

# Alaska Native people's perceptions, understandings, and expectations for research involving biological specimens

Vanessa Y. Hiratsuka\*, Jennifer K. Brown, Theresa J. Hoefft and Denise A. Dillard

Southcentral Foundation, Anchorage, AK, USA

**Objectives.** Members of racially and ethnically diverse groups have been persistently underrepresented in biomedical research in general, possibly due to mistrust with the medical and research community. This article describes the perceptions, understandings, and expectations of Alaska Native people about research involving the collection and storage of biological specimens.

**Study design.** Stratified focus groups.

**Methods.** Twenty-nine focus groups with Alaska Native people (n = 178) were held in 14 locations using a semi-structured moderator guide. ATLAS.ti was used for thematic analysis through iterative readings and coding. Alaska Native peoples' perceptions, understandings, and expectations of researcher beneficence, informed consent processes, and provision of research findings were elicited.

**Results and conclusions.** Alaska Native people desired extensive disclosure of information beyond that typically provided in consent and results dissemination processes. Information germane to the motivation and intent of researchers and specifics of specimen storage and destruction were specifically requested. A clear and extensive process of informed consent and continued improvements in sharing results may enhance the transparency of research intent, conduct, and use of obtained results among Alaska Native people. Meeting expectations may improve relationships between researchers and the Alaska Native population which could result in increased research participation. Our findings offer a guide for researchers and communities when planning and implementing research with biological specimens.

**Keywords:** *Alaska; Indians; North America; focus groups research ethics; informed consent; results dissemination*

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Racially and ethnically diverse people have been persistently underrepresented in biomedical research and specifically in genomic research (1–8). American Indian (AI) and Alaska Native (AN) people have a documented history of mistrust with research which may partially account for lower levels of participation in research (1,9,10). The results of a recent ethical misconduct case with the Havasupai tribe where blood samples were in multiple research projects that were far afield of the study purpose within the informed consent further underscore the potential incongruence between AI/AN expectations of research and commonly accepted research practices with biological specimens (11). Since the signing of the Indian Self Determination Act (Public Law 93-638) which made it possible for American Indian and Alaska Native tribes to enter into funding agreements and self-govern health services,

AI/AN tribes and groups are increasingly assuming ownership and control of research with people in their communities. For instance, in Alaska, Alaska Native health research requires approval by at least 1 and often 2 tribal leadership groups in addition to Institutional Review Board approval with review consisting of detailed evaluation of proposals, recruitment materials, consent forms, and result dissemination plans. Given the limited empiric investigations of the understanding, perceptions, and expectations of AI/ANs when biological specimens are collected and stored for research, there is the potential for research processes to be incongruent with what AI/ANs need in order to participate in research.

A collection of stored samples dating back to the 1940s from US-funded Alaska research projects resides in the Alaska Area Specimen Bank (AASB) in Anchorage, Alaska. Following the Indian Self Determination

Act, Alaska Native Tribal Health Organizations (THOs) have assumed management of their healthcare system and in 2004, they assumed shared ownership of the AASB. Management of the AASB is provided by the Alaska Area Specimen Bank Working Group (AASBWG) with membership composed of representatives from THOs as well as the Center for Disease Control and Prevention's Arctic Investigations Program (CDC-AIP) and the state Division of Public Health. The AASBWG formulates policies and procedures regarding the collection and long-term storage of human biological samples in the AASB as well as ensuing research. To guide policy and procedure development, the AASBWG posed the question of how ANs view the collection and use of biological samples.

Funding was sought at the request of tribal and other leadership to answer questions about the views of AI/AN people germane to their oversight of an existing specimen bank in Alaska. Southcentral Foundation, a tribal health organization (THO) in Southcentral Alaska, began a multi-phased research study on the ethical and cultural implications of research involving collection and storage of specimens among AN people. To date, this is the first study offering in-depth accounts of AN perspectives directly from the stakeholder (community and tribal leadership), despite a rich history of research collecting and storing biological specimens within AN communities. The lack of prior empirical research suggested the use of qualitative methods would best support an initial exploration of themes. Since the inception of our study, Williams et al. (2010) have provided valuable insight into the perspectives of Southwestern AI and Latino communities about low-risk health research (12). Our study adds to their findings and additionally addresses perceptions of research with biological specimens, banking, and storage which may be greater than minimal risk to the participant and community. This information may help researchers increase AN research participation by taking participant and community understanding, perceptions, and expectations into consideration and may also help researchers and ethicists evaluate and modify proposed frameworks of consent for working with populations underrepresented in research.

## Materials and methods

Twenty-nine focus groups were held in 14 Alaskan communities. A moderator of AN/AI heritage facilitated each focus group with an assistant who acted in a supportive role, obtained informed consent in accordance with current federal regulations, audiorecorded the proceedings, and took notes. All groups were held in English. The Alaska Area Institutional Review Board reviewed and approved all aspects of the study which was subsequently approved in individual communities by their tribal authorities. We used a purposive sampling design and included AN community members in both rural and urban areas of Alaska. We worked with community members who were identified by tribal leadership and trained in focus group recruitment methods by our research team to invite a diverse participant pool to participate within each community.

Eight groups were with individuals over the age of 40, 8 groups were with individuals aged 18–40, and 13 groups were with individuals self-identified as tribal community leaders. This demographic stratification was implemented given norms of respect for elders in the AN community and the recognition that younger participants may have been reluctant to speak freely in front of their elders. The focus group questions (Table I) were designed to elicit participants' views on a number of issues related to the conduct of research using biobanked specimens. This included general thoughts on research involving the collection and storage of specimens, when re-consent might be applicable, and return of research results. All focus group recordings were transcribed by a professional transcription service. The program ATLAS.ti 5.2 was used to assign codes and perform textual analysis (Scientific Software, Berlin). Two members of the research team independently coded each transcript and subsequently met to resolve any coding differences through mutual consensus. The final coding framework was additionally reviewed with the remainder of the team and research consultants who are expert in qualitative research and research ethics. Using the coded data, participant responses were examined for emergent patterns and themes.

*Table I.* Focus group questions

Question 1	What are some words that come to your mind when you think about research?
Question 2	What do you think about researchers collecting samples such as blood, tissue and saliva from you for studies?
Question 3	What are your thoughts about researchers collecting a sample from you and storing it for some period of time in a specimen bank for future research?
Question 4	For instance, what should happen once you pass away? What if your parents gave permission when you were a child and now you are an adult? What about those samples which were collected when research rules were different?
Question 5	What would your thoughts be if your sample was linked to your medical records?

## Results

Characteristics of the 178 focus group members are summarized in Table II. Members were mostly AN (98%) with some non-AN leaders, female (68%), many had attended college (66%), and the majority had not previously participated in a research project (69%). Of those who reported previous participation in a research project, 53% reported providing a biological specimen for research. Of those providing a specimen, 41% reported giving permission for a research specimen to be stored.

Analysis of the focus group discussions elicited 3 main themes – AN peoples' perceptions, understandings, and expectations about the beneficence of researchers, informed consent, and sharing research findings with research participants. Concepts described within this article were reflected across both community member and community leader groups. In the interest of maintaining a higher level of individual- and community-level confidentiality, we have not included individual characteristics with our illustrative quotes.

### Researcher beneficence

Participants expressed considerable interest in the background and characteristics of those conducting the research. More specifically, many participants commented on the motivation or intent of researchers in conducting research on AN people and/or AN communities and ways they could discern beneficence versus personal gain. One participant alluded to her sense of mistrust about researchers' intentions this way: “[I want to] know exactly what the people that are doing the research, exactly what their true intentions are and [I] think that sometimes their true intentions aren't really given . . . they don't fully explain exactly what they need that information for.” Participants additionally expressed interest in a detailed explanation of the researchers' rationale and intent in

collecting and storing a biological specimen during and after the study. Some wanted the possibility of profit for the researcher discussed and others mentioned non-monetary profits such as career advancement as important pieces of knowledge.

### Informed consent

Participants clearly mentioned community consent as important elements of consent. However, participants more fully delineated their thoughts about consent framed from the viewpoint of an individual. Participants emphasized that mental processing time is required to be fully informed. Clear language, free of legal jargon, in the informed consent form as well as during the informed consent process was mentioned. One participant also recommended training of research staff and participants on research ethics as well as researcher's receiving training on cultural context to ensure a minimum level of understanding before permission is given. Participants also commented that consent documents should clearly specify the data and/or biological specimens the researchers are collecting, the study questions, and specifics about specimen storage and reuse. For instance, participants expressed curiosity about what type of container specimens are stored in, how exactly specimens are preserved over time (e.g. how they are protected from freezer burn), and the security of the storage facility. Our participants also suggested including additional information regarding the care of specimens. Specifically, individuals mentioned a “destroy by” date or the option for choosing to have the sample destroyed after a participant's death.

Participants expressed a range of opinions regarding consent for specimen use in future studies. Some recommended re-contact each time the specimen is used, while others only wanted to be contacted for sample use in a different study. Some participants suggested presenting

*Table II.* Characteristics of focus group participants (n = 178)

	All participants (n = 178)	Community member (n = 82)	Leader (n = 81)
Male sex (%)	38.2 (68)	36.6 (30)	40.7 (33)
Alaska Native (%)	97.8 (174)	100.0 (82)	95.1 (77)
Age groups (years %)			
18–34 years	25.3 (45)	45.1 (37)	6.2 (5)
35–54 years	41.0 (73)	35.4 (29)	49.4 (40)
Over 55 years	32.0 (57)	17.1 (14)	43.2 (35)
Highest level of education (%)			
Less than high school/high school graduate/GED	28.7 (51)	23.2 (19)	24.7 (20)
Some college (including trade school)	52.8 (94)	56.1 (46)	55.6 (45)
Bachelors degree or higher	12.9 (23)	13.4 (11)	14.8 (12)
Prior participation in research (%)	30.9 (55)	30.5 (25)	33.3 (27)
Prior participation in research providing biological specimen (%)	16.3 (29)	15.9 (13)	17.3 (14)

a variety of specimen use options (i.e. types of studies) as well storage and destruction options in the informed consent form, with the option to accept or decline each option. Some individuals wanted the researcher to be very clear about whether or not information collected in the course of the study or the individual's specimen would be released to another organization.

### Sharing research findings

Many participants reported not being aware of the results of prior research studies. Some participants expressed interest in receiving individualized results based on the data and biological specimens they provided. When commenting on a specific study that a participant had been part of, he stated "I never heard any results. Our specimens [are] just being kept, being used however they might. What I would like to see is if specific tests are run. I would like to know the results". Some participants stated they wanted to be notified if anything was wrong with their health. Another participant commented how feedback ceases at the end of funding for a research project, stating "Once the money is gone, we don't know what happened. That's the end of it. Some of them were good projects. Others were not so good but it lasts as long as the money lasts." In addition to return of individual results, participants were highly interested in learning about the benefit of their individual contribution to the overall study. One participant stated "I'd be curious of my own sample and how it reflected or benefited the outcome of all the research, the results and their findings, if it was beneficial or non-beneficial." Participants also expressed a desire of learning the public health implications of research findings as explained by a participant who stated "I'd like to know the results and whatever the issue is, how we can help communities, how we can help one another. Just what the next steps are. Where do we go from here?" Participants also expressed a desire to receive information from researchers even before results are compiled such as information about the progress of the study. A few participants connected the lack of results with AN/AI distrust of researchers with 1 participant speculating on the implications not returning results: "... a lot of the researchers were always promising verbally that they were going to share the information with you and ... more than half the time they never see that the results of the data after they leave your community. That's part of the reason why a lot of the Natives in small communities don't trust the researchers." Discussions about results dissemination also linked back to assessments of researcher beneficence.

### Discussion

Contemporary research standards stipulate participants should receive full disclosure of relevant information in order to decide whether to participate in a research (13).

Although the review and approval of research by tribal authorities in Alaska offers an additional assessment of the balance of risks and benefits to communities, AN participants' description of relevant information went beyond the purpose of the research, the duration of participation, foreseeable risks and benefits, researcher conflict of interest, and available alternative procedures with respect to informed consent. Most notably, information in order to assess the beneficence of the researcher and detailed information about the handling and storage of specimens is missing or hard to capture in typical informed consent forms and processes. Participants expressed an interest in understanding the intent not only of the research but of the researcher's interest in conducting that particular research, in that particular manner, with that particular group of people. When conducting research with Alaska Native people, researchers may enhance their relationship with potential research participants if they make themselves available to answer potential participants' questions as they have them.

The apparent disconnect between the current research practices in Alaska which are increasingly comprehensive and AN perceptions of practices suggests that implementation of new practices does not immediately change perception. More outreach may be needed to disseminate information about additions to research practice and the expressed intent of these changes. For instance, tiered or multi-layered consent approaches have been explored in recent publications (14,15) and used by multiple researchers in Alaska contributing to an existing specimen bank.

Alaska Native (AN) participants also introduced several options to include in the consent form including a specimen destruction date. Concerns raised about how specimens would be destroyed or handled in the case of a participant's death may be related to cultural norms where all pieces of the body are viewed as important (16). Hence, incorporating a destroy-by date and more detailed information about the specimen destruction process into the consent form was mentioned by multiple participants across Alaska. The recent Havasupai case (17) ended with a ceremonial return of the samples that were then destroyed and likewise, most of our participants emphasized the importance of treating the physical specimens with respect.

Public trust also hinges to some extent upon public access to research results (18–20). Mistrust among AN people may also be related to lack of awareness of results dissemination of previous studies. Unfortunately, history has shown the undesired effects of this perception that results are not shared with individuals and communities, a form of research referred to as "helicopter research" by our participants. By not sharing findings or not disseminating findings in the expected way, there may be a resultant risk of lower interest in future participation

*Table III.* Recommendations for researchers

1. Be readily available to answer potential participants' questions as they have them.
2. Gain awareness of past clinical and social science research and surveillance projects, including community stigmatizing research conducted within the Alaska Native community.
3. Honour the community and individual participant's expectations of the return of results, data, and specimens collected during the study.
4. Actively address and dialogue with community leaders and community members on your research project and other research conducted in the community.
5. Work with the community to determine how to treat collected data and specimens with respect.
6. Consider both the return of individual results as well as sharing results on how individual contribution impacted the findings of the overall study.
7. Provide clear, jargon-free information in the informed consent including a set data and specimen destruction date.
8. Give potential participants the options for participation in the study through the use of tiered or multi-layered consent approaches.
9. Share information on the study progress and preliminary results to individual participants and participating communities during and after the study.
10. Allow community leaders to review and comment on study findings prior to peer review publication and presentation.

in research and ensuing perceptions of self-serving motivations and intentions on the part of researchers. It is important for researchers to be aware of community and participant expectations regarding the return of results and the link to trust of researchers. Including discussion of results dissemination as part of disclosure of relevant study information may help AN people weigh the benefit of participating in research, while also creating an agreement to which AN people can hold the researchers accountable. For this reason, we recommend that dissemination of results, including individual-level results, be discussed in the informed consent process (20). We also recommend progress of the study be shared.

This study provides an overview of the views and beliefs of an indigenous population about research with stored biological specimens. The study had several limitations that affect the scope of the findings. The intent of the qualitative approach was not to reveal the representativeness of expressed beliefs but the range of beliefs among AN people about a handful of key domains. The original set of focus group questions was quite lengthy and the number of questions and follow-up prompts had to be reduced to minimize participant burden. Additional qualitative work is recommended to explore other domains such as views of genetic research using collected specimens as well as to facilitate more in-depth discussion of important constructs such as ways to provide information about researcher beneficence. Quantitative methods would be necessary to delineate the relative predominance of views. Furthermore, there are 231 AN tribes and groups, yet focus groups were held in only 14 locations within Alaska. It is possible that responses from AN communities that declined participation in the project may differ from the responses that were shared within this project. This study also highlights the need to explore several other issues in greater depth including: (1) the views of

researchers about issues related to the collection and use of specimens among indigenous peoples; (2) best practices in maintaining contact with research participants during the course of the study; and (3) the best ways to communicate results to individual participants.

Notwithstanding these limitations, the range of opinions shared offers a guide for researchers and AI/AN communities when partnering on research projects (Table III). Each community will be distinct in their expectations regarding research, however, and continued dialogue on participant expectations and how researchers can meet these expectations within each community is recommended.

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**\*Vanessa Y. Hiratsuka**

Southcentral Foundation, Research Department  
4105 Tudor Centre Drive  
Anchorage, AK 99508  
USA  
Email: vhiratsuka@scf.cc