The Alaska Area Institutional Review Board
Why Have an Institutional Review Board

- To protect research participants
- To ensure review meets federal standards
- To encourage health research
- Assist tribes and researchers in understanding and meeting federal requirements
- Receive federal funds
Regulations that Protect Participants in Research

- 45 CFR 46
- 21 CFR 50, 56
- 45 CFR 160, 164
- The Belmont Report
What is Generalizable Knowledge

Knowledge related to health that can be applied to populations - not just the population being studied.

“For the greater good”
Who are “Investigators”

The federal Health and Human Services regulations use the term “investigator” to refer to an individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent, interacting with subjects, communicating with the IRB...
What is a Research Participant

Means a living individual about whom an investigator (whether professional or student) conducting research obtains:

- Data through intervention or interaction with the individual, OR
- Identifiable private information
Research plan makes adequate provisions for monitoring safety.

Additional safeguards for participants likely to be vulnerable to coercion or undue influence.

Adequate provisions to protect privacy and maintain confidentiality.

Tribal Review of Research.

Waiver of consent obtained.
Criteria for Review of Research

- Risks to participants are minimized
- Selection is equitable
- Informed consent will be obtained
- Risks are reasonable in relation to anticipated benefits
- Informed consent will be sought
§46.111 Criteria for IRB approval of research

(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.
Federal Review Criteria

- Evaluate consent
- Evaluate recruitment
- Analyze risks and benefits participation
- Evaluate science
- Adequate privacy and confidentiality
- Safeguards for vulnerable participants
- Waiver of consent criteria
Categories of Research

- Exempt Research
- Expedited Research
- Full IRB Review Research
Indian Health Service

- The Indian Health Service Federalwide Assurance is an umbrella FWA
- Signed by the Director of I H S
- Lists the National I H S Institutional Review Board (NIRB)
- Includes each I H S Area IRB
IHS IRB: The Two-Tier System

- National IHS IRB
- Area IHS IRBs:
  - Aberdeen
  - Alaska
  - Albuquerque
  - Bemidji
  - Billings
  - California
  - Nashville
  - Navajo
  - Oklahoma
  - Phoenix
  - Portland
  - Tucson

Francine Romero, MPH, PhD
WHAT IS IRB?
A committee designated to approve, monitor and review research involving human participants.

- AAIRB - Alaska Area Institutional Review Board

IRB FACTS

- Required by 45CFR 46
- All members are volunteers
- Main job is to protect participants in research
- Evaluate Consent process
- Evaluate Recruitment process
- Evaluate risks and benefits of project
- Evaluate science
- Review not less than 1 time per year
- Review meets Federal standards
Tribal Health Organization Research Review

- Regional Board of Directors
  - Research Review Committee
  - Research Ethics Review Board (sometimes advisory)
  - Human Studies Committee
  - Scientific Advisory Board
  - Village/Tribal Councils
  - Privacy Officers
  - Privacy Board- if consent not obtained health record access requested
Successful research projects in Alaska

- Early Detection of Primary hepatocellular carcinoma
- People Awakening Project - Mohatt at UAF
- Estimating helicobacter pylori in Alaska Native people
- Education and Research Toward Health (EARTH)
- Center for Alaska Native Health Research (CANHR)
Opportunities to improve

- University of Pennsylvania - The Genographic Project

- Arizona State University - The Havasupai – sharing diabetes research project samples with other researchers without re-consent of participants
  - The secondary use of research data should be assessed to ensure that identification of participants would not be harmful and community could not be identified.
Specimen Bank management

- Governed by Policy & Procedures
  - Developed by the Alaska Area Specimen Bank Working Group
  - Approved by Alaska Area & CDC IRB’s,
  - Approved by:
    - Tribal Health Organizations
- Managed day to day by the CDC’s Arctic Investigations Program
  - Specimen Bank Committee
    - Quarterly reports to ANTHC Health Research Review Committee
    - Annual report to the Alaska Area Specimen Bank Working group

Alan Parkinson, PhD
Alaska Area Specimen Bank

- Bank of unused biological specimens collected during research studies, public health investigations, and clinical testing since early 1960s

- Housed at the CDC Arctic Investigations Program building on Alaska Native Health Campus, Anchorage

- Considered a resource for improving the health of Alaska Native people
Alaska Area Specimen Bank Procedures for Research Using Banked Specimens

New Specimens Collected

- Concept approved by Tribal Health Organization
- Protocol Developed
- Approval by IRB, Tribal Health Organization, Specimen Bank Committee
- Study Begins
- Informed consent to store specimens for future research
- No: Participant recruitment, Testing and analysis, Study Ends-Report distributed
- Yes: Specimens Banked
- Specimens Discarded

Use of Banked Specimens

- New Idea
- New Idea Related to Existing Protocol
- Amendment to Protocol
- Study Begins
- Informed consent required if Personal Identifiable Information used
- Yes: Testing and analysis, Study Ends-Report distributed
- No: Residual Specimens returned or destroyed
Native Research Network

- Health research network for American Indian and Alaska Native researchers and those working with Indian Country
  - Save the date- June 3-6, 2013, Phoenix, AZ
Who are the Committee Members?

A committee of 11 volunteers

- Gender mixed (7 women 4 men)
- 8 Native Members
- 4 Physicians
- 3 Researchers
- 1 community member

Who are the Investigators?

The HHS regulations use the term “investigator” to refer to an individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent, interacting with subjects, communicating with the IRB...

Investigator Responsibilities

- Investigator has primary responsibility
- Tribal review and community involvement
- Institutional Review Board
  - Big State University
  - Area Review Board (Indian Health Service)
National Congress of American Indians Research Resource Center

- NCAI- An American Indian and Alaska Native Organization
- NCAI Policy Research Center- Supports Indian Country in shaping its own future as the leading center for tribally driven policy research
Research Involving Specimens

- March 2007 PRIM&R white paper
- The Stored Tissue Issue - Weir/Olick
- National Institutes of Medicine - report on Tissue Samples in the Laboratory
- The Indian Health Service Specimen Protocol
- The Alaska Area Specimen Banking Protocol
Resources

- DNA on Loan: Arbour and Cook
- NCAI Research Regulation: Puneet Chawla Sohota
- Transforming Genetic Research Practices: Fryer-Edwards
- National Science Foundation
- The Immortal Cells of Henrietta Lacks
- CIHR Guidelines for Health Research Involving Aboriginal People
Submission Packet to the IRB

- Cover letter to the IRB describing the project and signed by the Principal Investigator
- Completed AAIRB form, signed by the PI
- Scientific Protocol
- Short Abstract of the Protocol
- Consent/Assent Documents
- All Recruitment Materials

- A stated plan for data management
- A data abstraction tool
- One copy of the original funding document
- Curriculum vitae for the PI and Co-PI
- Name of the onsite project manager
- A copy of the university IRB letter of approval, if applicable
Comprehensive Solutions

The Industry’s Most Complete Solution
IRBNet’s unmatched suite of electronic solutions drives compliance and productivity for your Administrators, Committee Members, Researchers and Sponsors. These powerful research design, management and oversight tools support your IRB, IACUC, IBC, COI and other Boards with a unified solution.

Flexible, Intuitive and Easy to Use
Your own forms. Your own processes. Your own standards. Powerful reporting and performance metrics. The data you need. From electronic submissions to form wizards, to agendas, minutes, and more. Our easy to use, web-based tools are rapidly launched and backed by our best practices expertise and the industry’s leading support team.

Secure, Reliable and Cost-Effective
IRBNet’s secure web-based solution is accessible to your research community anytime, anywhere. Our enterprise-class technology is cost-effective and designed to accommodate institutions of any size.
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.
Who Has Authority

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.
Contact Information

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Alaska Area Institutional Review Board (I.H.S. #2)