



## **Comments by National Congress of American Indians**

**Prepared for**

**National Committee on Vital and Health Statistics (NCVHS)  
Subcommittee on Privacy, Confidentiality, and Security**

**April 17, 2012**

The National Congress of American Indians (NCAI) appreciates the opportunity to provide comments and other information to the National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Privacy, Confidentiality, and Security regarding the need to protect small populations, including tribal communities and American Indian and Alaska Native peoples who participate in health research.

NCAI is the oldest and largest national organization representing the interests of American Indian and Alaska Native tribal governments in the United States. It is a membership organization that serves the interests of the 566 federally-recognized tribes, state-recognized tribes, and American Indian and Alaska Native citizens. In 2003, NCAI established the National Congress of American Indians Policy Research Center (NCAI PRC) to serve as a tribally-driven center, focusing solely on issues facing tribal communities. The NCAI PRC provides the resources and tools necessary to inform public policy debates with meaningful information and assist in shifting the discourse in Native policy from a problem-focused approach to truly proactive, future-thinking strategy development. The NCAI PRC's tribal research regulation work serves to support tribal leaders in ensuring research that is conducted on their lands and with their citizens is ethical, affirms tribal sovereignty, and contributes to community well-being.

There has been a long and challenging history of research in American Indian and Alaska Native communities. American Indian and Alaska Native people are one of the most heavily-studied groups in the United States. Unfortunately, the long history of research in Indian Country has included some instances of harm to American Indian and Alaska Native tribes and peoples. Many Native peoples are wary of research and do not trust researchers. This is largely due to the fact that the term "research" generally reminds Native peoples of the myriad projects historically conducted that did not benefit Native communities, and even, in some cases, resulted in harm to these communities.

The most recent, public example of harmful research in Indian Country is described in the now-infamous lawsuit the Havasupai Tribe filed against the Arizona Board of Regents. In February 2004, the Tribe filed the lawsuit, charging that researchers from Arizona State University (ASU) misused blood samples taken from tribal members. The Tribe claimed that tribal members were told their blood samples would be used for a study on the genetics of diabetes. However, the samples were also used for studies on schizophrenia, inbreeding, and possible migration patterns of the tribe's ancestors from Asia to America. The case was recently settled out of court. This case sent waves throughout Indian Country and the research world, with many tribes and American Indian and Alaska Native organizations, including NCAI, passing resolutions expressing support for the Havasupai Tribe's lawsuit against the Arizona Board of Regents. This case also caused many American Indian and Alaska Native communities to seek new ways to protect themselves from being deceived about the purposes of research projects and to control how their communities are portrayed in publications or presentations by researchers.

NCAI advocates that the sovereignty of tribal governments, as nations, be acknowledged in all aspects of research regulation and efforts to protect small populations. Specifically, NCAI submits comments that call for:

- A. Continuing and close review of research with American Indian and Alaska Native tribes and peoples by IRBs;
- B. Providing oversight of and protection over informed consent processes in all research involving American Indian and Alaska Native tribes and peoples, especially as regards:
  - o Instances where informed consent processes must consider both individual and tribal consent;
  - o Proposed secondary uses or analyses of data collected;
  - o De-identification of data due to the small size of communities and unique characteristics of American Indian and Alaska Native tribes and peoples in the larger population;
- C. Including tribal IRBs and other research review processes in health research review regulations; and
- D. Coordinating across tribal, national, regional, institutional, and community-based research review bodies to clarify issues of responsibility for protection of small populations; oversight authority; application expectations and reporting requirements for investigators; and the ways research review regulation coordination serves to protect and advance tribal sovereignty.
- E. Including American Indian and Alaska Native peoples and Indigenous researchers in public health research, especially as regards:
  - o Data Collection Efforts (e.g., oversampling, alternative, and longitudinal designs)
  - o Data Reporting Efforts
  - o Pathway Development Efforts

NCAI urges NCVHS to be conscious of the challenging and complex history that American Indians and Alaska Natives have faced and continue to face with regards to research, as well as to be mindful of the opportunity NCVHS has to foster a meaningful research ethic going forward so that research can have a positive impact in American Indian and Alaska Native contexts. NCAI advocates that all research conducted with American Indian and Alaska Native tribes and peoples should be developed in full consultation and in equal partnership with tribal leaders over the course of the entire research process, including: research design, data collection, data analysis, and reporting and dissemination. Tribal leaders have the best sense of what kinds of research and data would be most helpful to their citizens. Furthermore, given the diversity and uniqueness of American Indian and Alaska Native communities, the potential risks, benefits, and considerations related to participating in a research study will vary by tribe and by research study. For this reason, **American Indian and Alaska Native individuals and tribes must have the opportunity to consent to participate in research in an informed and ethical way.**

**American Indian and Alaska Native tribal nations are recognized sovereign nations with the authority to regulate all affairs on their lands, including research.** A tribe's sovereignty is critical to consider as part of examining research regulation policy in Indian Country. The Obama Administration has specifically committed to direct government-to-government dialogue with tribal nations through the President's 2009 Executive Memorandum directing all federal agencies to comply with Executive Order 13175. This type of direct consultation is necessary for major proposed policy changes, such as those related to human subjects protections in research.

These comments emerge from the NCAI Policy Research Center's work related to tribal research regulation and reflect NCAI's best experience and insight to date given our work in the tribal research regulation domain, but we also acknowledge that we continue to consult with tribal leaders and researchers to shape ongoing best practice toward protecting American Indian and Alaska Native tribes and peoples and encouraging meaningful research.

**A. Continuing and close review on a consistent and regular schedule by Institutional Review Boards (IRBs) should be required for studies conducted with American Indian and Alaska Native tribal nations and communities.**

NCAI recommends that studies conducted with American Indian and Alaska Native tribes and peoples require some form of **continuing review**. The timeframe should be agreed upon by the American Indian and Alaska Native tribal nation or community at the beginning of the project development. NCAI recommends this review happen at least every two years and in the project's final year. In the Havasupai Tribe's case mentioned above, the university IRB did not review the study after the first approval. Secondary data analyses were conducted that were not authorized by the original consent process. Ongoing review by the IRB might have identified the unapproved secondary use of the data and residual harm to the tribe.

IRBs should consider continuing review for studies that qualified for expedited initial review in cases where research is being conducted where issues related to **individual and tribal consent** are involved, where **anonymity and confidentiality** have been guaranteed to research participants and/or tribes, or where any **secondary analyses of data** are being proposed.

NCAI recommends that all studies conducted with American Indian and Alaska Native tribal nations and communities that **pose greater than minimal risk** should be required to have continuing review annually regardless of whether the remaining study activities only include those that could have been approved under expedited review or would fall under the revised exempt status. We believe that continuing review of research studies will ensure that secondary analyses are not being conducted without consent and that the rights of American Indian and Alaska Native tribes and peoples are being protected throughout the research process.

**B. Providing oversight of and protection over informed consent processes in all research involving American Indian and Alaska Native tribes and peoples.**

*Consent Issues*

NCAI recommends that a **standardized general consent** form should not be used. "Blanket consent" or general consent was used in the *Havasupai Tribe v. Arizona Board of Regents* case and harm resulted. NCAI recommends specific informed consent forms which detail how specimens and data can and will be collected and used. All secondary uses of collected specimens and data should require an additional consent process. Informed consent forms should also be clear, understandable, and specific enough to ensure an informed consent can be solicited. NCAI also recommends that **options be provided** for research participants on informed consent forms (e.g., checkboxes for what types of research they do and do not want their data used for) to ensure a clear, full-disclosure process. The Belmont Report's principles of autonomy and respect for persons require honoring decisions and wishes of research participants, rather than blanket use of their specimens and data without their explicit consent for specific purposes. Many American Indian and Alaska Native peoples believe that specimens and blood are considered sacred as they contain a person's essence and spirit. For this reason, sharing specimens between investigators or moving them from facility-to-facility is worrisome and spiritually concerning for tribal nations and peoples. By providing a full detailed informed consent form, tribal participants will have the option to determine how their specimens and data can be used.

NCAI acknowledges the need to generate an ongoing dialogue across research review boards at the tribal, community-based, regional, institutional, and national levels to clarify issues of responsibility for protection of human subjects; oversight authority; application expectations and reporting requirements for investigators; and how research review regulation coordination serves to protect and advance tribal sovereignty. **Tribal consultation on informed consent processes** will be important as part of any

decision-making about standardizing consent forms and generating best practices in the context of research with American Indian and Alaska Native tribes and peoples.

NCAI recommends that all secondary uses of collected specimens and data should require an **additional consent process**. Additionally, clearly defined choices or checkboxes should be incorporated into the informed consent form for participants to specify which types of studies and how they would or would not like to participate. Individuals should have option to identify their own categories of research they would permit or disallow. The ability of participants to self- identify their own categories of research they would permit or disallow should be clearly explained and defined in the informed consent process. However, NCAI cautions against using consent processes to garner **blanket consent** before future and secondary aspects of research design and data use have been determined. While many members of the general population may have a better sense today than in past about research and their rights, researchers and research review bodies should not transfer responsibilities around consent processes to potential participants. Researchers and research review bodies have significant responsibilities to ensure consent processes are informed and that human subjects are protected throughout the entire research process.

NCAI recommends that **waiving consent should not be permissible** under any circumstances for research involving collection and study of existing data and biospecimens. It does not matter if existing data and specimens were collected originally for research or other purposes. All secondary use of data and specimens should require informed consent by research participants. Again, *Havasupai Tribe v. Arizona Board of Regents* is a perfect example of an instance of unauthorized secondary use that can clearly result in harm of research participants when the full intention of a study is not disclosed. Under current tribal laws, there are some instances in which consent for secondary use is required from both the tribal nation and individuals due to the sovereign status of American Indian and Alaska Native tribal nations, as they have the jurisdiction to regulate research including specimen and data use.

NCAI recommends that the regulations be clarified regarding the current practice of allowing research on **biospecimens that have been collected outside the research study** to require consent, regardless of whether a research participant's identity is never disclosed to the investigator. NCAI is concerned with the secondary use of these specimens without informed consent due to potential for harm of the individual participants and tribal communities as groups. Biospecimens that are collected outside of the research study such as **"left-over" tissue and blood** may be considered sacred by tribal nations and peoples and so sharing them between investigators or moving them from facility-to-facility may circumvent the human subject protection provided as part of informed consent processes.

NCAI recommends that **limited data sets should not be shared** outside the original research team without permission from individual research participants and tribal nations involved in the study. This kind of sharing of data without tribal authorization was part of the problem in the *Havasupai Tribe v. Arizona Board of Regents* case. The sharing of data outside the original research team falls under NCAI's broader concern about secondary use of specimens. There are models for making data accessible to outside research teams without compromising tribal confidentiality, such as a **data enclave** – or a secure space for researchers to perform analyses that require a protected or controlled environment. The National Institutes of Health has offered data enclaves as an option for the original research team to retain control over data, but to provide the aggregate results of secondary analyses to outside requesting research teams in an ethical way.

NCAI recommends that the requirements of individual countries be followed for specimens and data collected outside the United States. However, if those countries do not have regulations or standards, then the minimum ethical requirements adhered to in the United States should still be followed. The **sovereignty of international governments** should be respected, just as tribal nations' sovereignty is important to consider in research regulation.

### *Secondary Use or Analyses of Data*

NCAI recommends that **future research use of data** initially collected for non-research purposes require informed consent for secondary analysis or research conducted on data and specimens. NCAI is concerned about the precedent of secondary use due to the potential for harm on research participants, such as in the *Havasupai Tribe v. Arizona Board of Regents* case, where participants were not made aware of, let alone asked to consent to, the secondary use of specimens collected from them for another study. Regardless of whether the secondary data could be identifiable or not, some American Indian and Alaska Native peoples believe that human tissue, blood, and other biological specimens are sacred as they contain a person's essence and spirit. For this reason, sharing specimens between investigators or moving them from facility-to-facility is worrisome and spiritually concerning for tribal nations and peoples. Other potential harm may occur when tribal nations' names are linked to biological specimens, genetic material, or other kinds of data. Even when a sample or data point does not identify the individual participant, the tribal nation may be named. If specimens and data are then used for secondary analysis in ways not authorized by the tribe, there is the potential for group harm and stigmatization of the tribe in resulting publications and reports.

NCAI acknowledges the **Alaska Area Specimen Bank** as a potential model of tribal oversight of research that ensures ethical and informed collection and management of biological specimens in a way that provides crucial data to researchers. The Alaska Area Specimen Bank includes biological specimens donated by nearly 92,000 people, most of whom are Alaska Native. The Arctic Investigations Program of the Centers for Disease Control (CDC) in Anchorage, Alaska, houses the specimen bank. The biological specimens in the bank have been collected from Alaska Native people who have participated in research studies, public health investigations, and clinical testing over the last half century. Oversight of the Specimen Bank is now provided by the Alaska Area Specimen Bank Working Group, which includes representatives from the CDC and Alaska Native tribal and community organizations. This Working Group is responsible for the development of policies and procedures governing the collection, storage, and reuse of specimens. Researchers wishing to use specimens contained in the bank must obtain permission to use stored specimens from the Tribal Health Organization of the area where the study participant's specimens were collected and the Alaska Area IRB. Research study proposals must have tribal approval before any research activities are allowed to begin.

NCAI recommends that any future use of data that were collected whether anticipated or not require consent for secondary analysis or research conducted on data and specimens. Unanticipated harm to individuals or tribal communities may result from secondary use of biological specimens and other data. Therefore, **informed consent should be required for any proposed secondary use of data**. Even if an individual is not identifiable in the data, a tribe may be. As sovereign nations, tribes have jurisdiction over research conducted using information collected on their land and from their citizens; and, as such, their rights must be considered as part of the informed consent, data reporting, and data ownership processes.

### *De-identification of Data*

NCAI recommends that IRBs work to ensure that researchers abide by data sharing, use, review, and dissemination agreements stated in research review applications; and that IRBs pay particular attention to the **complexities around de-identification of data** due to the small size of tribal communities and unique characteristics of tribal nations and peoples in the larger population that may require initial and continued research review. For example, commitments to guarantee that an individual research participant's data (who is also a member of a tribe) will be confidential *and* to return data collected to a tribe as a part of a data sharing agreement may prove difficult given that the amount of de-identification of an individual's data required to ensure confidentiality may result in data being returned to the tribe that is largely unusable.

NCAI recommends that IRBs should consider potential group harms to historically marginalized populations and other vulnerable groups, including American Indian and Alaska Native tribal nations and communities. **Group stigmatization** and harm is a very real risk of research conducted in Indian Country as is shown in the past case of Barrow Alcohol Study.<sup>1</sup> In this case, researchers stigmatized the community by stating that the tribe was “practically committing suicide” due to alcohol abuse, and there were resulting painful implications for the community. IRBs should be directed by federal regulations to consider group risks when dealing with American Indian and Alaska Native tribal nations and communities and other similarly distinct groups and communities. While stigmatization is a significant concern, **group harm** can also manifest in impacts on how individuals understand themselves and their life chances, as well as on relationships between individuals of a particular group. Consider the idea that some genetics research that explores human histories and origins may challenge a group’s understanding about their own origins and genealogy, or determine that biological bounds between two people may or may not exist, which could impact family and community relationships.

**C. Including tribal IRBs and other research review processes in health research review regulations is important because tribal IRBs and other research review boards have unique knowledge about tribal and local contexts that should be respected.**

Notably, tribal nations have a variety of research review structures. Some tribal nations have their own formal IRBs, while others have developed alternative forms of research review committees or processes. The local research review process a tribe has developed, regardless of its form, can help to ensure risks specific to the population will be minimized. **Tribal IRBs** and other review boards may have more insight about potential participants’ ways of life, cultures, languages and community traditions that could inform decisions about human subject protection and research risk. They may also know and understand more about the issues and disparities the community faces and have ideas of how to be proactive and best address these issues. University and federal review boards should also be encouraged to include American Indian and Alaska Native peoples and researchers to serve on research review bodies, especially when research with American Indian and Alaska Native tribes and peoples have been put forth. This is particularly important in the case of research review in an urban Indian context, where there may not be a formal tribal governance mechanism to provide research review.

NCAI recommends that **there should not be a requirement for only one IRB of record for multi-site studies**, especially when American Indian and Alaska Native tribal nations and peoples are research participants in the study. All participating tribal nations who have active IRBs or review boards should be provided with the opportunity to review the study. If tribal nations choose to defer to one IRB for a multi-site research study of which they are participants that is their option. However, there should not be any mandate for one IRB of record for multi-site studies because local tribal IRBs and research review boards have unique knowledge about a community’s history that is important to consider. Therefore, a tribal nation IRB might have different and/or more restrictive guidelines than the federal guidelines. In order for successful collaboration and trust of research studies with American Indian and Alaska Native tribal nations, tribal sovereignty should be respected and tribal government IRBs should be provided the opportunity to review multi-site research studies.

However, NCAI reiterates its acknowledgement of the need to generate an ongoing dialogue across research review boards at the tribal, community-based, regional, institutional, and national levels to clarify issues of responsibility for protection of human subjects; oversight authority; application expectations and reporting requirements for investigators; and how research review regulation coordination serves to protect and advance tribal sovereignty. This will aid researchers who have to coordinate across several research review boards – and where some of their efforts may be duplicated – as part of multi-site studies because there is not enough coordination on the part of research review boards themselves.

NCAI holds that a **local tribal IRB** or research review board is vital to the review process because these committees generally consists of members from the community or those that are actively engaged in the best interests of the community. Local IRBs add to the protection of research participants through an understanding of the unique knowledge of local context, including history of research in tribal community and past harms resulting from research – about which nearly every American Indian and Alaska Native tribal nation would have stories. Historically, federal IRBs do not have adequate representation of tribal members as evidenced by the creation of the American Indian and Alaska Native Health Research Advisory Council.

Although there may be inefficiencies with multiple IRB reviews or local tribal IRB review along with a university review, the benefit of research participant protection is worth the extra time and process. When it comes to research with American Indian and Alaska Native tribes and peoples, NCAI advocates that it is better to have a **thorough review of a research study by a tribal IRB** than to rush the process without community or tribal involvement. Not having local IRB review increases the risk of harm to research participants later in the project, when effects are irreversible as occurred in the *Havasupai Tribe v. Arizona Board of Regents*.

NCAI recommends that if only one IRB of record is allowed for multi-site studies with American Indian and Alaska Native tribal nations, that the study team be required to use the **tribal IRB as the one of record**. Alternatively, the research team could submit their research proposal to a university IRB in addition to, but not in place of, an application to a tribal IRB. Allowing the option for only one IRB of record could allow some researchers to engage in “IRB shopping” and bypass tribal research regulation processes in order to avoid community involvement in publications, ownership of data, and data analyses.

NCAI supports the use of **HIPAA Privacy Rule standards** for identifiable and de-identifiable information and data sets. These standards are appropriate for most types of research studies and data. Employing different standards for different types of research could be confusing and lead to inconsistent application of those rules. For some social and behavioral research, individual participants may wish to be identified to “receive credit” for their contribution. In these cases, the informed consent form should explicitly have the option for participants to be identified or not be identified.

NCAI recommends that **DNA and biospecimens should be considered identifiable** in and of themselves because genome sequencing technology is making it more possible to link DNA with an individual. As noted above, NCAI is concerned about secondary use of data, so rigorous data protections should be applied to genetic information and specimens containing DNA. As noted above, NCAI advocates specific informed consent be required for all studies in which an individual’s DNA or data are used, and that general informed consent not be allowed.

NCAI recommends **there should not be an absolute prohibition from re-identifying data sets** that were previously de-identified. Sometimes it is necessary to link back to individuals to share with them test results found in research related to their health. There may also be a future need to go back to individuals for new informed consent for secondary use of specimens and data in future studies.

NCAI recommends **there should be a prohibition on sharing data sets with third parties**, regardless of whether they are subject to the HIPAA rules or not. Sharing data sets with individuals outside the original research team is very concerning to NCAI given the *Havasupai Tribe vs. Arizona Board of Regents* case. Sharing of this information is fine if tribal or individual participant consent is given but such tribal government consent should be sought and required in the new regulations.

NCAI acknowledges that it may be helpful to collect more data about participants in human subjects research, including number of participants being reported to a central authority. NCAI also agrees that it may also be helpful to **collect data on adverse events for central databases**. However, NCAI

recommends that before any such data collection is mandated or conducted, there should be **formal consultation with tribal governments** under the tribal consultation policy. American Indian and Alaska Native tribal nations are sovereign governments and are often reluctant to engage in research studies and share their data when there has not been prior consultation about the research process. For more information on NCAI's recommendations for effective federal data collection in American Indian and Alaska Native communities, please see the white paper, "Federal Data Collection in American Indian/Alaska Native Communities" that is attached.

Empiric data on adverse events in research studies would be a helpful resource. In particular, having such data sorted by study population, with separate data collected explicitly from research studies including American Indian and Alaska Native communities, would be very useful. However, as noted above, any such data collection should be preceded by formal consultation with American Indian and Alaska Native tribes, which have a government-to-government relationship with the federal government. The DHHS American Indian and Alaska Native Health Research Advisory Council (HRAC), which includes tribal leaders from diverse regions, would be an excellent resource for beginning such consultations.

**D. Coordinating across tribal, national, regional, institutional, and community-based research review bodies to clarify issues of responsibility for protection of small populations; oversight authority; application expectations and reporting requirements for investigators; and the ways research review regulation coordination serves to protect and advance tribal sovereignty.**

NCAI recommends coordination between federal agencies on regulations regarding the protection of research participants. A *single guidance document* would be helpful and would help to ensure consistency in protections for research participants. NCAI also recommends formal consultation with American Indian and Alaska Native tribal nations before such a guidance is developed. **Tribal consultation** would help ensure that the unique concerns and contexts of tribal nations are included in the guidance document. Different types of research may involve unique considerations as well. However, a single guidance document could include such exceptions where they may exist (e.g., for surveys or interviews as used in education or behavioral research) while still including a uniform minimum ethical standard for all types of research.

NCAI recommends that protections provided to research participants under the Common Rule should be applied to all research projects not just federally funded studies. Establishing a **standard for research protections** regardless of the funding sources helps to prevent harm to research participants.

**E. Including American Indian and Alaska Native peoples, tribes, and Indigenous researchers in public health research.**

*Data Collection Efforts*

American Indian and Alaska Native people comprise a relatively small percentage of the overall US population. As a result, it is difficult to collect data that are accurate and generalizable across Indian Country. In large-scale studies of the general US population, the sample sizes taken from American Indian and Alaska Native communities are often too small to produce reliable data across diverse geographic regions. Yet, we recommend that AI/AN communities be included in data collection by federal agencies whenever possible, particularly for large national data sets. Specifically, we encourage federal agencies to plan and consider research designs that **oversample American Indians and Alaska Natives** in their major data collection efforts so meaningful data with adequate sample size and power can be collected. Furthermore, we ask that American Indian and Alaska Native data be **reported regardless** of how small the number of study participants and how large the margin of error. Oftentimes, large national studies collect data on American Indian and Alaska Native populations, but the final reports state that data from these communities are not being reported due to small sample size resulting in what NCAI



has referred to as the “Asterisk Nation” problem where data on Native communities is reported with an asterisk indicating that sample sizes are too low to be significant.

In addition, data should be collected from AI/AN communities regularly over long periods of time. **Longitudinal data** collection facilitates assessments of program effectiveness over time, as well as traces trends in various issues facing Indian Country. Longitudinal data collection may also help to overcome problems of small sample size in some cases. Even if there are not enough data in a particular year to make generalizations across Indian Country, analysis of data accumulated over several years may allow for drawing more robust conclusions. For data collection efforts that are based on small samples taken often over time, such as the new Census data collection methodology, longitudinal data collection is even more important. Consistent data collection over time in AI/AN communities also helps to build trust and stronger long-term relationships between federal agencies and Indian Country. Finally, longitudinal data collection can help to justify federal agency budget requests. Data demonstrating improvement in outcomes for AI/AN communities based on past program efforts can help to make the case for increased resources allocated for Indian Country.

NCAI also recommends that federal agencies explore **alternative research designs** that seek to include American Indian and Alaska Native peoples in public health research. In a recent report on the Special Diabetes Program for Indians, Dr. Yvette Roubideaux reported that the Indian Health Service (IHS) had employed a translation science methodology with 66 demonstration projects that produced findings that had significance and validity matching that of studies employing a randomized controlled trial design. The report she referred to has not yet been released, but NCAI hopes to learn from the work of IHS and to share aspects of that design with other federal partners.

#### *Data Reporting Efforts*

The OMB 1997 Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity establish two ethnicity categories – ‘Hispanic or Latino’ and ‘not Hispanic or Latino’ – and a minimum of five race categories – American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. While it is unclear what the **HHS guidance is on how these data will be reported**, there is a concern that HHS may go the way of other federal agencies that have opted to not report American Indian and Alaska Native data when respondents “check the Hispanic or Latino box” along with the American Indian and Alaska Native box or when Native people report more than one race and are reported as mixed race. Where Native people already struggle extensively with data quality issues, the implementation by federal agencies of these OMB Revisions has the potential to further diminish the data reported by federal agencies on American Indian and Alaska Native peoples or to strengthen that data reporting. The US Census Bureau has opted to take one of the most expansive approaches to implementing these revisions by reporting American Indian and Alaska Native alone, in combination, and alone and in combination with other races and ethnicities. We would encourage other federal agencies to provide access to as much data on American Indian and Alaska Native people as possible while still honoring individual and tribal anonymity and confidentiality issues.

#### *Pathway Development Efforts*

One of the key ways that HHS can help to protect small population, particularly those in Indian Country, is to support efforts to **prepare American Indian and Alaska Native people** to complete health research degrees and gain access to health policy skills and trainings. As reported in a *Science* article (Ginther, et al., 2011) entitled, “Race, Ethnicity, and NIH Awards, there is a gap in how minority investigators fare when competing for NIH research funding: “After controlling for the applicant’s educational background, country of origin, training, previous research awards, publication record, and employer characteristics, we find that black applicants remain 10 percentage points less likely than whites to be awarded NIH research

funding” (p. 1015). As such, NIH has made efforts to prepare minority junior investigators to compete for health research funding. Similarly, there is an increasing emphasis on translation science and dissemination efforts that recognize that science needs to be developed with community application in mind in ways that ensure culture is considered a central part of research design initiatives. To support both of these trends, it is essential that other federal agencies work to increase the number of American Indian and Alaska Native health science researchers, health policy researchers, and health research administrators. In this way, there will be more American Indians and Alaska Natives prepared to serve in a decision-making capacity at the federal level to advocate on behalf of small populations and develop research designs that stem from culturally- and community-based needs and values. There are inspirational examples from New Zealand and Canada about their efforts to prepare Indigenous doctorates that could provide some insight on this front, as well as opportunities to work more closely with tribal colleges and universities in the US to prepare health researchers, policy makers, and administrators.

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[http://www.uaf.edu/irb/readings/BAS\\_Case\\_Study.pdf](http://www.uaf.edu/irb/readings/BAS_Case_Study.pdf)