


Ethics in Biobanking- The Alaska Area Specimen Bank

Development of the
AASB Policy



Why Revisions?



The intent of these policy revisions is to build upon our founding operating principles and partnerships to continue to meet the vision and mission of the Alaska Area Specimen Bank.

Today's Presentation



Brief background on biorepositories and the unique history of the AASB



The Vision and Mission of the AASB



The Key Principles of the AASB



The method and approach to policy revisions



General overview of policy revisions proposed

What is a BIOREPOSITORY?



Secure Investment
Bank



Archive,
collection, library



Evidence
for clinical and
epidemiological
investigations

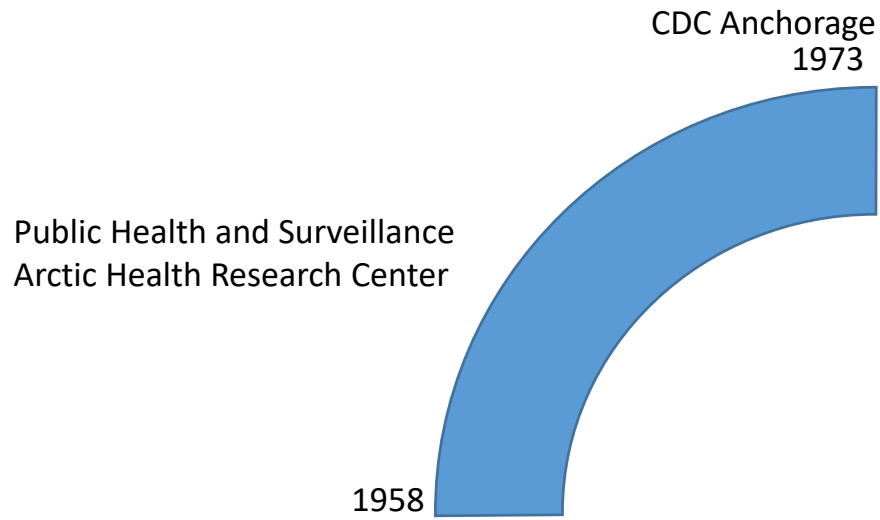


Tool Kit for
development of
treatments and
preventions

What does a BIOREPOSITORY do?

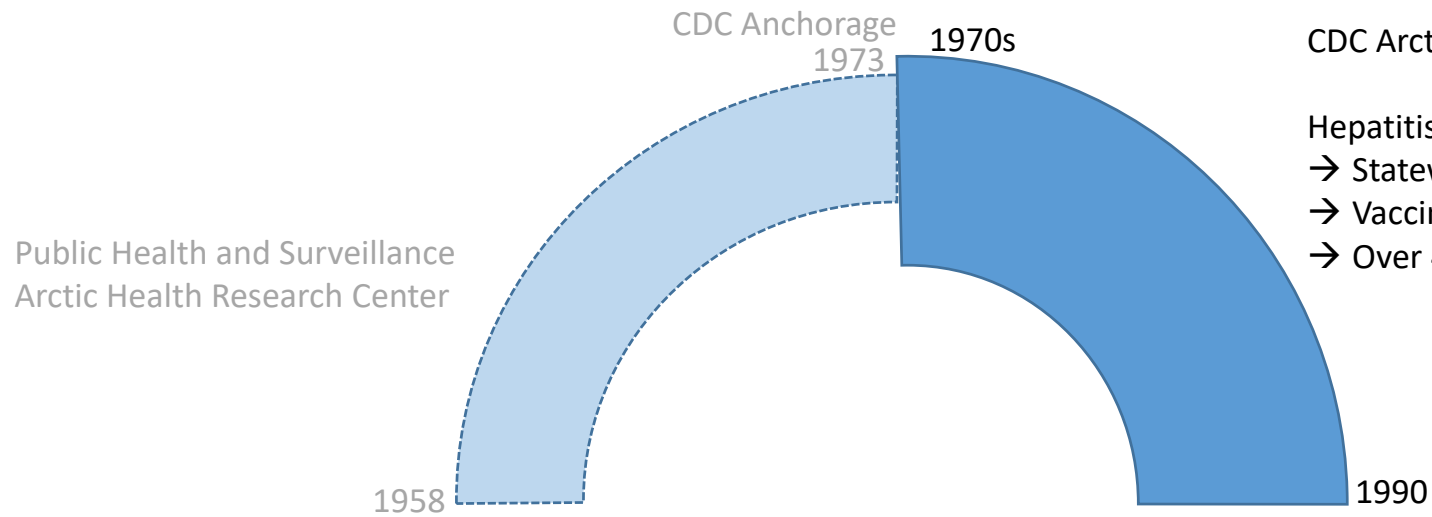


AASB History



The Alaska Area Specimen Bank: a tribal-federal partnership to maintain and manage a resource for health research. *Int J Circumpolar.* 2013 Apr 16; 72-20607

AASB History



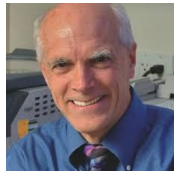
CDC Arctic Investigations Program

Hepatitis B Public Health response

→ Statewide serosurveys

→ Vaccination Programs

→ Over 400,000 specimens collected



AASB History



ANTHC Board of Directors signs first contract with Alaska Area Indian Health Service in 1998.

CDC Anchorage
1973

1970s

CDC Arctic Investigations Program

Hepatitis B Public Health response

→ Statewide serosurveys

→ Vaccination Programs

1990

1998



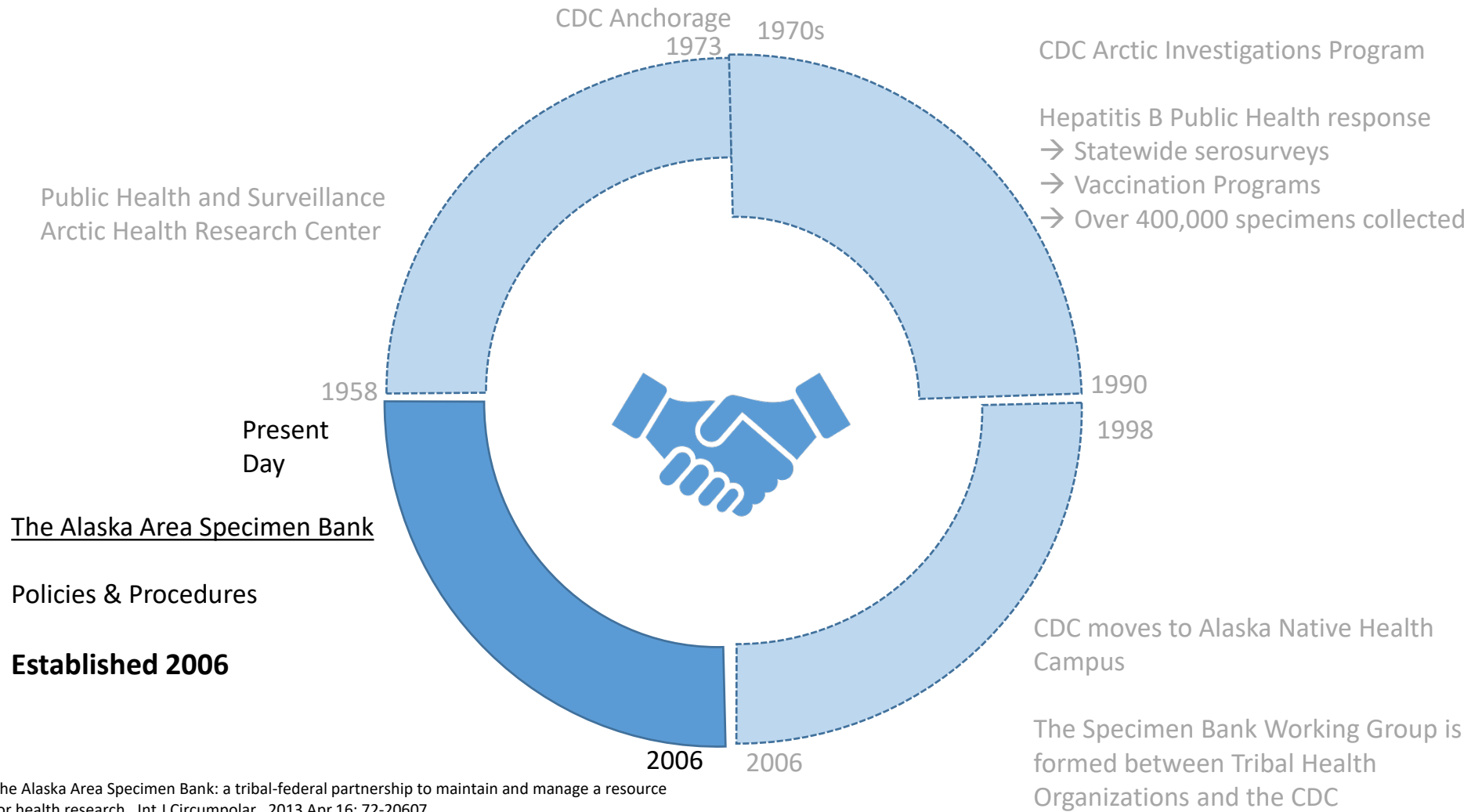
CDC moves to Alaska Native Health Campus

The Specimen Bank Working Group is formed between Tribal Health Organizations and the CDC

2006

The Alaska Area Specimen Bank: a tribal-federal partnership to maintain and manage a resource for health research. *Int J Circumpolar.* 2013 Apr 16; 72-20607

AASB History





2006

The Alaska Area Specimen Bank
Policies and Procedures

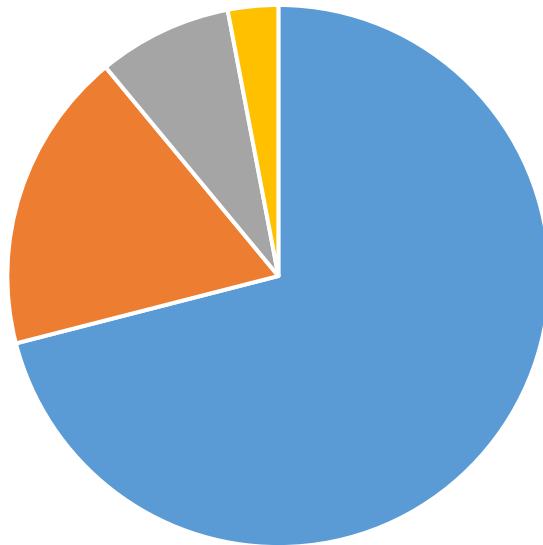


The AASB – What it is, What is in it, today



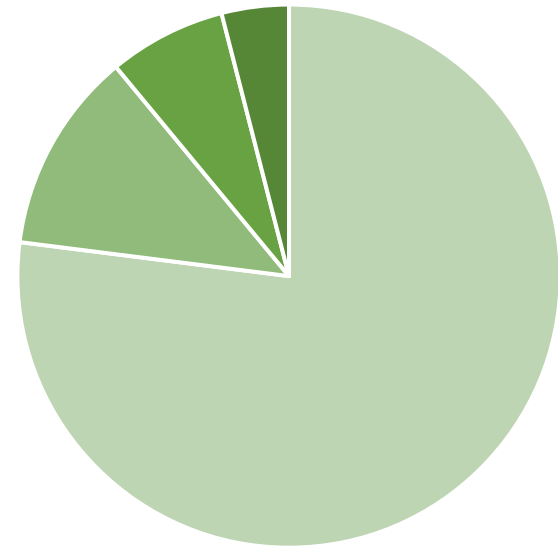
***85-90% Collection from Alaska Native & American Indian persons
Specimens – Geographic Diversity from Across Alaska***

Reasons for original collection

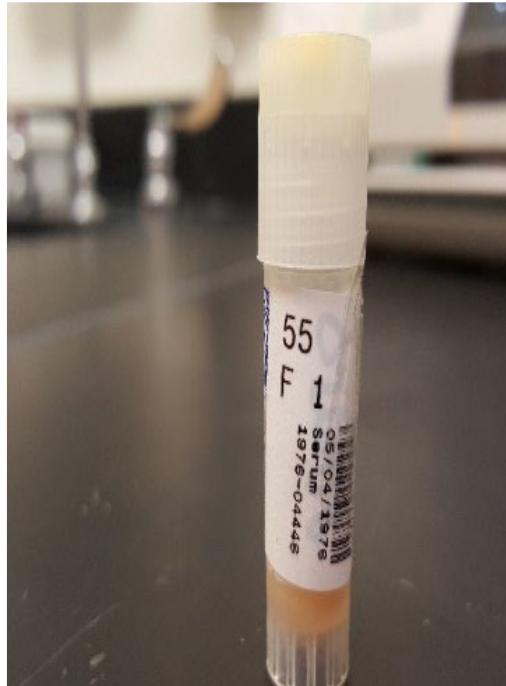


- Public Health - Hepatitis B 1980-1990
- Public Health (Infectious Disease)
- Health Research
- Historic

Specimen Type



- Serum
- Bacterial Isolates
- Original NP/OP swabs
- Other





ALASKA AREA SPECIMEN BANK

Why store specimens?

Specimens in the bank can provide a way to learn about the health of Alaska Native people over time. What is learned could help improve lives.

Where did the specimens come from?

The specimens are from research studies, outbreaks and medical procedures. Most of the specimens are from Alaska Native people. The bank has been saving specimens since the 1960s. Most specimens were collected to learn about infectious diseases like hepatitis.

How are specimens stored?

Specimens are stored in small tubes and kept frozen. The tubes are labeled with a number linked to a person's name and birthdate. Specimens are stored safely in special freezers with limited access.

Who manages the Alaska Area Specimen Bank?

The Alaska Area Specimen Bank is managed by the Alaska Native Health Center, which is part of the Alaska Native Tribal Health Consortium.

How can a researcher or other individual get permission to use specimens?

Specimens contained within the bank are the property of the individuals who consented to have their specimens stored. Future tests on these specimens which use your name or other identifiers will not be done without consent.

Any future testing which will not use your name or personal identifiers will only be done with the approval of the Alaska Area Institutional Review Board, your THO and ANTHC when ANTHC staff/facilities are involved, or the ANMC health records are accessed.

Alaska Area Specimen Bank's mission makes sure human specimens:

- Are secured in storage facilities for future use
- Are used to address health concerns of Alaska Native people

Specimen: a sample of blood, tissue or body fluid from human beings which can be used for testing or research.

"The AASB is used to conduct research and remains a carefully managed resource to improve the health of the Alaska people.... Over time, the ownership, informed individual specimens have been determined Alaska Native example the risk fe

QUESTIONS?

Alaska Area Specimen Bank (AASB) Policy

The Vision

The Alaska Area Specimen Bank will be a quality resource for research in accordance with the health priorities of Alaska Native people

Alaska Area Specimen Bank (AASB) Policy

The Mission

To ensure that stored biologic specimens are available for secondary use in accordance with the conditions of informed consent, the health priorities of Alaska Native people, and the principles of good scientific methods.

1. To provide a central, **quality** controlled, **secure** storage repository for biologic specimens collected from Alaskan study participants **for research** purposes.
2. To ensure **proper management**, regarding human subjects review and informed consent, of all biological specimens collected from patients or study participants (diagnostic, research, etc.) that are retained for any time period that is needed to test the specimen as planned in the research protocol.

Alaska Area Specimen Bank (AASB) Policy

The Mission

To ensure that stored biologic specimens are available for secondary use in accordance with the conditions of informed consent, the health priorities of Alaska Native people, and the principles of good scientific methods.

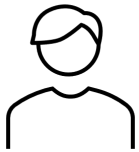
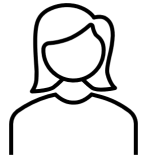
3. To ensure that the uses of specimens stored in a banking facility:
 - i. Are based on the health concerns and **health priorities of Alaska and the Arctic**, with special emphasis for health concerns and **health priorities of Alaska Native people**, in accordance with the joint health-related missions of Alaska Native Tribal Health entities, and
 - ii. Will meet all federal, tribes and tribal health organizations standards regarding **privacy, research ethics and protection of human subjects**
 - iii. Will seek **approval from tribes/tribal health entities** for anonymous testing of specimens obtained under the authority of those tribes or tribal health entities.
4. To **provide a system** by which specimens can be accessed for research.

Key
Principles
of the
AASB

Individual
Ownership

Good
Custodianship

Access and
Utilization



Individual participants retain ownership of specimens and associated data.

Ownership

Good Custodianship



TRANSPARENCY TO
STAKEHOLDERS



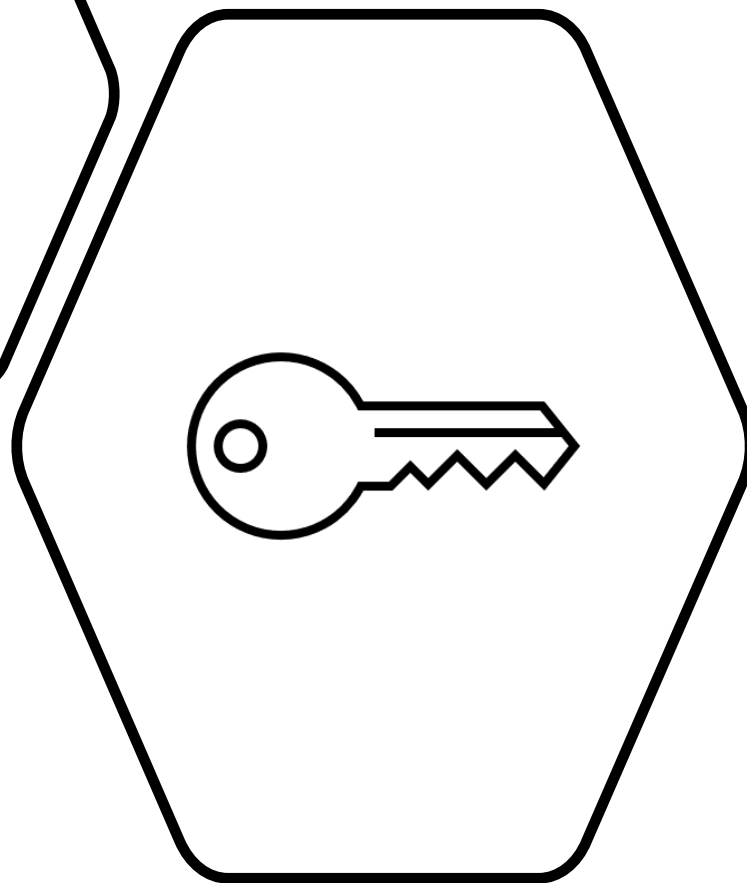
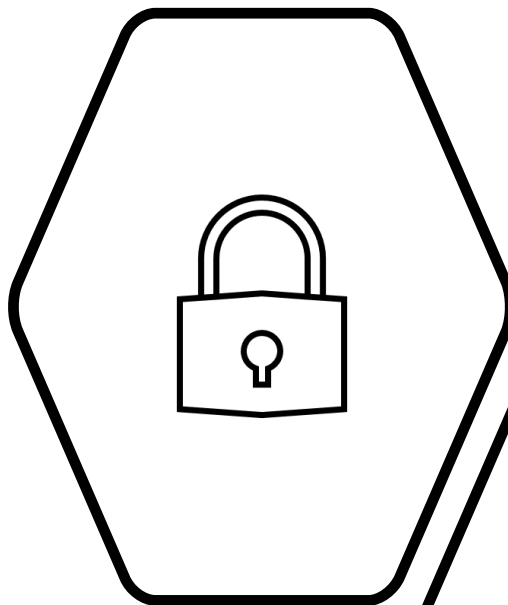
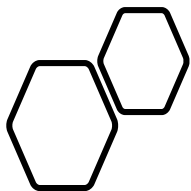
MAINTAINS SECURITY
OF PRIVATE
INFORMATION



QUALITY ASSURANCE



GOOD LABORATORY
PRACTICES



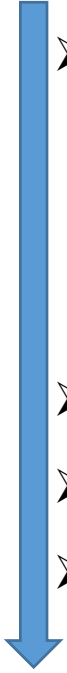
Access & Utilization

WHO	Who can access?
WHAT	What specimens are available?
WHERE	Where will the specimens be used?
HOW	How will specimens be accessed safely and securely?
WHY	Why are the specimens being used, what is the purpose?

Adapting the AASB from Past to Present

2006

The Alaska Area Specimen Bank
Policies and Procedures

- 
- New developments in
 - Biorepository science and innovation
 - Genetics Research
 - Individualized Medicine
 - Upgrades to biospecimen handling, automation and data security
 - Evolving federal laws and regulations (i.e. OHRP/ Final Rule)
 - Continuing support for Tribal Sovereignty

2021

Revising the AASB Policy

Step 1

- Identify & Review Best Practices

Step 2

- Identify Key Elements

Step 3

- Evaluate Current AASB Policy with Key Elements

Step 4

- Incorporate New and Update Existing (Draft)

Step 5

- Review and Discuss with Tribal-Federal Partnership
- Stakeholder Focus Groups, Open forums
- THE AASB POLICY SUMMIT

Overview of Policy Revisions



2006-current

- **Vision/Mission**
- Governance
- Principles of Operation
- Regulations
- Operation Procedures



2022 Proposed

- **Vision/Mission**
- Governance
- Principles of Operation
- Regulations

Key Components that Remain the Same



2006-current

- **Vision/Mission**



2022 Proposed

- **Vision/Mission**



Key Components that will be Expanded



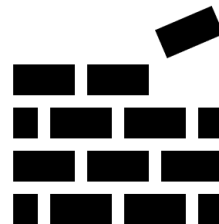
2006-current

- Governance
- Principles of Operation
- Regulations



2022 Proposed

- Governance
- Principles of Operation
- Regulations



Key Components that will be Expanded

1 of 2

Key Component	Existing	Additions
Governance	Oversight Committee, Working Group, Tech Team, Director, Co-Chair	Further definitions to roles and clarify key responsibilities How and When the Policy Document is reviewed, What timeframe and by Whom
Principles of Operation	Ownership	Statement regarding historic samples with no documented consent Regulations and Ethics surrounding specimens from a deceased person Policies surrounding genetics-based research and genetic material
	Good Custodianship	The policies & principles the bank will be operated by

Key Components that will be Expanded

2 of 2

Key Component	Existing	Additions
Principles of Operation	Good Custodianship	Specific Reporting Responsibilities – Define reporting requirements
	Access and Utilization	Guidance surrounding genetics-based research, genetic material.
Regulations	All applicable OHRP (IRB), OSHA, Biosafety, HIPAA, information security, CDC-specific regulations	OHRP – The Final Rule (2020) -changes to definitions of biospecimen and secondary use CDC Sample Management and Data Securities Policies

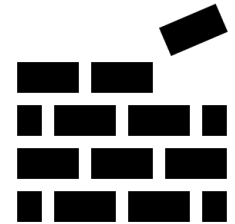
AASB Policy revisions will build upon our founding principles to achieve our vision and create a policy document that provides continuing and current operating guidance.



2022 Proposed



2006-current



The Vision

The Alaska Area Specimen Bank will be a quality resource for research in accordance with the health priorities of Alaska Native people

Thank you



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Biorepository Best Practices Resources List

- *American Indian and Alaska Native Genetics Resource Guide: Tools for Tribal Leaders and Citizens*
- *International Society for Biological and Environmental Repositories—4th Edition (ISBER)*
- *National Cancer Institute (NCI) Best Practices for Biospecimen Resources*
- *U.S. Centers for Disease Control and Prevention (CDC) – Sample Management Policy*
- *Code of Federal Regulations (CFR) 2019 ‘Final Rule’ – updates to Institutional Review Board policy*