



## National Congress of American Indians

### Comments on Draft NIH Genomic Data Sharing Policy

November 20, 2013

The National Congress of American Indians (NCAI) is the oldest and largest national organization representing the interests of American Indian and Alaska Native tribal governments in the United States. NCAI is a membership organization that serves the interests of the 566 federally-recognized tribes, state-recognized tribes, and American Indian and Alaska Native tribal citizens. As stated in the Preamble to the NCAI Constitution, NCAI serves:

“to secure to ourselves and our descendants the rights and benefits [of] the traditional laws of our people to which we are entitled as sovereign nations; to enlighten the public toward the better understanding of the Indian people; to preserve rights under Indian treaties or agreements with the United States; to promote the common welfare of the American Indians and Alaska Natives.”

As part of our work to affirm tribal sovereignty and secure our ability to continue to live as Native peoples, NCAI recognizes that research can add value to Native communities when it is driven by tribal leaders and developed in an ethically and meaningfully way. As such, NCAI established the National Congress of American Indians Policy Research Center (NCAI PRC) in 2003 to serve as a tribally-driven center, focusing solely on issues facing tribal communities. We assert that tribes have sovereignty over research that happens on their land and with their citizens and that research ethics must acknowledge the need to *both protect and benefit* Native people through research development.

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.

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. A major part of the work of the NCAI PRC has been to engage with tribal leaders and federal partners around data sharing and genetics research. For example, in September 2013, we launched the American Indian & Alaska Native Genetics

Resource Center (<http://genetics.ncai.org>) to provide tribal leaders and researchers with information on genetics research development in Native communities.

This initiative recognizes the 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.

It is in the spirit of affirming tribal sovereignty, traditional laws, and the role of appropriate research that NCAI submits comments on the Draft NIH Genomic Data Sharing Policy. There are five overarching points we want to highlight in these comments, including:

- **Tribal nations have sovereignty over research conducted on tribal lands and with tribal citizens;**
- **Researchers must secure active tribal approval for the collection, use, and sharing of tribal data;**
- **There are successful models of tribally-driven data sharing that serve to both protect and benefit Native people;**
- **Research ethics need to acknowledge the importance of community consent alongside individual consent; and**
- **Research ethics need to include protections for biological samples collected from both living and deceased human beings.**

NCAI is interested in ongoing engagement with institutions like NIH about how ethics and data sharing protocols need to evolve to acknowledge tribal sovereignty. In addition, our NCAI Policy Research Center has developed a range of educational materials to inform researchers and academic institutions about the particularities of tribal research regulation that are highlighted below:

*[Research that Benefits Native People: A Guide for Tribal Leaders](#)* (2009). With financial support from the Administration for Native Americans, the NCAI Policy Research Center partnered with the First American Land-grant College and Organization Network (FALCON) and the National Indian Child Welfare Association (NICWA) to create a curriculum and in-person training to equip tribal leaders, Native students, and other Native community members to understand and manage research and program evaluation. Participants are presented with typical research scenarios faced by tribal leadership and staff. The curriculum was developed in response to requests from tribal leaders who wanted resources to make better decisions about the proposed research in their communities and was launched in September 2009 following pilot use in several tribal communities. The five modules of this research curriculum have been field tested and are being used with tribal communities at their request and as funding is available. It emphasizes the validity of Indigenous knowledge while highlighting the benefits of western research methods when used in an ethical and community-informed manner.

['Walk Softly and Listen Carefully': Building Research Relationships with Tribal Communities Report](#) (2012). In partnership with Montana State University's Center for Native Health Partnerships, the NCAI Policy Research Center developed a resource guide to provide insights for researchers committed to developing research that benefits Native peoples.

[Data Control Options for American Indian/Alaska Native Communities](#) (2012). An information sheet that highlights data sharing concerns and methods for use with tribal nations.

[Research Regulation in American Indian/Alaska Native Communities: Policy and Practice Considerations](#). This paper describes different ways to institutionalize research regulation in communities and reviews the legal basis for tribal regulation of research. It then describes different kinds of research review board structures communities might use and the pros and cons of each board structure. Possible review board options include Institutional Review Boards (IRBs), community advisory boards (CABs), and other review board structures. This paper also discusses jurisdictional issues, such as what kinds of research should be reviewed by community boards and how these boards might relate to federal and university research regulatory bodies. Finally, a brief discussion on methods for enforcing community research review decisions is included in this paper.

[Research Regulation in American Indian/Alaska Native Communities: A Guide to Reviewing Research Studies](#). This paper provides a detailed discussion of each stage of research review from study proposals to publications. This paper is meant to serve as an interactive guide for communities to consult when they are reviewing research studies and includes a detailed checklist that can be used in the review process. The paper begins with a description of components that should be included in research proposals, such as informed consent procedures, data collection/storage methods, and budget/funding sources. Next, the paper describes issues communities may wish to consider when reviewing research proposals including control of data through written contracts and tribal law. Finally, the paper discusses community review of ongoing research studies and research publications, which can be a complex and challenging process.

[Federal Data Collection in American Indian/Alaska Native Communities](#). This paper presents recommendations to federal agencies for data collection in American Indian/Alaska Native (AI/AN) communities. The National Congress of American Indians Policy Research Center has developed this paper in response to numerous requests from federal agencies soliciting advice about how to improve data collection processes in AI/AN communities. Overall, we recommend that federal agencies openly consult with tribal governmental officials, and seek their insights and support. This paper is meant to serve as a guide for federal agencies engaged in data collection, as well as the analysis, interpretation, and implementation of data in the development of policies and programs.

In addition to the overarching points noted above, NCAI provides the following comments on the specific elements of the Draft NIH Genomic Data Sharing Policy:

## **I. Purpose**

As part of the purpose and expectation set forth in the Draft NIH Genomic Data Sharing Policy, we recommend an amendment to the sentence that currently reads, “Sharing research data supports the NIH mission” to “Sharing research data in an appropriate way supports the NIH mission” in order to acknowledge the spirit of the mission that calls for the application of knowledge in a way that enhances health, lengthens life, and reduces illness and disability. Current research ethics protocols have emerged in large part because there has been (and continues to be) inappropriate sharing of research data.

## **II. Scope and Applicability**

It is not clear from the language provided under the Scope and Applicability section whether and how this policy applies to NIH-funded research that involves large-scale genomic data that has been collected from humans who have since passed away (or who are now deceased). It will be important to include information on the ethical protocols and policies involving biological samples and other data from deceased human beings.

In addition, the Scope and Applicability section should speak to how this Policy takes into account the National Institutes of Health Guidance on the Implementation of the HHS Tribal Consultation Policy, specifically as the HHS Tribal Consultation Policy affirms the following:

“Indian Tribes exercise inherent sovereign powers over their citizens and territory. The U.S. shall continue to work with Indian Tribes on a government-to-government basis to address issues concerning Tribal self-government, Tribal trust resources, Tribal treaties and other rights. Tribal self-government has been demonstrated to improve and perpetuate the government-to-government relationship and strengthen Tribal control over Federal funding that it receives, and its internal program management. Indian Tribes [sic] participation in the development of public health and human services policy ensures locally relevant and culturally appropriate approaches to public issues” (pp. 2-3).

Control of data collected from tribal citizens and on tribal territory is a critical component of tribal sovereignty and impacts tribal participation in the development of public health and human services policy.

## **III. Effective Date**

No comments.

## **IV. Responsibilities of Investigators Submitting Genomic Data**

### **A. Data Sharing Plans**

There should be a protocol established for Institute or Center Program or Project Officials to follow if the data sharing plans involve tribal data to ensure that tribal sovereignty is being maintained. The National Institutes of Health Guidance on the Implementation of

the HHS Tribal Consultation Policy refers to the development of an NIH Tribal Consultation Advisory Committee (TCAC) who could assist with the development and/or oversight of this protocol. In addition, HHS has an American Indian/Alaska Native Health Research Advisory Council (HRAC) and the Secretary's Tribal Advisory Committee that could also assist.

In addition, as part of the [Briefing Book](#) published for the 2013 White House Tribal Nations Conference that took place in November 2013, NCAI recommends President Obama and his Administration take the following action:

“Convene a tribal consultation at the level of the HHS Data Council and develop an agency-wide policy on data management in Indian Country. Echoing the call from the HHS American Indian and Alaska Native Health Research Advisory Council (HRAC), NCAI requests that HHS convene a tribal consultation at the level of the HHS Data Council and develop an agency-wide policy on data management in Indian Country” (p. 20).

## B. Nonhuman and Model Organism

### 1. Data Submission Expectations and Timeline

It is not clear from the language provided under the Nonhuman and Model Organism section whether nonhuman data includes data that has been collected from humans who have since passed away (or who are now deceased). It will be important to include information on the ethical protocols and policies involving biological samples and other data from deceased human beings.

### 2. Data Repositories

The Alaska Area Specimen Bank (see <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3629262/>) has established tribally-driven and culturally appropriate protocols for the management and sharing of biological data collected from Alaska Native peoples. It could be listed as a resource for researchers and Institute/Center Program or Project Officials who need guidance on appropriate methods for managing and sharing genomic tribal data in a way that honors tribal sovereignty and the need to both protect and benefit tribal people through research.

## C. Human Genomic Data

### 1. Data Submission Expectations and Timeline

Guidance to govern human genomic data submission timelines and data release expectations needs to acknowledge tribal sovereignty over data collected on tribal lands and with tribal citizens. Most recently we have raised concerns about “passive approval” language included in NIH Funding Opportunity Announcements (see <http://grants1.nih.gov/grants/guide/pa-files/PAR-11-346.html>) where publication

timelines and research expectations are seemingly put at odds with tribal sovereignty over data. In order to uphold tribal sovereignty and ensure that research protects and benefits Native people, NIH policies and published language must honor tribal oversight of research that takes place on tribal lands and with tribal citizens. We are eager to continue to engage with NIH about how to affirm tribal sovereignty in research and produce research that has meaningful impact – we believe these are not conflicting aims.

De-identification to protect individuals from whom data is collected may need to take place at both an individual and a tribal level, meaning that there is a need for data sharing protocols that protect a person's identity and the identity of the tribe that person belongs to in the case of American Indian and Alaska Native data. This is especially true given the persistent violations and stigma facing tribal members when these protocols are not in place and data is shared without both individual and tribal consent and de-identification. De-identification of tribal data may be complex due to the small size of communities and unique characteristics of American Indian and Alaska Native tribes and peoples in the larger population. Protocols for the review of tribal data sharing requests must take this complexity into account.

## 2. Data Repositories

The registering of studies with human genomic data should take into account tribal sovereignty over data as detailed above with regards to de-identification of data, individual and tribal consent, and management of biological data collected from individuals who have since died. Timelines for registering this data should acknowledge the time it takes to secure tribal approvals. In addition, the Alaska Area Specimen Bank (see <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3629262/>) has established tribally-driven and culturally appropriate protocols for the management and sharing of biological data collected from Alaska Native peoples. It could be listed as a resource for researchers and Institute/Center Program or Project Officials who need guidance on appropriate methods for managing and sharing genomic tribal data in a way that honors tribal sovereignty and the need to both protect and benefit tribal people through research. Tribes and researchers working with tribal data should not be compelled to share data if tribes have not approved data sharing.

## 3. Tiered System for the Distribution of Human Data

While current ethics protocols require informed consent from individuals, there is a need to expand these protocols in the case of data collected on tribal lands and with tribal citizens to also require the informed consent of tribes for data usage. This is important for both primary data collection and use and secondary data collection and use as there have been documented instances of harm to individual tribal members and tribal nations from inappropriate and unethical secondary use of data (e.g., diabetes research data collected by researchers at Arizona State University that was later used in secondary research on schizophrenia). While case was settled out of court, it 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 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. Again, protocols in use by the Alaska Area Specimen Bank may be instructive.

#### 4. Informed Consent

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. NCAI is concerned about secondary use of data, so rigorous data protections should be applied to genetic information and specimens containing DNA. 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 that future research use of data require informed consent for secondary analysis. 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 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.

While current ethics protocols require informed consent from individuals, there is a need to expand these protocols in the case of data collected on tribal lands and with tribal citizens to also require the informed consent of tribes for data usage. This is especially crucial in the context of open-access to data. There should be an additional layer of consent required for data from tribal citizens to ensure appropriate de-identification and to prevent harm in the case of providing open-access to that data. Again, protocols in use by the Alaska Area Specimen Bank may be instructive. Where university Institutional Review Boards can oversee research through a particular set of ethics, tribal research review bodies may also need to be consulted to ensure for cultural and community protections that existing research ethics ignore.

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. 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 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.

## 5. Institutional Certification

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.

Further, where university Institutional Review Boards can oversee research through a particular set of ethics, tribal research review bodies may also need to be consulted to ensure for cultural and community protections that existing research ethics ignore. Risks to tribes are a priority and must be considered and prevented as they are never justified. The same survey instrument or types of questions might be considered



minimal risk in one population, but greater than minimal risk with another group. For example, questions about topics that have been historically sensitive in American Indian and Alaska Native communities, such as alcohol use or genetic risk, may be considered higher risk than if the same questions were asked of other groups. Individual studies should be assessed by local IRBs or review boards to determine what level of risk is posed to potential study participants. 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.

While current ethics protocols require informed consent from individuals, there is a need to expand these protocols in the case of data collected on tribal lands and with tribal citizens to also require the informed consent of tribes for data usage. This is important for both primary data collection and use and secondary data collection and use as there have been documented instances of harm to individual tribal members and tribal nations from inappropriate and unethical secondary use of data (e.g., diabetes research data collected by researchers at Arizona State University that was later used in secondary research on schizophrenia). This is also especially crucial in the context of open-access to data. There should be an additional layer of consent required for data from tribal citizens to ensure appropriate de-identification and to prevent harm in the case of providing open-access to that data. Again, protocols in use by the Alaska Area Specimen Bank may be instructive.

De-identification to protect individuals from whom data is collected may need to take place at both an individual and a tribal level, meaning that there is a need for data sharing protocols that protect a person's identity and the identity of the tribe that person belongs to in the case of American Indian and Alaska Native data. This is especially true given the persistent violations and stigma facing tribal members when these protocols are not in place and data is shared without both individual and tribal consent and de-identification.

## 6. Data Withdrawal

Removal of data from NIH-designated repositories should also be possible when a tribe withdraws its consent to data that is identifiable at a tribal level.

## 7. Exceptions to Data Submission Expectations

Allowable exceptions to submitting data to NIH-designated data repositories should include instances where data is identifiable at a tribal level and the tribe has not provided consent for the sharing of that data.

## V. Responsibilities of Investigators Accessing and Using Genomic Data

### A. Requests for Controlled-Access Data

NIH Data Access Committees should have particular protocols in place related to requests to access controlled tribal data that speak to de-identification at a tribal level, tribal consent, and tribal protections. The NIH User Code of Conduct should also include language about protocols related to accessing, sharing, and using tribal data.

### B. Acknowledgement Responsibilities

The NIH should also expect investigators who access genomic datasets from NIH-designated data repositories to acknowledge all provisions related to data sharing set out in the particular study for which data was originally collected.

## VI. Intellectual Property

NCAI encourages the NIH to ensure its policy language about the patenting of genomic or genotype data and technology is consistent with its mission that calls for the application of knowledge in a way that enhances health, lengthens life, and reduces illness and disability. The interests of health and life must come before market and property interests.