTH BOARD**
  - **ASSOC of AMERICAN INDIAN PHYSICIANS**
  - **SHS STAFF**
- **GENERALLY NON-COMMITAL**

# **“DATA SHARING”**



- **ONGOING AT SHS SINCE THE BEGINING:**
  - **TRIBAL APPROVAL FOR 406+ PUBLICATIONS**
  - **COLLABORATIONS WITH OTHER INVESTIGATORS (WITH SAFEGUARDS FOR TRIBAL AND INDIVIDUAL CONFIDENTIALITY)**
  - **META-ANALYSES (eg EMERGING RISK FACTORS CONSORTIUM)**
  - **NIH WORKSHOP FOR NEW INVESTIGATORS, 2014**
  - **IMPROVED INMED AND OTHER STUDENT ACCESS**

# “DATA SHARING”



**Article 1, Section 8: To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes...**

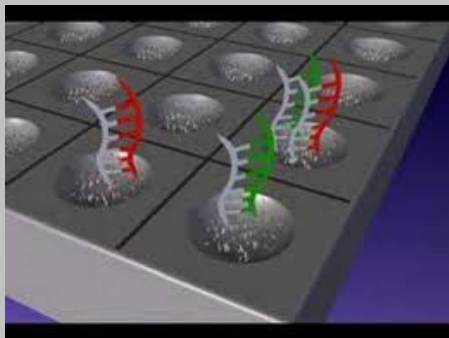
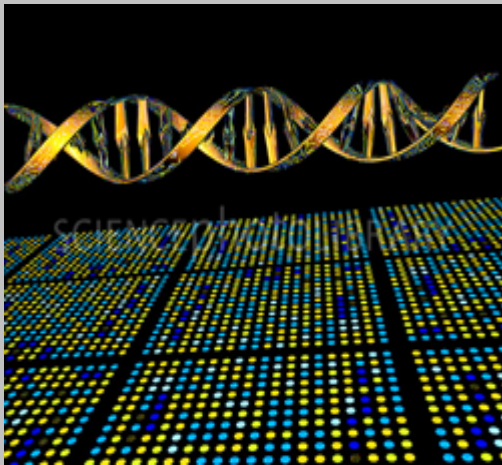
- **WHILE THE US CONSTITUTION DOESN'T DIRECTLY SPECIFY THE SOVEREIGNTY OF TRIBES**
- **TRIBAL SOVEREIGNTY IS WELL ESTABLISHED IN US LAW**
- **SHS INVESTIGATORS HAVE CONSISTENTLY MAINTAINED TO NIH THAT THERE NEEDS TO BE A GOVERNMENT TO GOVERNMENT DISCUSSION RELATED TO “DATA SHARING” FOR RESEARCH**

# **“DATA SHARING”**

- **CONSIDERATIONS:**
  - **TRIBAL SOVEREIGNTY AND POTENTIAL COMMUNITY HARMS**
  - **SMALL NUMBERS MAKE CONFIDENTIALITY DIFFICULT**
  - **TRIBAL IDENTIFICATION ESSENTIALLY ASSURED**
  - **MANY TRIBAL RESOLUTIONS ASSERTED OWNERSHIP OF DATA**
  - **WHAT INSTITUTION(S) WOULD BE MOST ABLE TO DISTRIBUTE THE DATA AND SAFEGUARD TRIBAL INTERESTS?**
  - **IF TRIBES ASSERTED OWNERSHIP AND ISOLATED THEIR DATA, IT WOULD LOSE POWER AND UTILITY TO OVERALL AMERICAN INDIAN HEALTH GREATLY LIMITED**



# “DATA SHARING”



- **GWAS TECHNOLOGY AND NIH POLICY DRAMATICALLY CHANGED ENVIRONMENT FOR SHS**
  - 2006-2007
  - ANCILLARY STUDY NOT FUNDED
- **COLLABORATION WITH CALICO/PAGE AFFECTED**
- **SITUATION SIMILAR WITH TOPMED**



# **INCONSISTENTLY APPLIED 2008 NIH GENOME-WIDE DATA SHARING POLICY**

- **NIDDK – GRANTS WAIVER OF NIH GENOME-WIDE DATA SHARING POLICY FOR ITS FIND STUDY – SHS PARTICIPATES AS REPLICATION POPULATION**
  - **IYENGAR ET AL., PLOS GENET. 2015 AUG 25;11(8):E1005352**
- **NHGRI – PAGE STUDY**
  - **SHS NOT INCLUDED IN ADDITIONAL GENOME-WIDE FOCUS BECAUSE NHGRI WOULD NOT GUARANTEE A WAIVER FROM REQUIRED DATA SHARING**
- **NHLBI – TOPMED**
  - **SHS NOT INCLUDED IN MAJOR GENOME-WIDE SEQUENCING INITIATIVE OF ALL OF ITS COHORTS**

# **WAYS TO CIRCUMVENT 2008 NIH GENOME-WIDE DATA SHARING POLICY**

- **INCONSISTENT POLICY LEADS TO INVESTIGATORS SOMETIMES BEING FORCED TO FOCUS GRANT APPLICATIONS ON CERTAIN FUNDING INSTITUTES IN ORDER TO GENERATE GENOME-WIDE GENETIC DATA**
- **2008 POLICY APPLIED TO GENOME-WIDE MARKER DATA**
  - **GENE-FOCUSED ANALYSES CONDUCTED**
    - MELTON P. et al GENET EPIDEMIOL. 2009; 33:766.
  - **PRIVATE FUNDING ALLOWS SOME GENOME-WIDE DATA GENERATION (THOUGH LIMITED DUE TO COST)**
    - COLE SA, et al. PROCEEDINGS OF THE AMERICAN SOCIETY OF HUMAN GENETICS 2013 ANNUAL MEETING , BOSTON, MA, OCTOBER 22-26.
- **2015 NIH DATA SHARING POLICY INCLUDES GENE-FOCUSES ANALYSES CONDUCTED ON MULTIPLE PARTICIPANTS, FURTHER LIMITING WORK-AROUNDS**

# INNOVATION AT WORK



- **iDASH:**
  - Dr. Lucila Ohno-Machado at UC San Diego
  - Dr. Elisa Lee (SHS)
- To develop an IT platform that would allow SHS dataset analysis without access to raw data
- Generally acceptable to tribes
- **University of North Dakota INMED**
  - Dr. Joy Dorscher
  - SHS Dakota Center
- Modification to SHS policy allowing expedited access to SHS dataset for medical students



# **IMPLICATIONS FOR INADEQUATE GENETIC STUDIES OF AMERICAN INDIANS**

- **LACK OF DATA ON US AMERICAN INDIANS (MOST DATA AVAILABLE ARE FROM CENTRAL AND SOUTH AMERICA)**
- **LACK OF UNDERSTANDING OF GENETIC ARCHITECTURE IN AMERICAN INDIANS AND RISK OF DISEASE RELATIVE TO OTHER POPULATIONS, INCLUDING MEXICAN AMERICANS WHO MIGHT SHARE SUSCEPTIBILITY ALLELES**
- **LACK OF ABILITY TO STUDY POPULATION GROUPS THAT HAVE UNIQUE GENETIC AND ENVIRONMENTAL INTERACTIONS AND THEIR CONSEQUENCES ON HEALTH**
- **INABILITY TO FULLY CHARACTERIZE DISEASE SUSCEPTIBILITY IN POPULATION GROUPS THAT SUFFER DISPROPORTIONATELY FROM COMPLEX DISEASES**

# “DATA SHARING”

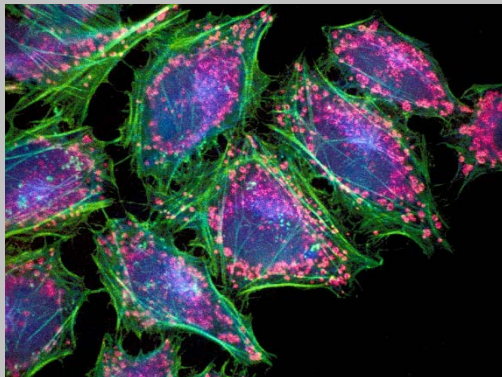


American Journal of  
**Epidemiology**

- TAKING A CUE FROM NIH, MANY JOURNALS BEGAN TO INSIST ON TRANSFERRING DATA TO A REPOSITORY
- GENERALLY A “PUBLIC” OR “INSTITUTIONAL” REPOSITORY THOUGHT TO HAVE PERSISTENCE
- ASSERTIONS FROM SHS THAT OUR STUDY REPOSITORY BEGAN IN 1988 AND OLDER THAN MANY...CONVINCING?



# HENRIETTA LACKS



- TREATED FOR CERVICAL CANCER AT JOHNS HOPKINS IN 1951
- BLACKS WERE REFUSED CARE IN MANY HOSPITALS IN THE REGION THEN
- A PORTION OF HER CERVICAL BIOPSY WAS USED IN AN ATTEMPT TO CULTURE HUMAN CELLS
- MULTIPLE QUESTIONS ON “CONSENT”
- NIH RELEASED WHOLE GENOME SEQUENCE DATA
- NIH NOW INCLUDES LACKS FAMILY IN DATA USE EVALUATION

# **“DATA SHARING”**



- **SHS BEGAN TO SENSE A SHIFT IN NIH POSITION AROUND 2014**
- **TENTATIVE OUTREACH FROM SOME INSTITUTES**
- **INTEREST IN DIRECT COMMUNICATION WITH TRIBAL LEADERS**
- **INCREASED RECOGNITION OF TRIBAL GOVERNMENT**
  - **eg. SEE “SINGLE IRB” REGULATIONS FOR MULTI-SITE STUDIES**

# “TRIBAL CONSULTATION”

- The deadline for Tribal leaders to submit nomination letters for NIH’s Tribal Consultation Advisory Committee has been extended to November 28, 2014. Please contact Dr. Kathy Etz with any questions at [NIHTribalCommittee@od.nih.gov](mailto:NIHTribalCommittee@od.nih.gov).
- Pursuant to Presidential Executive Order No. 13175, November 6, 2000, and the Presidential memoranda of September 23, 2004, and November 5, 2009, the National Institutes of Health (NIH) **is establishing** a Tribal Consultation Advisory Committee (TCAC). The NIH TCAC **shall serve** as an advisory body to NIH, helping to ensure that Tribes and AI/AN (American Indian/Alaska Native) people have meaningful and **timely input**

# “PRIVACY” TODAY

## Equifax data breach could create lifelong identity theft threat

Adam Shell, USA TODAY Published 7:00 a.m. ET Sept. 9, 2017 | Updated 10:08 a.m. ET Sept. 9, 2017



Share your [feedback](#) to help improve our site experience!

# “PRIVACY” TODAY

Facebook Manipulated 689,003  
Users' Emotions For Science



How Target Figured Out A Teen  
Girl Was Pregnant Before Her  
Father Did

- There's no need to get experiment participants to sign pesky consent forms as they've already agreed to the site's data use policy. (referring to Facebook)
- Ever get a call from your credit card company wondering if you really intended to buy X ? Or if you are really in Atlanta, GA?



# “PRIVACY” TODAY



- DNA Evidence Collected Secretly; Judge OK's Use at Rape, Abduction Trial
  - Detectives follow suspect and recover fast food leftovers in K-Mart trash can
- DNA profile of a **family member** is sufficiently close match to evidence in “Grim Sleeper” case
  - Undercover detective works at Pizza Hut, collects DNA from cup after serving suspect

# **“SOCIAL MEDIA”**



- **JUNE, 2014**
- **TWITTER PREVIOUSLY ALLOWED LIMITED ACCESS TO ABOUT 1% OF “TWEETS”**
- **NOW EXPANDED TO THE ENTIRE DATA SET, SINCE 2006**
- **TWITTER IS CONSIDERED A “PUBLIC SPACE” AND “OBSERVATION” ALLOWED ??**
- **TWITTER “SUGGESTS” THAT INVESTIGATORS NEVER REVEAL SCREEN NAMES**
- **DOES TWITTER RETAIN ANY LEGAL RIGHTS TO “DISCOVERIES”?**

# **“PRIVACY” TODAY**



**SANFORD**<sup>™</sup>  
HEALTH



- **BIOBANKS BECOMING COMMON**
- **NOT ALL USE CONSENT**
- **MOST CONSENTS VERY BROAD**
- **NEONATAL BLOOD SPOTS**
- **HOSPITAL PATHOLOGY COLLECTIONS**
- **LUMACAFOR FOR CYSTIC FIBROSIS**
  - **CF FOUNDATION, 2 BILLION, ROYALTIES**
  - **PATIENTS=\$333,000/YR**

# HOW TO REACH US



- <http://strongheart.ouhsc.edu>
- Marcia O'Leary, RN
  - Missouri Breaks Industries Research Inc
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