

Tribal Approaches to Human Subjects Research Protections

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American Indians in Oklahoma

- Oklahoma has the second largest population of American Indians in the U.S.: 392,000
- 38 distinct, federally recognized tribes maintain their headquarters in the state
- 18 tribes not recognized by the U.S.
- 25 Native languages are spoken in Oklahoma



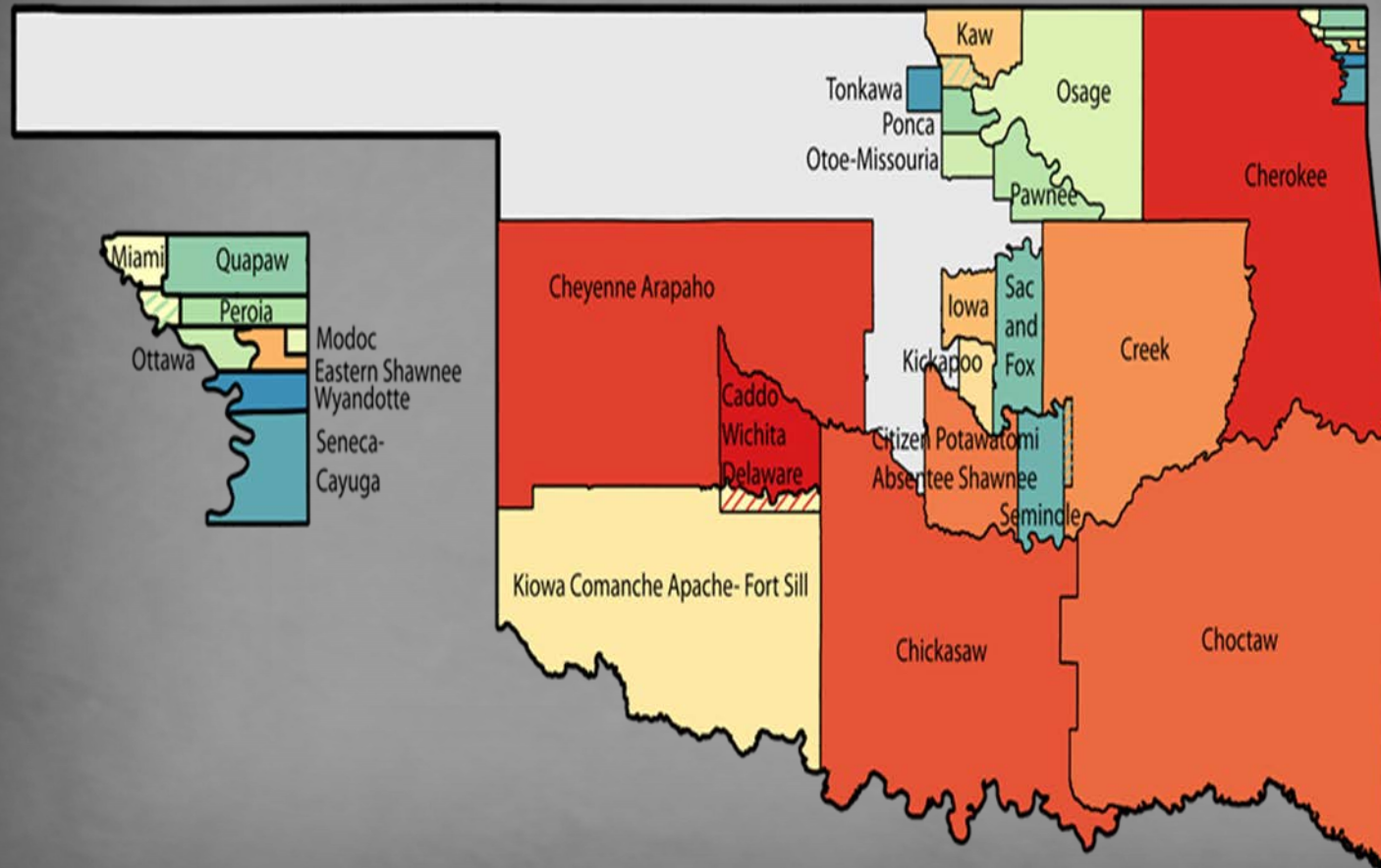
American Indians in Oklahoma

- Each Oklahoma tribe has its own unique history, culture, language, practices and governance
- There are similarities, but also many differences between tribes
- The majority have sovereign nation status
- **Non-reservation based (Osage Nation)**
- **170,000 (43%) OK American Indians reside in urban areas**



American Indians in Oklahoma

Territorial Jurisdictions



The Chickasaw Nation

- 13 counties in rural, south-central Oklahoma
- *356,301 residents
- *35,065 Native Americans (user pop.)

*Based on 2013 U.S. Census estimates



The Chickasaw Nation



Tribal IRBs: Distrust of Research

- Research driven by entities outside of tribe
- Lack of understanding and respect for tribal culture and priorities
- Unilateral dissemination of findings
- Misrepresentation, stigmatizing and/or stereotyping results
- Sense of being over-researched and exploited



Role of Tribal IRBs

“Tribally based institutional review boards (IRBs) are addressing these issues in an effort to control new health science research, set their own research agenda, and protect their people in the same spirit as has been accomplished through the perpetuation of **sovereignty rights.**”

(Morton, et al, American journal of public health, 12/2013, Volume 103, Issue 12, pp. 2160 - 2164)



CNDH IRB

1998

- Chickasaw Nation RRB established by Executive Order Governor Bill Anoatubby
- *Chickasaw Health Research Act of 1998 (legislative)
- Membership: heavily scientific; quarterly meetings
- Ten Tribes alcoholism study and Parke-Davis diabetes study



CNDH IRB

2001

- Executive policy statement: Tribal Regulations for Research*
- Federal Wide Assurance: OSDH IRB (REACH 2010 project)
- 1st IRB training (IHS NIRB, Salt Lake City, UT)

2002

- NARCH: regular monthly IRB meetings



CNDH IRB

2003

- **Final policies:** Chickasaw Nation Health System
- **Application documents:**
 - Research contract
 - Investigator agreement
 - Review checklists

2004

- Registered IRB



CNDH IRB

Chickasaw Nation Human Research Protection Program

- Guidance from the Office of Human Research Protections (OHRP), federal codes and CNDH policies
- Promotes inter-divisional collaboration to ensure protection of subjects throughout the Chickasaw Nation
- *Protect the safety of our research participants and guard the integrity and heritage of the Chickasaw Nation*



CNDH IRB

Selected Current Projects:

- Tribal Health and Resilience in Vulnerable Environment (THRIVE)
- Disparities and Outcomes Associated with Colorectal and Lung Cancer Screening among the Citizens of the Chickasaw Nation
- Climate Change, Heat Exposure, and Acute Morbidity in a NA Population
- Identifying Postpartum Intervention Approaches to Prevent Type 2 DM and CVD in AI Women with Previous GDM
- Strategic Prevention Framework – Tribal Incentive Grant (SPF-TIG)
- Cultural Assessment of Obesity in American Indian Preschool Children: A Qualitative Study of Parents and Caregivers
- Mechanisms and Predictors of Pre-eclampsia in Minority Women with Impaired Glucose Level
- Prenatal Conditions and the Pathways to Obesity and Diabetes in Children
- ELSI: Center for American Indian Alaska Native Genomic Research*
- Numerous language and culture projects



CNDH IRB Policies: Preface

“The Chickasaw Nation has the inherent *sovereign authority* to govern itself, and to provide for the health and general well-being of the Chickasaw people and the American Indian people it serves.... according to the highest standards of *ethics*...

Furthermore, the Chickasaw Nation recognizes the value of medical, social and physical science research... [and] may participate in research projects that are of *value to the interests* of the Chickasaw Nation, the Chickasaw people and the American Indian people it serves.”



CNDH IRB Policies

CNDH Institutional Review Board Policy

- Purpose
- Functions
- Operations
- *Authority*
- *Jurisdiction*
- Structure
- *Membership*
- Reporting
- Review of findings, dissemination



CNDH IRB Policies

CNDH Participation in Research Policy

- CNDH shall implement *tribal guidelines* pertaining to the review, approval and participation in research conducted...*within the CNDH service area*
- The *merit* of all proposed research projects...shall be reviewed to determine whether or not the Chickasaw Nation will *participate*, or *allow the conduct* of such research within its territorial jurisdiction
- The processes for the review, approval and conduct of research will be in *conformance* with Chickasaw Nation policy
- The CNDH will not participate in any proposed research that includes the *denial of medical treatment to patients*



CNDH IRB Policies

Participant Rights Pertaining to Research Policy

- To receive voluntary and written, fully informed consent of the project's purpose, interventions, risks and benefits
- To receive an explanation of procedures, duration, experimental nature and options/alternatives
- To receive copies of all documentation
- To retain the right to refuse or withdraw without penalty or eligibility for services



CNDH IRB Policies

Release and Dissemination of Research Results Policy

- *Ad hoc* review and approval of all publications prior to dissemination
- “Publications”: all presentations, written reports, papers, manuscripts, abstracts and journal or book articles, including academic treatises
- *45 days* to review and respond
- *No passive approval*
- *Consistent* with the goals, intent and *interests* of the Chickasaw Nation
- Represent the Chickasaw Nation without unfair *stigma/harm* to the community



CNDH IRB Policies

Release and Dissemination of Research Results Policy

- *Multi-tribal* data should not be presented as representative of any particular tribe, only as representative of individual participants
- Title of presentations or individual slides should be clear as to who and what is being represented
- Results should *not be generalized* to an entire tribe, only to the individual participants in the research project



CNDH IRB Policies

Expedited Review Policy

- Chair or administrator
- No more than minimal risk to participants
- Meet the criteria as defined by the Office of Human Research Protection (OHRP)
- *Compliance with IRB policy “Release and Dissemination of Research Results and Findings”*



CNDH IRB Policies

Exempt Policy

- Federal policy provides for exemption from IRB review for certain types of research
- *Exemption from IRB review does not apply to dissemination of findings.* Any and all publications of research results must receive prior review and approval by the CNDH IRB



CNDH IRB: Additional Protections

- Research application
- *Research investigator agreement (PI)*
- Investigators statement



CNDH IRB: Additional Protections

Research Investigator Agreement

- Conduct the study in accordance with the Nation's *research policies* (provided with application)
- **INDEMNIFICATION:** The Investigators shall each be responsible for their own negligent and intentional acts and omissions with their general and professional liability governed by the terms of the *Oklahoma Governmental Tort Claims Act, 51 Okla.* The Nation shall be responsible for its own negligent and intentional acts and omissions with the Nation's liability covered under terms of the *United States Federal Tort Claims Act.*
- Non-discrimination clauses (preferential hiring)



CNDH IRB: Additional Protections

Research Investigator Agreement

- It is specifically acknowledged and agreed by the parties that any and all research data and findings...shall be and *sole ownership of same shall be retained and vested with the Nation*
- Publication and/or dissemination of the Agreement's outcomes and/or results are a mutually beneficial goal and *each party* will be permitted to present or publish (consistent with policy)
- At the end of the Agreement, the Nation, as owner, may disseminate, present, and/or publish previously disseminated information *without Investigators' consent.*



CNDH IRB: Additional Protections

Research Investigator Agreement

NON-DISPARAGEMENT:

Each Institutional Investigator and Principal Investigator...along with the Nation, stipulates and agrees that...none of the parties shall...make any *disparaging remarks* of any sort or otherwise communicate any disparaging information about the other... including on social media.

Further, each Investigator Institutional Investigator and Principal Investigator, along with the Nation, agree to take no action of any nature which is intended, or would reasonably be expected, to *harm the other party or its reputation* or which would reflect or reasonably lead to *unfavorable publicity* of that party.



CNDH IRB: Additional Protections

Consent and PHI authorizations

- No *broad consent*: specific use (including data/specimens to be collected)
- No *secondary* use/sharing of data without prior approval
- *Expiration dates* for permission/data use
- No recruitment contact *lists*
- No language requiring *participant costs* for additional care
- *Local* contact person information
- **Repositories*: separate consent form; specific as possible

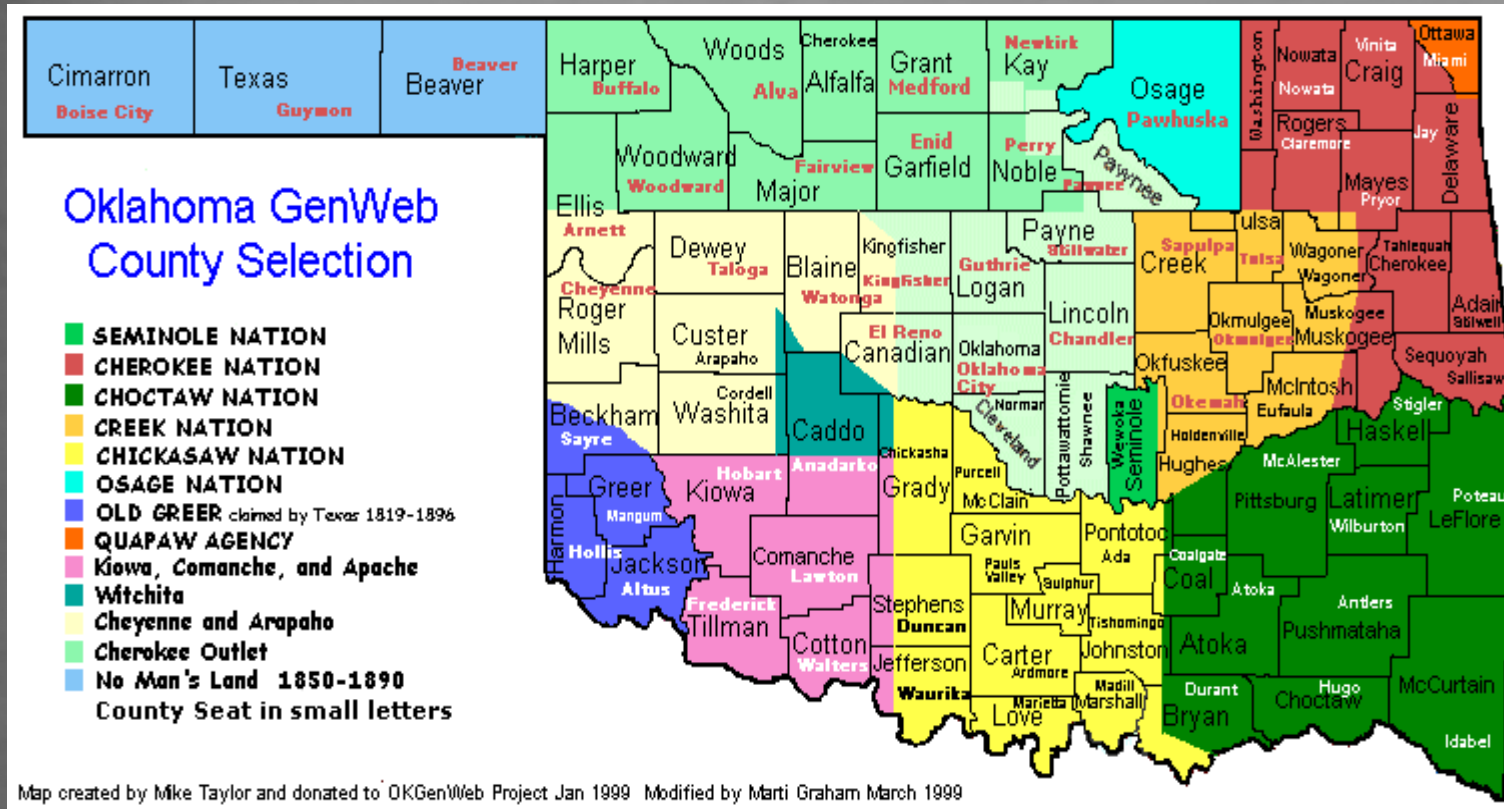


Oklahoma AI IRBs

- Cherokee Nation
- Chickasaw Nation Department of Health
- Choctaw Nation
- Oklahoma City Area Indian Health Service



Oklahoma AI IRBs



Oklahoma IRBs: Benefits

- Community of ethical tribal research protections
- Challenge and promote professional competence
- Sounding board for tough/novel issues
- Resolve differences but also agree to disagree
- Facilitate processes with research partners
- Educate research partners/institutions
- Highest level of protections for individual AI research participants and tribal communities



Oklahoma IRBs: Benefits

National impact:

- TODAY study AI publications subcommittee (nat'l P&P)
- Manuscript: Chadwick, J., Copeland, K., Daniel, M., Erb-Alvarez, J., Felton, B., Khan, S., Saunkeah, B., Wharton, D., & Payan, M. (2014). Partnering in research: A national research trial exemplifying effective collaboration with American Indian nations and the Indian Health Service. *American Journal of Epidemiology*, Nov., 2014, 1-6.
- 2016 USPHS Scientific and Training Symposium: 1st place poster



Extending Research Protections to Tribal Communities:

Ethical Justification

- Freeman (2004, Sahota 2007): application of Belmont's individualistic ethical principles to tribal communities
- Wallwork (2008): adding ethical treatment of groups to moral individualism of Belmont
- Quigley (2012): individualistic bioethical principles apply to cultural groups who share a common harm or burden
- Mikesell (2013): research ethics should focus on community as well as individuals; is not ethical unless results in tangible community benefits



Extending Research Protections to Tribal Communities:

Ethical Justification

CBPR- preferred research approach in many tribal communities

- Collaborative research method; not an ethical framework
- Requires faithful and considerate adherence all phases
- Requires application within context of Belmont's principles (i.e., community consent)
- Literature consensus: CBPR and Belmont principles appropriate but not sufficient for community protections; need for additional ethical contexts/dimensions



Extending Research Protections to Tribal Communities:

Ethical Justification

- *Sovereignty*: provides the right for tribal self-determination, including conduct of research
- Most commonly invoked justification for extending community protections, including CBPR
- Respect for sovereign rights is a broader expression of respect for autonomy, persons
- Sovereignty is a political-legal institution defining internal and external relationships between nations
- Sovereignty has ethical implications, but alone is insufficient moral justification



Extending Research Protections to Tribal Communities:

Ethical Justification

- *Solidarity principle*: obligates a social group (i.e., tribe) to provide for and protect its common/shared interests and its people, especially the most vulnerable
- Demands obligations independent of values or actions of those outside the group (tribe)
- Interdependence/interrelatedness
- Community expression of justice (and beneficence)
- It is the inherent collective responsibility (solidarity) for tribes' continued survival and flourishing that provides the moral legitimacy to tribal research protection efforts (and beyond)



Tribal Self-determination



Sovereignty Solidarity



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