

Alaska Area Specimen Bank

“A Resource for Improving the Health of Alaska Native Peoples”

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Arctic Investigations Program (AIP)



- Field station of CDC located on the Alaska Native Health Campus
- Infectious disease prevention and control research studies through applied epidemiology, laboratory, computer and statistical sciences

AIP Staff

- Epidemiology
 - Medical epidemiologists
 - Research nurses
 - Surveillance epidemiologist
- Laboratory
 - Microbiology
 - Molecular Diagnostics
 - Specimen Bank
- Statistics & Information Management
- Administration



Bullwinkle, our parking attendant

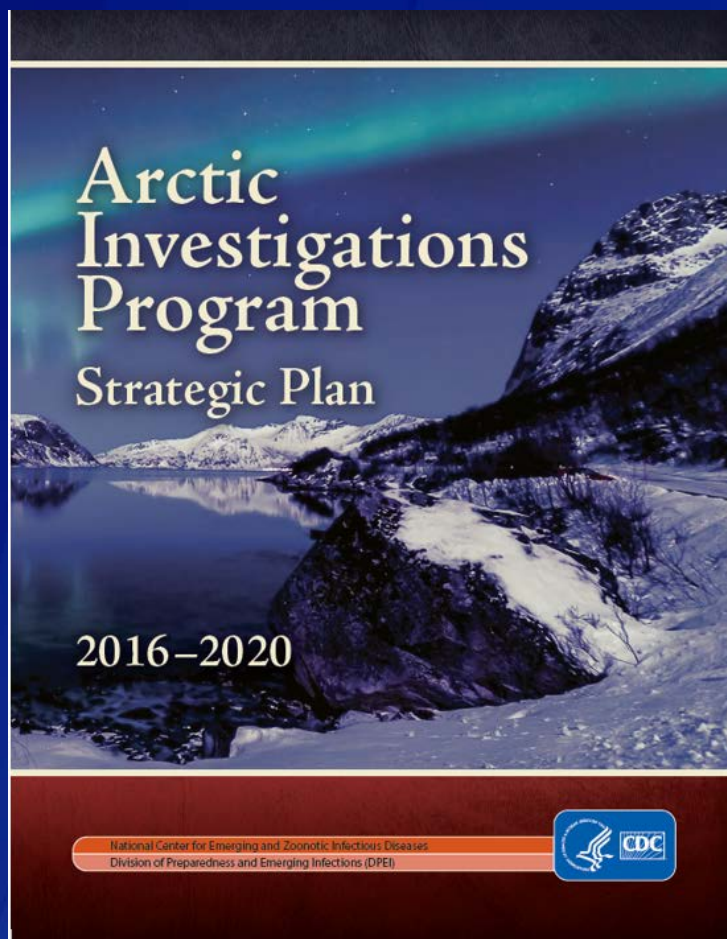


AIP's Mission



- To prevent infectious disease morbidity and mortality in peoples of the Arctic and Subarctic
- Special emphasis on diseases of high incidence and concern among indigenous peoples

AIP's Priorities



Priorities

The CDC Arctic Investigations Program has adopted the following top five Priorities for the period 2016–2020:

- Reduce the burden of disease and health disparities among Alaskans caused by respiratory infections, *Helicobacter pylori* gastric infections, viral hepatitis, and emerging invasive or antimicrobial-resistant infections.
- Strengthen infectious disease monitoring in the circumpolar north through enhancements to laboratory-based surveillance, use of electronic health records and biorepositories, and collaborations such as the International Circumpolar Surveillance system.
- Support efforts to improve access to in-home water and sanitation services for circumpolar populations.
- Provide leadership for domestic and international activities to promote improvements in health and well-being among indigenous populations in the Arctic region and the U.S.
- Respond to infectious disease threats to Arctic and sub-Arctic populations caused by the rapidly changing climate and environment.

Alaska Area Specimen Bank (AASB) Outline

- Introduction
- Management
- Informed consent
- Utilization of specimens
- Costs
- Current holdings
- References



Introduction

- Human health research in Alaska addresses:
 - Health disparities
 - Improves health of all Alaskans
- Conducted by agencies of the Public Health Service
 - Arctic Health Research Center
 - Alaska Area Native Health Service (AANHS)
 - Indian Health Service (IHS)
 - CDC
- Currently being conducted by
 - Alaska Native Tribal Health Organizations (THOs)
 - Academic, government and other tribal partners of THOs
 - CDC's Arctic Investigations Program (AIP) and other CDC programs



Introduction

- Testing of previously collected biologic specimens can:
 - Allow assessment of disease prevalence
 - Contribute to the understanding of the natural history of disease
 - Benefit the health and well-being of populations
- Some examples include:
 - Used of stored specimens allowed identification of alpha fetoprotein as a pre-diagnostic marker of hepatocellular cancer
 - Determination of the prevalence of infections with *Helicobacter pylori* – has served as a starting point for research into prevention and control measure

Management of the AASB

History

- Prior to 1999, specimen bank co-managed by CDC's AIP and AANHS.
- Use of stored specimens governed by AANHS guidelines and serum bank protocol.
- Public Law 93-638 (1975):
 - Alaska Native peoples assumed responsibility for their health care
 - AANHS and IHS activities transferred to Alaska Native Tribal Health entities
- Specimen bank became known as the Alaska Area Specimen Bank

Management of the AASB

Policies and Procedures

- Defined and managed under a research protocol, approved by:
 - Alaska Area and CDC Institutional Review Boards (IRB)
 - Alaska Native Tribal Health Organizations
- Purpose:
 - conditions of informed consent
 - health priorities of Alaska Native peoples
 - principles of good scientific methods
- Ownership
 - Individual ownership vs. THO ownership

Alaska Area Specimen Bank Policies and Procedures

Purpose

To ensure that stored biologic specimens collected as part of research studies are used in accordance with the conditions of informed consent, the health priorities of Alaska Native people, and the principles of good scientific methods.

Introduction

Extensive human health-related research has been conducted in Alaska for many years, particularly among Alaska Native people, to address health disparities and to improve the health of all Alaskans. Much of this research was conducted by agencies of the Public Health Service: The Arctic Health Research Center (1948-1973) the Alaska Area Native Health Service (AANHS), The Indian Health Service (IHS), and the Alaskan field station, known since 1989 as the Arctic Investigations Program (AIP) of the National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC). It was the policy of these agencies to save and store biological specimens from human subjects research (any biological material, including, but not limited to, serum, plasma, cell suspensions, and other body fluids; cultures of etiologic agents, and tissues) that were not utilized in the course of a study. Testing of previously collected biologic specimens can allow the assessment of disease prevalence or contribute to the understanding of the natural history of disease, and thus benefit the health and well-being of the Alaska Native population without the need to collect new specimens. A

Management of the AASB

Policies and Procedures

- Objectives:
 - secure storage
 - proper management
 - approval for secondary use is based on:
 - health concerns of Alaska Native peoples
 - in accordance with health-related missions
 - meet Federal, Tribal and THO standards for privacy, ethics and protection of human subjects

Management of the AASB

Alaska Area Specimen Bank Work Group

- Oversight provided by the AASB Working Group
 - Formulates policies and procedures regarding the collection and storage of biological materials.
 - Meets annually
 - Includes representation from
 - CDC Arctic Investigations Program
 - Alaska Native Tribal Health Organizations
 - Health Research Review Committee
 - Alaska Area Institutional Review Board

Management of the AASB Specimen Bank Committee



- Manage day-to-day operations
- Ensures that specimens are used in accordance with the Policies and Procedures
- Meets monthly
- Includes research staff from:
 - CDC's Arctic Investigations Program
 - Alaska Native Tribal Health Consortium

Management of the AASB Specimen Bank Committee

- Specimen Bank Committee responsibilities:
 1. Reviews new/renewed protocols, consent forms
 2. Specimen collection, processing, shipping
 3. Ensures
 - specimens are of high quality
 - complete information
 - privacy and confidentiality are protected
 4. Oversees
 - accessioning, data management, quality control/quality assurance
 - specimen withdrawals



Informed Consent

- Informed consent
 - Study participant agrees to have remaining specimen saved for future testing.
- Two parts:
 - Consent to be in a research study
 - Consent to store and test specimens at a later date

Example of a consent form

1. We would like to save any unused biological specimen in the Alaska Area Specimen Bank.
2. This biological specimen may be used for future testing.
3. Future tests on the biological specimen which use your name or other identifiers **will not** be done without your consent, including tests for HIV, family diseases, or drugs.
4. Any future anonymous testing will only be done with the consent of [insert name of your Alaska Native Tribal Health Organization].
5. You may request to have your biological specimen removed from the Specimen Bank at any future date by calling Dr. Karen Rudolph, Director, Alaska Area Specimen Bank at the Centers for Disease Control and Prevention (CDC) You may use this free telephone number 1-800-699-0767.
6. If you do not want to have your biological specimen kept, this would **not** change the care that you have a right to receive from your Alaska Native tribal health organization, or the Alaska Native Medical Center or prevent you from being in the study.

Check below:

I understand the biological specimen saving information as explained above and:

- () I agree to have my left over biological specimen from this study kept for possible future testing as explained above.
- () I do not agree to have my left over biological specimen from this study kept for future testing. These samples should not be used for anything but this research study, and the samples should be respectfully destroyed 12 months after the study ends.

Participant (print)

Date of Birth

Signature of participant

Date

Witness initials

Signature of Interpreter (if required)

Date

Informed Consent - 2

- Specimens are linked to study participant and research protocol.
 - Anonymous specimens are not stored
- Minimum of three identifiers required:
 - Study participant's name, Date of birth (or medical record number), Date of specimen collection
- Can participate in a study without having specimens stored long-term.
- Banked specimens can be discarded at any time at request of consenting individual.

Informed Consent - 3

- Future testing – related or not related to original study
 - Requires amendment and approvals
 - New research protocol
- Banked specimens linked to personal identifying information requires individuals to provide consent.
- Banked specimens from deceased individuals – THO provides guidance.
- Anonymous testing – does not require individual consent; needs THO approval

Utilization of the AASB Research Studies

Specimen
REQUEST
(Withdrawal)

PI submits
specimen request

Proposal
reviewed by
AASB Committee

Protocol
Developed

Are specimens available
Review language in consent
Scientific validity
Depletion of specimens
Active vs. inactive protocol

PI completes
specimen release
form

Specimens are
retrieved from
the bank

Alaska
Area IRB
Approval

Appropriate
Tribal
Approvals



Utilization of the AASB

Clinical and participant requests

Specimen
REQUEST
(Withdrawal)

- Specimen requests – clinical purposes
 - assist with diagnosis or care
 - requires signed consent from patient and letter from requesting physician
- Participant requests
 - have specimens removed from long-term storage at any time
 - specimen will be discarded in a manner similar to other clinical specimens

Utilization of the AASB Specimen Deposits

Specimen
STORAGE
(Deposit)

PI notifies AASB
Director of intent to
deposit specimens

Proposal
reviewed by
AASB Committee

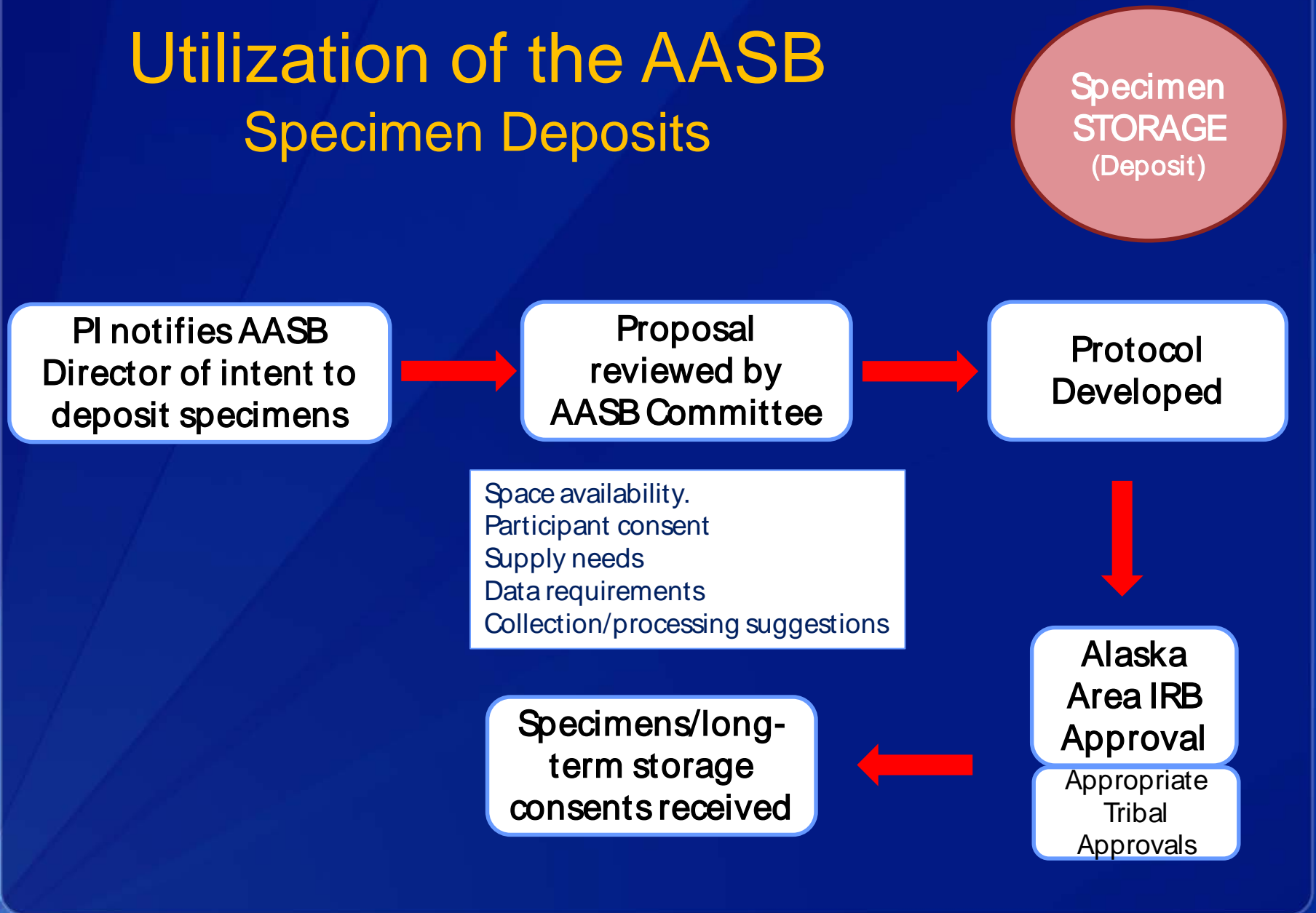
Protocol
Developed

Space availability.
Participant consent
Supply needs
Data requirements
Collection/processing suggestions

Specimens/long-
term storage
consents received

Alaska
Area IRB
Approval

Appropriate
Tribal
Approvals



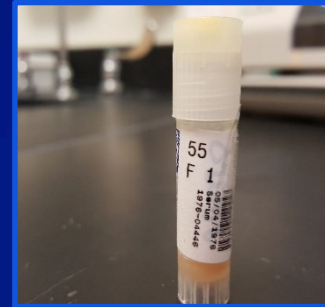
AASB Costs



- Supported from CDC AIP's base funds
- ANTHC funds specimen bank technician
- Investigators can help offset costs
 - direct costs in submitted budget
 - used to purchase consumables and equipment for the repository
- Not a requirement

How are Specimens Stored in AASB?

- Cryogenic vials
- Each tube has a unique number
- Data on each specimen
 - Person (name, DOB, MR#)
 - Specimen date
 - Specimen type
 - Protocol collected under
- Container, Layer and Position (CLP)



What is Currently Banked in the AASB?

	Aliquots	Specimens	People
Total	618,170	343,332	104,508
Specimen Types			
Serum	508977	277789	84404
Plasma	9131	6287	3378
Bacterial cultures	50518	33501	21138
Urine	2015	1212	1036
Cord blood	1805	1238	1233
NP/OP swabs	26184	26010	10725
DNA	11653	10714	6985
Other*	5342	4044	2017

*Other includes: body fluids, tissues, white blood cells and whole blood

Specimen Bank Use - Examples

- High prevalence of *Helicobacter pylori* in the Alaska Native population and association with low serum ferritin levels in young adults.
 - Parkinson A.J. et al., Clinical and Diagnostic laboratory immunology. 2000. 885-888.
- Estimating the date of hepatitis C Virus (HCV) infection from patient interviews and antibody tests on stored sera.
 - Bruden D.L. et al., Am J Gastroenterology. 2004. 99:1517-1522.
- Declines in traditional marine food intake and Vitamin D levels from the 1960s to present in young Alaska Native women.
 - O'Brien D.M. et al., Public Health Nutr. 2016 Jul 28:1-8

For more information:

The Alaska Area Specimen Bank: a tribal-federal partnership to maintain and manage a resource for health.

- Parkinson, A.J., et al. Int J Circumpolar Health 2013, 72:20607

Also – AASB Policies and Procedures document available upon request.

Questions?