



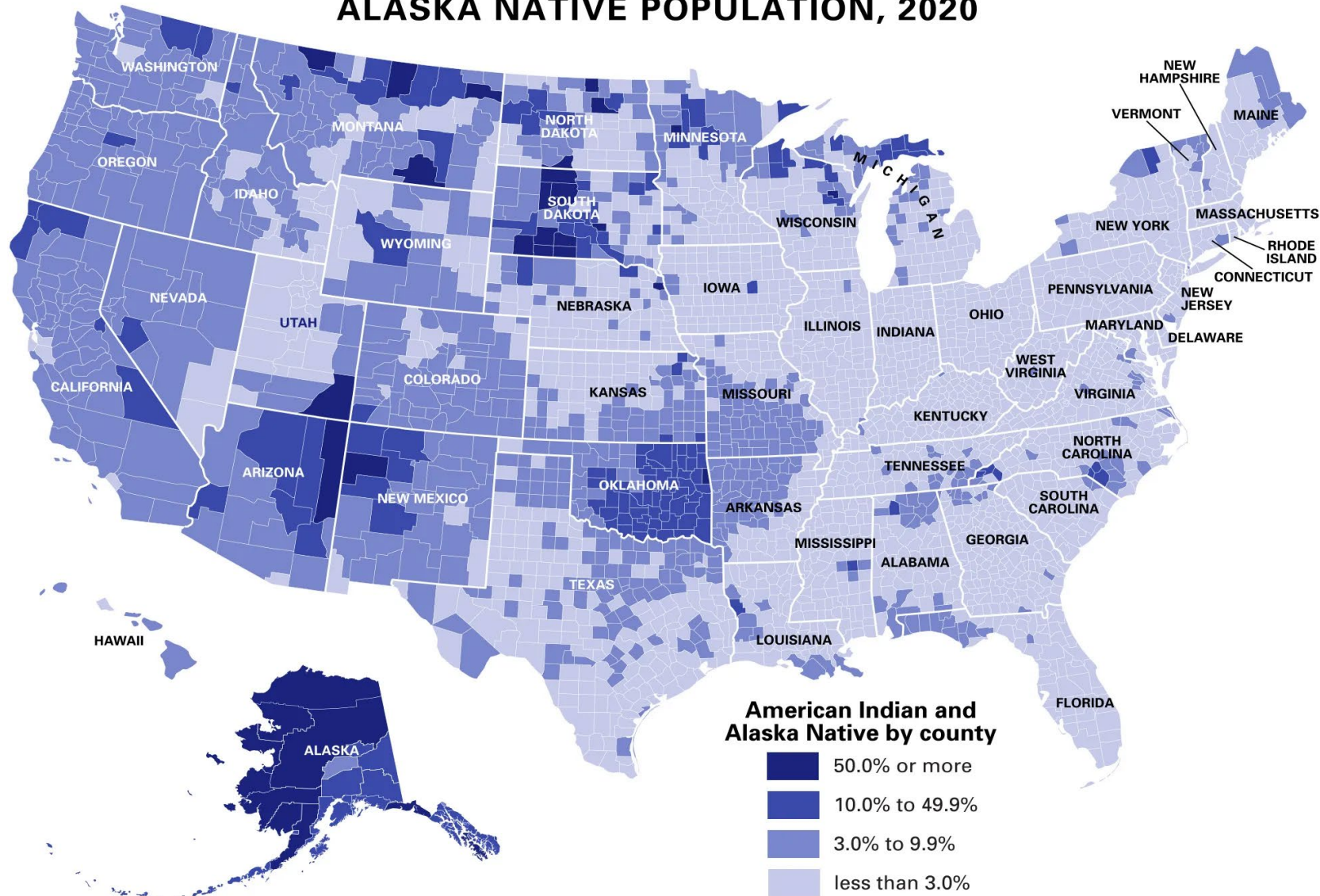
Extending Research Protections to Tribal Communities

The Chickasaw Nation Department of Health
Division of Research

Bobby Saunkeah, RN, BSN, MHE
Chair, CNDH IRB
Human Protections Administrator

*the
Chickasaw
Nation*

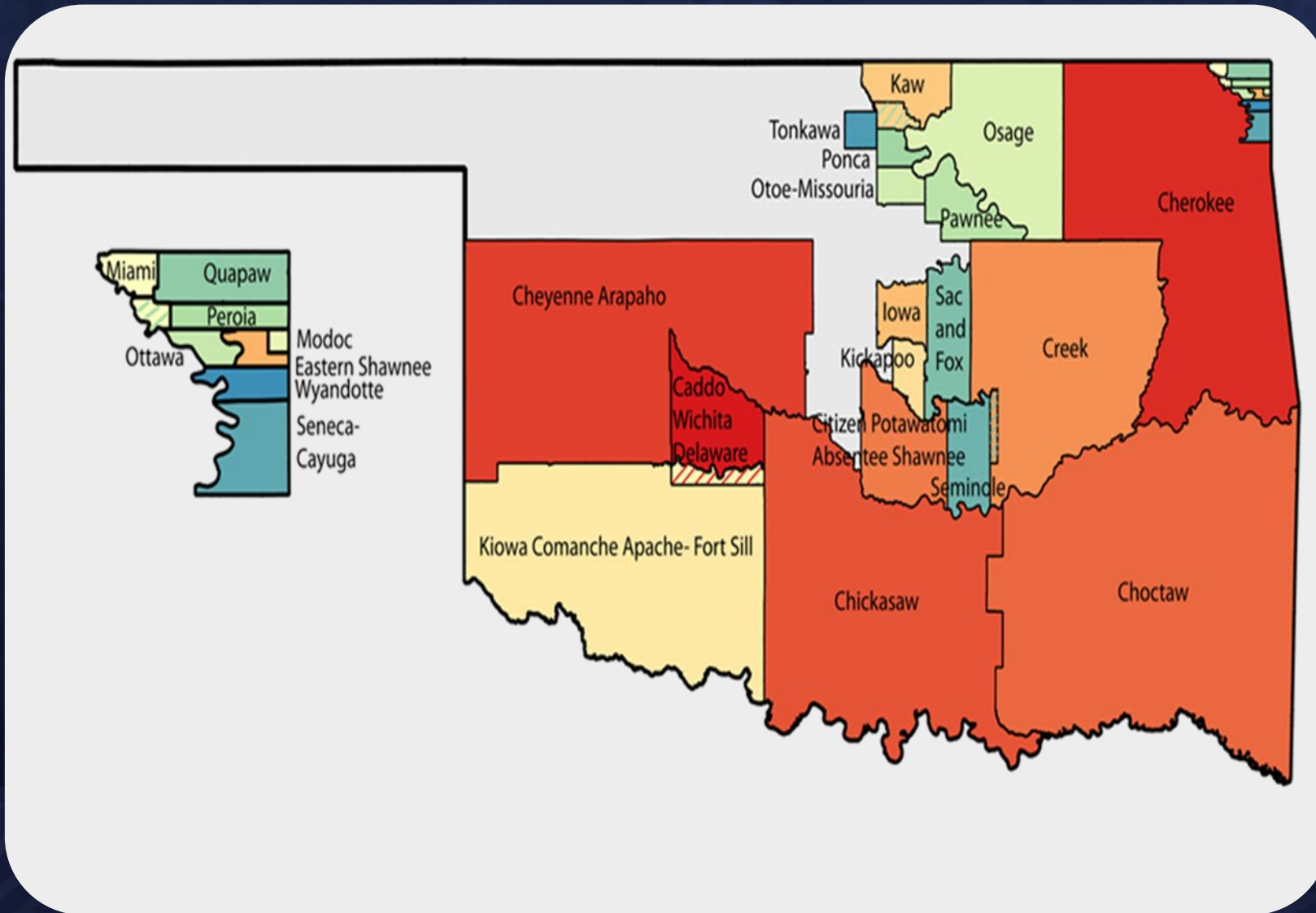
AMERICAN INDIAN AND ALASKA NATIVE POPULATION, 2020



Source: U.S. Census Bureau, Census 2020

Note: The map shows the percentage of the total U.S. population at the county level that reported their race as American Indian and Alaska Native alone or in combination in the 2020 U.S. census.







Troubled History of Research with Tribes

- Research driven by entities outside of the tribe
- Little or no benefit to tribes; overt harm
- 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



Troubled History of Research with Tribes

- Havasupai Tribe v. the Arizona Board of Regents (2004)
- Arizona State geneticist
- DNA for type 2 diabetes
- Broad consent: “study the causes of behavioral/medical disorders”
 - Schizophrenia
 - Origen/Migration studies
 - Inbreeding
 - Alcoholism



Troubled History of Research with Tribes

Community Based Participatory Research (**CBPR**)/Tribal Participatory Research (**TPR**): preferred research approach in many tribal communities

- Collaborative **research method**; not an ethical framework
- Requires faithful and considerate adherence to **all phases**
- Requires application within **context** of Belmont's research ethics principles
- Literature consensus: CBPR/TPR and Belmont principles appropriate but **not sufficient** for community protections; need for additional ethical contexts/dimensions



Belmont Research Ethics Principles: Respect for Persons, Beneficence and Justice (1979)

Individual participant

- Informed voluntary consent
- Individual assessment of personal risk/benefit
- Fairness in recruitment and selection of participants

Tribal community participant

- Tribal review and approval
- Tribal determination of risk/benefit/harm
- Target population of convenience v. exclusion



Additional Ethical Considerations

- “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)



Additional Ethical Considerations

- *Sovereignty*: the **right for tribal self-determination and self-governance**, including conduct of research.
- Within the context of Belmont's research ethics principles, respect for sovereign rights is a broader expression of **respect for autonomy, persons**.
- Within the context of Belmont's research ethics principles, *solidarity* is the 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.

- (Saunkeah , Beans , Peercy , Hiratsuka & Spicer (2021): Extending Research Protections to Tribal Communities,

The American Journal of Bioethics)



Extending Research Protections to Tribal Communities

- **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**.
- **Beauchamp & Childress** (2019): **Havasupai** case underlines need to attend to **group**, as well as individual, harms.



CNDH IRB

Chickasaw Nation Human Research Protection Program

- 1998: Chickasaw Nation RRB established by Governor E.O.
- Chickasaw Health Research Act of 1998 (legislative)
- Guidance from the Office of Human Research Protections (OHRP), federal codes, Indian Health Service and CNDH policies.
- 2004 Federally registered IRB, FWA, written policies, legal agreement

*Protect the safety of our individual research participants
and guard the integrity and heritage of the Chickasaw
Nation*



CNDH IRB

Membership Structure:

- Physicians
- Health Professionals (Nursing, Public Health, Pharmacy)
- Language, Culture and History reps
- Community Members (Non-Scientific members)
- Legal Advisor
- Privacy Officer
- Bioethicist
- Ad Hoc



CNDH Research Input/Navigation/IRB Process

- Research Office first POC
- Discussion with potential researchers
- Determine interest/CNDH priorities
- Joint meeting
- Administration approval
- Grants/contractual process
- IRB process (preliminary/primary review, research agreement)
- Electronic IRB Management Software



Navigating IRB Review Jurisdiction in Tribal Communities

- Tribal review bodies
- Indian Health Service Regional IRBs
- Indian Health Service National IRB
- Tribal-affiliated Health Boards/Consortia
- Academic/University IRBs
- Reliances



CNDH Current Topics of Discussion/Consideration

- Genomic Research/Medicine
 - Bio-banking/disposition of biological samples
 - Data ownership/stewardship
 - Data Use/Sharing Agreements
 - Tribal data repositories
 - Intellectual property
 - Commercial/industry interests
 - Social media research
-
- CNDH First American Research Center



CNDH IRB Policies

- A tribal IRB or tribe can decide not to implement Broad Consent; the Common Rule clarifies that this exception includes any **written tribal laws**.
- The Common Rule does not include specific procedures for tribal review but does require federally-funded researchers to obey state, local, and **written tribal laws**.
- NIH data management/sharing policy tribal supplement (2022): Ensure research practices are aligned with the **laws, policies and preferences (written or not)** of AI/AN community partners.



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 reservation.



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
- Results should **not be generalized** to an entire tribe, only to the individual participants in the research project



CNDH IRB Policies

All proposed research projects must be **reviewed and approved** by the CNDH IRB, regardless of review by any other external research review entity.



CNDH IRB Policies

- ...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

Exempt Policy

- Only the CNDH IRB chair and/or administrator may determine if the proposal meets the criteria for exemption; **in no case shall a research investigator associated with the project** make that decision.
- *Exemption from IRB review does not apply to dissemination of findings.*



CNDH IRB: Additional Protections

Consent and PHI Authorizations

- **Expiration Dates** for permission/data use/PHI
- **Tribal Principal Investigator** - onsite research partner
- **Repositories** - separate consent form; specific as possible



Random Final Thoughts

- Build Relationships
- Respect
- Culture
- Develop Trust
- Equal partnerships
- Genuine interest
- Humility
- Whose priorities?
- Sovereignty/Solidarity
- Share



Thank you!

Contact Information:

Bobby.Saunkeah@Chickasaw.net

(580) 421-4562

