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

Alan J. Parkinson Ph.D.,
Director Alaska Area Specimen Bank
CDC Arctic Investigations Program
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

- 266,353 specimens
- 83,841 persons
  - 85% Native
- Specimens belong the Alaska Native people held in trust for the benefit of future generations
  - Individual specimens remain the property of the individual who gave consent to have the specimen stored
The Specimen Bank

Specimens are stored in freezers (-30°C)

Each specimen has a unique number

Linked by computer to a person's name, specimen date, type, and reason why the specimen was drawn
## Alaska Area Specimen Bank

### Inactive Specimens

<table>
<thead>
<tr>
<th></th>
<th>Specimens</th>
<th>People</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td>266,353</td>
<td>83,841</td>
</tr>
<tr>
<td><strong>Male</strong></td>
<td>120,583 (45%)</td>
<td>40,241 (48%)</td>
</tr>
<tr>
<td><strong>Alaska Native/American Indian</strong></td>
<td>247,161 (93%)</td>
<td>71,446 (85%)</td>
</tr>
<tr>
<td><strong>Died</strong></td>
<td>57,118 (21%)</td>
<td>14,345 (17%)</td>
</tr>
</tbody>
</table>

### Specimen Type

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>254,833 (95.7%)</td>
</tr>
<tr>
<td>Plasma</td>
<td>5,430 (2.0%)</td>
</tr>
<tr>
<td>Bacterial Cultures</td>
<td>2,155 (0.8%)</td>
</tr>
<tr>
<td>Urine</td>
<td>1,080 (0.4%)</td>
</tr>
<tr>
<td>Cord Blood</td>
<td>1,010 (0.4%)</td>
</tr>
<tr>
<td>Other*</td>
<td>1,845 (0.7%)</td>
</tr>
</tbody>
</table>

*other includes body fluid, DNA, Swab, Tissue, White cells, and Whole Blood.
Alaska Area Specimen Bank
Active and Inactive Specimens, by year collected

Specimens by year

Number of specimens


- Active protocols (2011 incomplete)
- Long-term specimens

Contemporary Consent Process
For specimen banking begins
Alaska Area Specimen Bank

Inactive Specimens, by Region of Residence

Region

- Yukon-Kuskokwim: 41%
- Anchorage: 24%
- Norton Sound: 10%
- Kotzebue: 7%
- Bristol Bay: 6%
- Southeast: 5%
- Interior: 4%
- Barrow: 3%
- Other/non: 0%
Specimen Bank use


Specimen Bank use


- A Specimen bank survey of the prevalence of *Coxiella burnetti* infection in residents of the Pribilof Islands Alaska (CDC and AAIRB approved January 2013)

- Pilot study: Seroprevalence of infections caused by various zoonotic & parasitic agents (*Brucella*, *echinococcus*, *toxoplasma*, *trichinella*, *Francisella tularensis*, *arboviruses*) in Alaska Native hunters (Testing underway...2012-13)

- Pilot Study: Serologic survey of biomarkers for traditional marine diet and vitamin D levels in the YK Delta childbearing aged women. (AAIRB Approved February 2014)
Specimen Bank management

• Oversight by:
  – Alaska Area Specimen Bank Working Group
    • ANTHC, SCF, State of Alaska, Div. Public Health, CDC/AIP,
    • Alaska Area IRB; CDC IRB

• 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 Health Research Review Committee
    • Annual report to the Alaska Area Specimen Bank Working group
Policies for use

• Research that results in collection and use of stored samples requires approval from:
  – Tribal Health organization
  – Alaska Area IRB
  – Specimen Bank Committee
    • (Collection/Processing/Cost Discussion)

• Studies require the consent of the study participant in order to:
  – Take part in the study
  – Have specimens and identifying information stored for future use
    • Specimens can be discarded upon request at any time
Policies for use

• Consent issues
  – New studies using specimens together with identifying information and associated data will require re-consent
  – New studies using specimens not linked to a participants identifying information does not require re-consent
    • Tribal health organization consulted on use of identifiers to be used to select an appropriate sample.
Policies for use

• A researcher must agree to:
  – Use specimens as described in the approved protocol and consent
  – Not share specimens with other investigators
  – Obtain IRB renewal of the protocol annually
  – Return unused specimens at the end of the study
Policies for use

• A study ends...
  – The study objectives are met and IRB protocol closure procedures are initiated
  – If IRB renewal is not obtained
  – Three years after the last report or publication

• Specimen bank committee conducts a review of protocol and consent to determine data and specimen disposition
Conclusions

• The Alaska Area Specimen Bank is good example of an ethically managed research resource.
• Specimens are not sold or used for any commercial purpose. (A fee is sometimes charged to cover the cost of banking and shipping).
• Specimens are saved for research to improve the health of Alaska Native people.
The Alaska Area Specimen Bank: a tribal–federal partnership to maintain and manage a resource for health research

Alan J. Parkinson¹*, Thomas Hennessy¹, Lisa Bulkow¹, H. Sally Smith² and the Alaska Area Specimen Bank Working Group³

¹Arctic Investigations Program, Centres for Disease Control and Prevention, Anchorage, USA; ²Bristol Bay Area Health Corporation, Dillingham, USA; ³Joe Klejka, Yukon Kuskokwim Health Corporation; Mike Zacharof, Aleutian Pribilof Island Association; June Walunga and Emily Hughes, Norton Sound Health Corporation; Linda Clement, Metlakatla; Cristina Westlake, Maniilaq Health Corporation; Ileen Sylvester, Denise Dillard Southcentral Foundation; Terry Powell, Alaska Area Institutional Review Board; Joe McLaughlin, State of Alaska, Section of Epidemiology

Banked biospecimens from a defined population are a valuable resource that can be used to assess early markers for illness or to determine the prevalence of a disease to aid the development of intervention strategies to reduce morbidity and mortality. The Alaska Area Specimen Bank (AASB) currently contains

Citation: Int J Circumpolar Health 2013, 72: 20607 - http://dx.doi.org/10.3402/ijch.v72i0.20607
Questions....?

More Information Contact:
Alan J. Parkinson Ph.D
Deputy Director
CDC’s Arctic Investigations Program
907 729 3407
ajp1@cdc.gov
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

Specimens Discarded

Yes

Specimens Banked

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

Testing and analysis

Study Ends-Report distributed

Residual Specimens returned or destroyed
Ongoing Discussions...

• Policy & Procedures review and refinement
  – Continuous improvement

• Who speaks for the dead!
  – Legal vs cultural definition (Common Rule does not recognize the deceased)
    • Who then provides consent? family member or THO?

• Historical specimens without contemporary consent
  – Consent obtained when possible
  – Specimens may be used if de-identified
    • 3 levels of protection
      – THO, IRB, Health priority

• Expansion of Policy & Procedures to include banking of, tissue blocks, cells, human DNA

• Specimen Bank Costs