

# A Tribal Approach to Human Subjects Research Protections

The Chickasaw Nation Department of Health  
Division of Research and Population Health

Rev. Bobby Saunkeah, RN, MSHCE, CIP

Kiowa Tribe of Oklahoma

Chair, CNDH IRB

Human Protections Administrator

Michael Percy, MPH, MT(ASCP)H

CNDH Epidemiologist

IRB Administrator



# 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





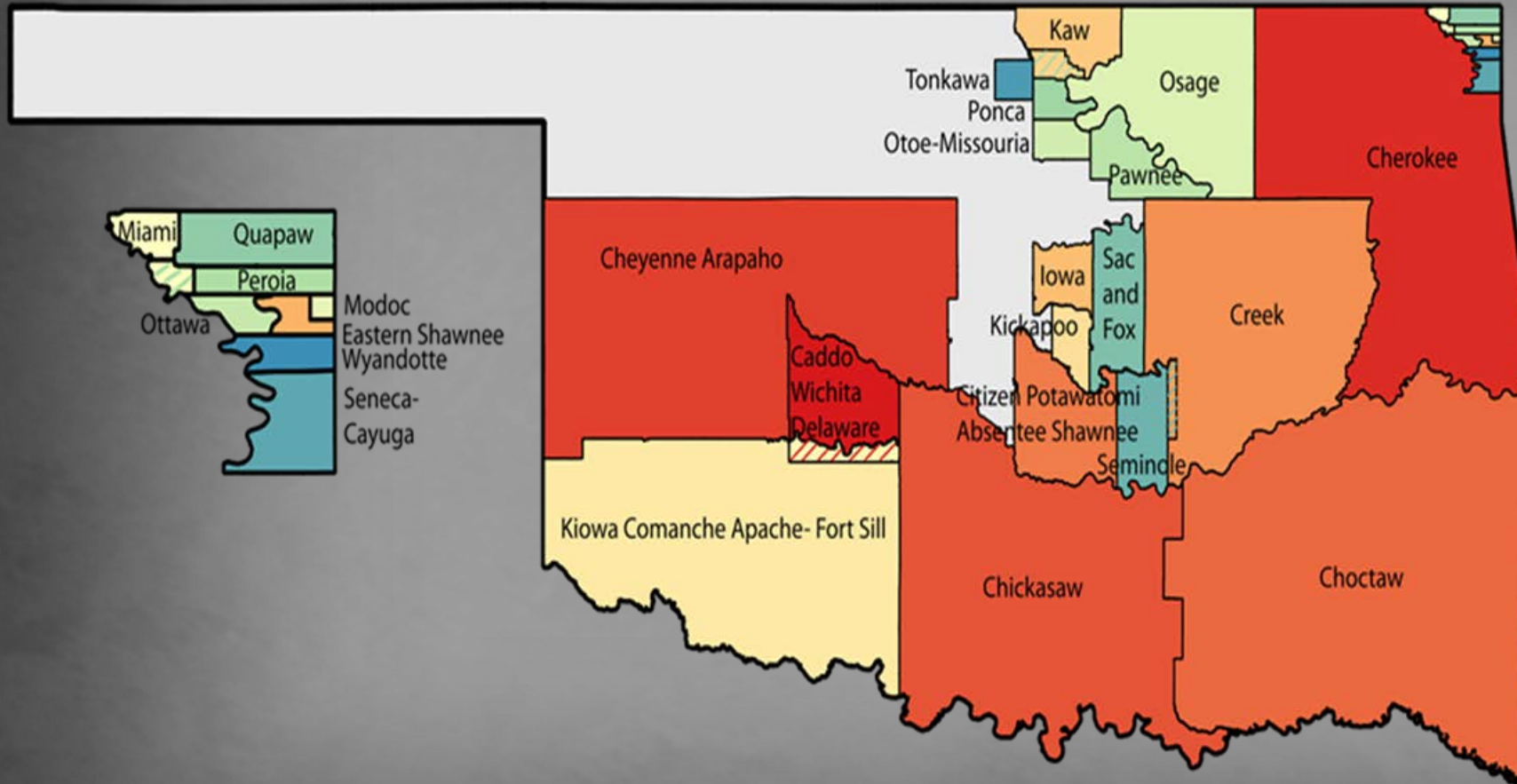
# American Indians in Oklahoma

- 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







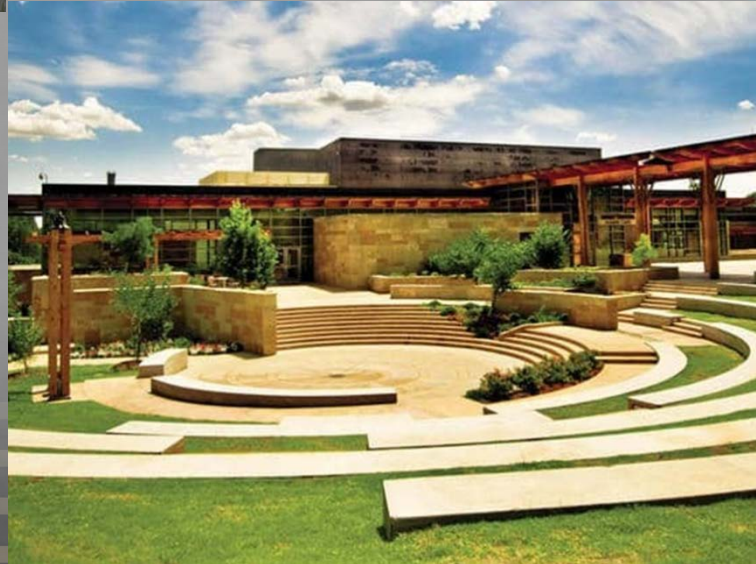
# The Chickasaw Nation

- 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





# 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

## 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 Recent 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

“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 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

## 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

All proposed research projects must be reviewed and approved by the Chickasaw Nation's designated review body, the Chickasaw Nation Department of Health Institutional Review Board, regardless of review by any other external research review entity.



# CNDH IRB Policies

It is specifically acknowledged and agreed by the parties that any and all research data and findings as generated and derived by virtue of the Investigator Agreement and research project **shall be and sole ownership of same shall be retained and vested with the Chickasaw Nation.**

Any and all use of data and findings, including genomic data, generated from research conducted within the Chickasaw Nation requires prior review and approval by the CNDH IRB. This includes all secondary use of **any data collected for research purposes.**





# 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

## 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 Policies

## Exempt Policy

Only the IRB Chair and/or Administrator or designee may determine if the proposal meets the criteria for exemption; **in no case shall a research investigator associated with the project** or a person with an obvious conflict of interest make the decision to exempt a study from IRB review.



# CNDH IRB: Additional Protections

## Research Investigator Agreement

This Agreement, made and entered into this \_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_, by and between the Chickasaw Nation Department of Health , a division of the Chickasaw Nation, a federally recognized sovereign Indian nation, hereinafter referred to as the “Nation,” of P.O. Box 1548 , Ada, OK 74821, and [ Insert name Investigator ], herein referred to as the “Institutional Investigator”, on behalf of [ Insert name of Principal Investigator ], hereinafter referred to as the “Principal Investigator” , [ Insert where affiliated and address ], the Institutional Investigator and Primary Investigator, herein referred to collectively as the “Investigators”





# 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

## 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: Challenges/Barriers

## Differences/disagreements:

- Cultural/tribal/IHS
- Structural
- Jurisdictional/geographical
- Personal/philosophical
- Gap: non-health research in IHS jurisdiction





## Oklahoma IRBs: Benefits

- Community of ethical tribal research review
- 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



AHÓ

[Bobby.Saunkeah@Chickasaw.net](mailto:Bobby.Saunkeah@Chickasaw.net)

(580) 421-4532

Chukmashki

[Michael.Peercy@Chickasaw.net](mailto:Michael.Peercy@Chickasaw.net)

(580) 272-2737

