Expanding Tribal Research Protocols:

Pandemic Genomics, Sovereignty, and Data User Agreements (DUAs)

AKIRP Conference 2022

Anchorage, Alaska

ROSWELL PARK
COMPREHENSIVE CANCER CENTER

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Center for Indigenous Cancer Research

Mission
MoU
Outreach
Education
Research
Patient Care

Working together—not competitively but collaboratively for the health of future generations (bundled-arrows approach) creates opportunities to braid treaty conversations, tribal/federal/state/county programs and area offices of IHS for the health and wellness of all peoples.

Tribal Research Codes: History

01

Know your tribe's current research review protocol.

02

Learn the history, evolution, changes, and amendments.

03

Be familiar with neighboring Native Nations research protocols and how you can work together.

04

Learn more about Indian Health Services IRBs (area and national).

05

Learn more about regional cancer centers, tribal colleges, universities and research organizations IRBs and their history and knowledge of tribal review processes.

06

Make informed decision on how to partner for research review.

Tribal Research Review Process – Tips for Sustainability

- Community friendly, passed successfully from one administration to the next, build on existing protocols instead of re-creating.
- Honor community voice and professionals in the development and discussion of protocol development.
- Ensure that advisory boards to tribal research protocol development are knowledgeable about current community contexts tribal infrastructures.
- Integrate research review process into long-standing and existing departments structures (e.g., create from within and train). Internal research review boards - business code offices, tribal employment rights, existing health leadership, cross-train courts).
- Next steps: Data User Agreements or DUAs.

Need for Equitable Data Use Agreements

- Data Use Agreements (DUAs) are legally binding contracts that stipulate terms related to limited transference of restricted data from one entity to another, to include procedures of data sharing, data access, and data licensing.

- DUAs drafted by institutions, universities, or organizations, are often one-sided.

- NIH Office of Science Policy (OSP) https://osp.od.nih.gov/about-us/

- HHS Office of Research Integrity - https://ori.hhs.gov/about-ori

- NIH Data Sharing https://grants.nih.gov/grants/policy/data_sharing/

  New NIH Policy on Data Management and Sharing (effective January 25, 2023)
  NIH has issued a new Final NIH Policy for Data Management and Sharing, which will require NIH funded researchers to prospectively submit a plan outlining how scientific data from their research will be managed and shared. On January 25, 2023, the new policy will come into effect and replace the 2003 NIH Data Sharing Policy currently in effect.

DUA Creation Process

To develop a DUA model respectful of cultural values, community priorities and tribal sovereignty…

Worked with team of Indigenous attorneys.

Systematic review: Tribal, University and federal DUAs.

Adapted through structured meetings between CICR and Indigenous attorneys.

Draft brought back to CICR community advisory board (CAB).

Reworked with Indigenous attorneys based on CAB feedback.

Submitted to Institutional legal (Roswell Park) for review and internal approval.

Gifted to Native Nations, NIH THRO, and the public domain for use.

Pandemic Genomics

Indigenous communities disproportionately impacted by the COVID-19.

Emergent conditions of the pandemic, concerns arise that Indigenous nations traded short-term needs for COVID-19 testing, surveillance, and vaccination with long-term, unrestricted access by non-tribal entities to Indigenous peoples' genomes which may undermine Indigenous data sovereignties.

frontiers

Empowering Equitable Data Use Partnerships and Indigenous Data Sovereignties Amid Pandemic Genomics

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Keywords: Indigenous[1], American Indian[2], COVID-19[3], genomics[4], Indigenous data sovereignty[5], data use agreements[6], broad consent[7], vaccine research[8]. (Min.5-Max. 8)

Abstract

The COVID-19 pandemic has inequitably impacted Indigenous communities in the United States. In this emergency state that highlighted existing inadequacies in US government and tribal public health infrastructures, many tribal nations contracted with commercial entities and other organization types to conduct rapid diagnostic and antibody testing, often based on proprietary technologies specific to the novel pathogen. They also partnered with public-private enterprises on clinical trials to further the development of vaccines. Indigenous people contributed biological samples for assessment and, in many cases, broadly consented for indefinite use for future genomics research. A concern is that the need for crisis aid may have placed Indigenous communities in a position to forego critical review of data use agreements by tribal research governances. In effect, tribal nations were placed in the unenviable position of trading short-term public health assistance for long-term, unrestricted access to Indigenous genomes that may disempower future tribal sovereignties over community members' data. Diagnostic testing, specimen collection, and vaccine research is ongoing; thus, our aim is to outline pathways to trust that center current and future equitable relationship-building between tribal entities and public-private interests. These pathways can be utilized to increase Indigenous communities' trust of external partners and share understanding of expectations for and execution of data protections. We discuss how to navigate genomic-based data use agreements in the context of

COVID-19 Prevention Network

The **COVID-19 Prevention Network (CoVPN)** was formed by the National Institute of Allergy and Infectious Diseases (NIAID) at the US National Institutes of Health to respond to the global pandemic. (Fred Hutchinson Cancer Research Center)

- Indigenous Panel formed to guide COVID-19 Prevention Network.
- Panel advised researchers conducting clinical trials of COVID treatments/vaccinees.
- Goal: Ensure that Indigenous communities are educated and had voice throughout process.

Data User Agreements (DUAs)

Benefit	Definitions of Responsibilities	Transparent Process	Minimum Qualifications
Disclosures	Qualifications	Dissemination	Data Management, Use, Sharing, and Ownership
Publications	Inventions	Damages	Dispute Resolution/Jurisdiction

DUAs - Exhibits

Project Scope and Parameters

Tribal Resolution

Study Protocol

Summary

Team work to create a strategic and sustainable DUA with a “Good Mind” or IK that looks forward seven generations and is reflective of the Two Row Wampum and the UN Declaration of the Rights of Indigenous People.

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Roswell Park Legal Team

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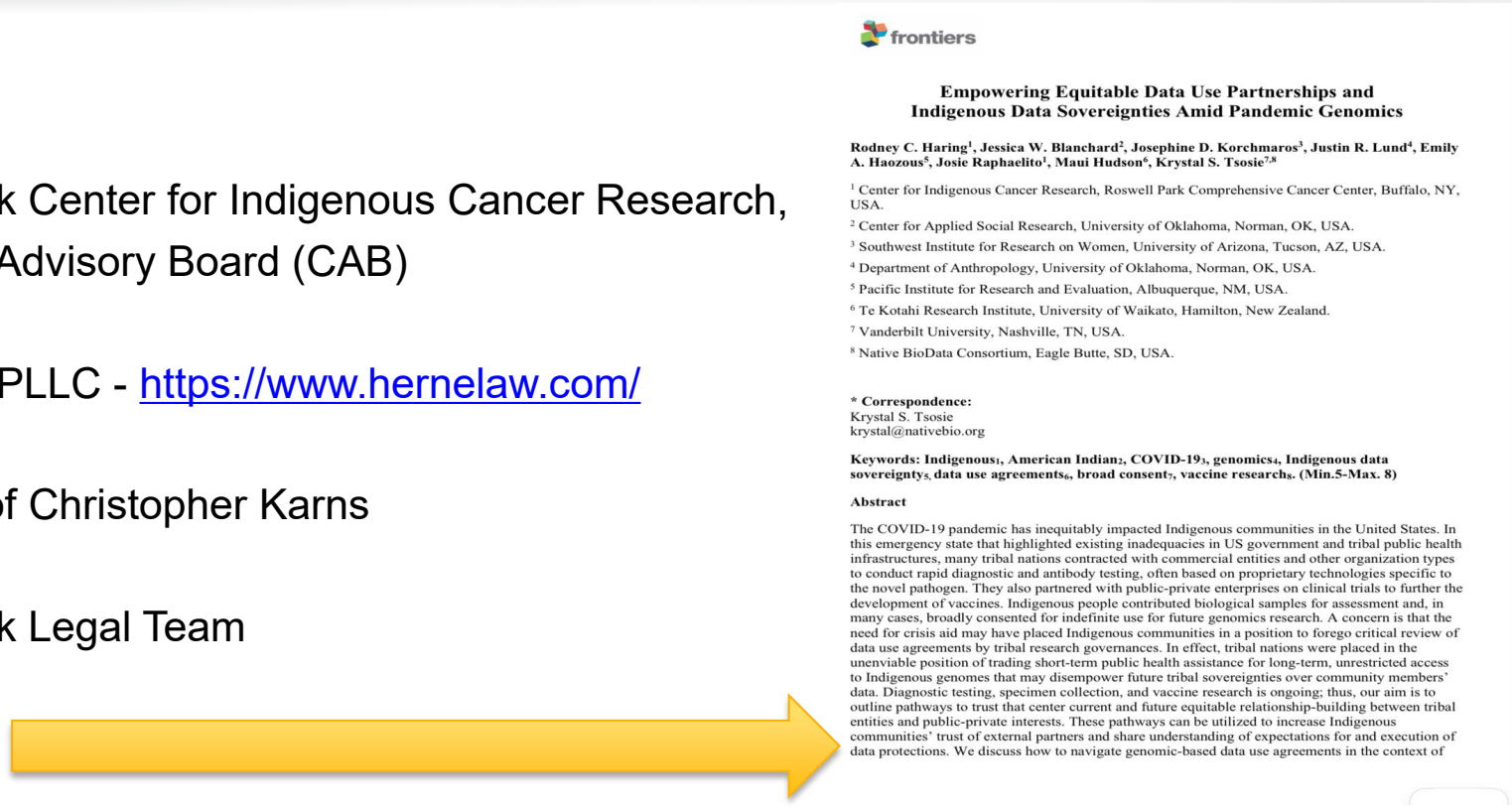

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