The Alaska Native Medical Center (ANMC)

ANMC offers comprehensive medical services and acute, specialty, primary and behavioral health care to Alaska Native and American Indian people living in Alaska. ANMC is also home to one of America’s most unique health care environments - a place where the highest quality care and cutting-edge technology meets special cultural and traditional services and customer experiences.

The award-winning medical center includes a 167-bed hospital, a full range of medical specialties, primary care services and labs. The hospital also works in close partnership with rural health facilities statewide to support a broad range of health care and related services.

http://anmc.org/
Alaska is the northernmost and westernmost state in the United States and has the most easterly longitude in the United States because the Aleutian Islands extend into the Eastern Hemisphere. Alaska is the only non-contiguous U.S. state on continental North America; about 500 miles (800 km) of British Columbia (Canada) separates Alaska from Washington. It is technically part of the continental U.S., but is sometimes not included in colloquial use; Alaska is not part of the contiguous U.S., often called "the Lower 48". The capital city, Juneau, is situated on the mainland of the North American continent but is not connected by road to the rest of the North American highway system.

https://en.wikipedia.org/wiki/Alaska
“When the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included”

The Indian Health Service (IHS) is responsible for providing federal health services to American Indians and Alaska Natives.

Indian Health Service
The Federal Health Program for American Indians and Alaska Natives

Our Mission: to raise the physical, mental, social, and spiritual health of American Indians and Alaska Natives to the highest level.

Our Goal: to assure that comprehensive, culturally acceptable personal and public health services are available and accessible to American Indian and Alaska Native people.

Our Foundation: to uphold the Federal Government’s obligation to promote healthy American Indian and Alaska Native people, communities, and cultures and to honor and protect the inherent sovereign rights of Tribes.

National IHS IRB (NIRB) Area IHS IRBs:
- Alaska
- Bemidji
- Billings
- Great Plains
- Nashville
- Navajo
- Oklahoma
- Phoenix
- Portland
- Tucson
45 CFR 46.111 Protection of Human Subjects
21 CFR 56.111 Criteria for IRB Approval of Research

- Minimization of risks
- Risk-benefit relationship
- Equitable selection
- Consent process

- Consent documentation
- Data monitoring
- Privacy/confidentiality
- Venerable subjects
Respect for persons: protecting the autonomy of all people and treating them with courtesy and respect and allowing for informed consent. Researchers must be truthful and conduct no deception;

Beneficence: The philosophy of “Do no harm” while maximizing benefits for the research project and minimizing risks to the research subjects;

Justice: ensuring reasonable, non-exploitative, and well-considered procedures are administered fairly — the fair distribution of costs and benefits to potential research participants — and equally.

The Belmont Report attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations. It is the outgrowth of an intensive four-day period of discussions that were held in February 1976 at the Smithsonian Institution’s Belmont Conference Center supplemented by the monthly deliberations of the Commission that were held over a period of nearly four years.

*It is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects.*

“...additional safeguards have been included in the study to protect the rights and welfare of these subjects”

Our job is to protect research participants.

- To protect research participants.
- To ensure health records research meets federal regulations.
- Ensure our research approval process meets federal standards.
- To provide a sound scientific and locally appropriate review.
- Assist our tribes and researchers in understanding and meeting the federal regulations.
- Protect research volunteers against unethical research practices.

a) IRB shall determine that all of the following ... are satisfied:
- (1) Risks to subjects are minimized ....
- (2) Risks to subjects are reasonable ....
- (3) Selection of subjects is equitable ....
- (4) Informed consent will be sought ....
- (5) Informed consent will be appropriately documented ....
- (6) When appropriate, monitoring the data collected ....
- (7) When appropriate, protect [privacy & maintain confidentiality] ....

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, ... additional safeguards have been included in the study to protect the rights and welfare of these subjects.
Alaska Area
IRB Members

11 volunteers

Working together to protect Alaska Natives and American Indians
Successfully entering a new submission is a lot like following a recipe.

Here to serve the Alaska Tribal Health System

New submission checklist:
- Cover letter describing the project Signed
- Complete AAIRB Application Form Signed by PI Dated
- Scientific Protocol
- Data management plan N/a
- Provide research variable list N/a
- Did they request a Waiver of Consent
  - Yes
  - No
    - If No, did they provide
      - Consent Form Assent Form
      - <8th grade F-K score
- Surveys N/a
- Study recruitment materials N/a
  - <8th grade F-K score
- Other IRB approval letters N/a
- Notice of Award Letters N/a
- CVs for all
- CITI Certificates 75% proficiency last 36 months for all
- Conflict of Interest Form for all
- Digital Signature

Please contact the Alaska Area IRB before starting and request a Welcome Packet. If new to research or if you need a little more help please feel free to request a consultation with the Alaska Area IRB Administrator.

Contact Us

Shared Inbox
AkaalaskaareaIRB@anthc.org

Terry Powell
AAIRB Administrator
(907) 729-3924

Tracy Boquist
AAIRB Coordinator
(907) 729-3917
The Alaska Area IRB Committee meets monthly.

IRBNet Submission Process

For a larger version of this document contact us.
What is an IRB?
An Institutional Review Board (IRB), also known as an independent ethics committee (IEC), ethical review board (ERB), or research ethics board (REB), is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans. A key goal of IRBs is to protect human subjects from physical or psychological harm, which they attempt to do by reviewing research protocols and related materials. The protocol review assesses the ethics of the research and its methods, promotes fully informed and voluntary participation by prospective subjects capable of making such choices (or, if that is not possible, informed permission given by a suitable proxy), and seeks to maximize the safety of subjects.

IRB Review
• Required by 45 CFR 46 (Common Rule)
• All members are volunteers.
• Main job is to protect participants in research
• Evaluate consent process
• Evaluate recruitment process
• Evaluate risks and benefits of research
• Evaluate science
• Review not less than 1 time year (Changing)

Types of Research
• Exempt
• Expedited
• Full Committee
Tribal sovereignty...

...in the United States is the inherent authority of indigenous tribes to govern themselves within the borders of the United States of America. The U.S. federal government recognizes tribal nations as "domestic dependent nations" and has established a number of laws attempting to clarify the relationship between the federal, state, and tribal governments.

NCAI’s Policy Research Center is a national, non-profit think tank dedicated to generating research and policy analyses that advance tribal sovereignty and emphasizes the strengths of American Indian and Alaska Native cultures.

“We believe that policy research should honor the government-to-government relationship and the sovereignty of American Indian and Alaska Native tribal governments” - NCAI

Click here to learn more about NCIA Policy Research Center

http://www.ncai.org/policy-research-center/about-prc/values-principles
Tribes have final authority for approval or disapproval of research. If Alaska Area IRB writes an approval letter, final approval of the research proposal is contingent upon Tribal approval.

**Jurisdiction of an IRB**
Protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.

The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and local policy. Research that has been reviewed and approved by an IRB may be subject to review and disapproval by officials of the institution. However, those officials may not approve research if it has been disapproved by the IRB.

**Alaska Tribal Health System**
- Aleutian Pribilof Islands Association
- Arctic Slope Native Association
- Bristol Bay Area Health Corporation
- Chugachmiut
- Copper River Native Association
- Eastern Aleutian Tribes
- Kodiak Area Native Association
- Manililaq
- Norton Sound Health Corporation
- Southcentral Foundation
- Southeast Alaska Regional Health Corporation
- Tanana Chiefs Conference
- Yukon Kuskokwim Health Corporation
The People Awakening Project was created by a group of Alaska Native community members and University of Alaska researchers in response to the Anchorage Daily News “People in Peril” series. Many people in Native communities no longer wanted to hear only lives in peril. They wanted to hear stories of hope and success. Our group wanted to look at sobriety, and not just alcohol abuse. Our guiding question was, “How do Native people live ‘clean’ and sober lives?”

If we knew more about the pathways to sobriety, treatment and prevention programs could use this knowledge of what works for Alaska Natives who are living a healthy life. The project had two aims. The first was to study the life stories of Alaska Natives living a life of sobriety. We wanted to discover what protected people from alcohol abuse and what helped others recover. The People Awakening Project collected over 100 life stories throughout the state. The second aim was to develop interviews from what we learned in the life stories. We wanted to see if we could measure these protective and recover factors in people’s lives. We found much strength in Alaska Native communities, families, and individuals. But importantly, we came to understand how it required community, family, and individual strengths working together to create settings protective from alcohol abuse. We discovered protective individual characteristics learned as a young person were an awareness of life goals, a belief in the ability to meet these goals, and a sense a person meets goals through the help of family and neighbors. Life stories also told of family and community characteristics that protect children from bad things happening, from exposure to trauma. These individual, family, and community characteristics contributed to a social environment for youth filled with sobriety role models, rules for sober behavior, and positive, sober peer influences. Mohatt et al.

[http://dhss.alaska.gov/dbh/Documents/01_External/People%20Awarening%20Project.pdf](http://dhss.alaska.gov/dbh/Documents/01_External/People%20Awarening%20Project.pdf)
The Canoe Journeys began in 1989 during the Suquamish Tribe’s “Paddle to Seattle.” The initial plan was to reclaim their aboriginal water ways. It has grown to become a Drug and alcohol free event that has life changing effects on everyone who participates. The University of Washington developed a canoe manual, Life Skills Instructor’s Manual, with help of Dr. Lisa Rey Thomas. This Canoe manual has become a best practice in Oregon State. The State of Oregon has added the Canoe Journeys to the Tribal Best Practices list. The nine Federally Recognized Tribes of Oregon have worked hard to prove that Culture is Prevention. Dr. John Spence and Caroline M. Cruz B.S., CPM, CPS wrote a paper together titled; Oregon Tribal Evidence Based and Cultural Best Practices. This paper has helped establish Tribal Best practices for the Tribes of Oregon.

Without their efforts, we would not be where we are today. When senate bill 267 and 770 were passed, we the Tribes, thought we were going to lose our grant money. Most Tribes did not have the infrastructure to get this accomplished on their own. We had an advantage with Caroline as our Tribal liaison at the state office. With Caroline’s experience and knowledge and John’s years of expertise knowing the language, they wrote a paper to assist the Tribes in complying with the Senate Bills. John is also our highly respected elder in Indian country. They helped us understand what needed to get done and they guided us through that process. Now we have “Tribal Better Practices” that are being recognized around the country. After all, we were doing a great job with mentoring, teaching, storytelling and demonstrating a great cultural way of life before the introduction of alcohol and drugs. We are on our way to recovery with the reintroduction of our cultural ways and teachings.
Contact Us
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