

# Frequently Asked Questions

## **Why did the National Congress of American Indians (NCAI) Policy Research Center develop this resource guide?**

Genetics research has become a prominent topic of discussion among American Indian/Alaska Native (AI/AN) communities. Tribal leaders have raised important questions about this type of research and expressed the need for more resources about genetics research that are specific to AI/AN communities. In June 2010, a session about genetics research was held at the Tribal Leader/Scholar Forum as part of NCAI's Mid Year Conference. The goal of the session was to begin a dialogue among tribal leaders about genetics research. The idea for the session grew out of a collaboration between the NCAI Policy Research Center and the National Human Genome Research Institute (NHGRI), which is part of the National Institutes of Health (NIH). During the session, tribal leaders expressed a desire for more information about genetics research. Session participants commented that they did not yet feel comfortable making decisions about this type of research yet because they needed more details and resources about genetics research. For this reason, the NCAI Policy Research Center and NHGRI decided to initiate the development of a genetics research resource guide for tribal leaders. Over two years, the NCAI Policy Research Center worked to develop the content of this web-based resource guide, with funding and support from the NHGRI. The resources included in this guide were developed by a team of authors with expertise in genetics research, particularly specific considerations for AI/AN peoples. Draft versions of the resource guide were thoroughly reviewed by a panel of AI/AN reviewers and scientists at the NHGRI.

## **How was the content of the guide developed? How were the authors selected?**

The questions that tribal leaders asked at the Mid Year session in 2010 served as a basis for content development. These questions included, "What is a gene? What is DNA? How is genetic research being conducted? How are genetic data being stored? What control do tribes have over genetic data?" Before developing any content for the resource guide, the project team administered a survey to NCAI Policy Research Center Advisory Council members and NHGRI scientists. The project team also met with the NCAI Executive Board, the NCAI Policy Research Center Advisory Council, and NHGRI scientists to seek their guidance about the project. Based on their feedback, the plans for resource guide content were further refined. The project team then sought out Native scholars and other researchers with particular expertise in genetics research, data sharing, ethical issues, and specific considerations for AI/AN communities. These experts in the field were asked to contribute writings to the resource guide. Specific sections of the guide were developed in response to the questions raised by tribal leaders. The draft resource guide was reviewed by a panel of AI/AN reviewers and NHGRI reviewers, and revised in response to their comments.

## **What is the goal of the guide?**

The goal of this guide is to provide tribal leaders and AI/AN peoples with the tools and information they need to make their own informed decisions about genetics research. **In this resource guide, the NCAI Policy Research Center does not take a stance in favor of or against genetics research.** Tribal governments and citizens must make those decisions for themselves. As sovereign nations, tribes have taken diverse positions on genetics research in the past, and some tribes have not

yet determined their views or policies on genetics research. The tools are provided to assist tribal nations and citizens in their decision making around genetic research, as well as to ensure protection for research participants and communities who do choose to engage in genetics research.

### **What are genes?**

“Genes” are units of information passed down from parents to child. They are molecules made up of DNA (deoxyribonucleic acid). More information about the [definitions of a gene, genetics research, heredity, and other scientific concepts in genetics research](#) is available in the resource guide.

### **What is genetics research?**

Genetics research includes a variety of research topics. These include the study of how genes might influence the health of a person, how genes can vary between individuals and groups of people, and the use of genetic information to study how human groups migrated in the past. More information on [types of genetics research related to health](#) is available in the resource guide.

### **Who conducts genetics research?**

Genetics research is conducted by scientists with expertise in this field. Genetics researchers can work in universities, federal government agencies, and private companies. These kinds of research organizations sometimes partner with tribes to conduct studies that include tribal citizens.

### **What are some examples of how genetics research has been conducted with tribes?**

In the past, there have been genetics research studies that were viewed as beneficial for some communities, while there have also been cases of research viewed harmful by some tribes. There have been recent cases of strong partnerships between tribes and researchers in genetics research. For example, pharmacogenetics is the use of genetic information to determine how well a patient will respond to a medication or treatment. There has recently been [pharmacogenetics research related to cancer conducted with tribes in South Dakota](#) and partnerships established between Pacific Northwest tribes and the University of Washington as part of the [Northwest-Alaska Pharmacogenetics Research Network](#) (NWA PGRN). A past case of genetic research that raised concern is the lawsuit filed by the [Havasupai Tribe](#) against the Arizona Board of Regents in 2004. The tribe filed this lawsuit because of their concerns about misuse of blood samples and genetic data, which were used for research not originally authorized by the tribe. This case raised issues around individual and tribal consent for how genetic data are used.

### **What issues might a tribe and its citizens consider when making decisions about genetics research?**

For tribes and their citizens who are thinking through their views on genetics research, the following questions may be helpful to consider:

1. Do we have all the information we need to assess a proposed genetics research project?
2. Does this genetics research fit with our larger community values?
3. What do we hope to gain from genetics research? What are the specific possible benefits to our

community from this type of research?

4. What are our concerns or fears about genetics research?
5. What do our elders think about research in general and genetics research specifically? Do they have guidance about spiritual or cultural concerns we should consider in research studies? What topics do elders feel are most important for us to research? What health problems do elders feel are most important for us to research?
6. What do our youth think about research in general and genetics research specifically? Do they have ideas about how research can help address the future needs of the tribe?
7. What are our views on the handling of blood and biological specimens? Are there spiritual beliefs or values we hold about human bodies or blood that need to be considered?

In deciding whether or not to engage in a specific genetics research study, tribal leaders might consider the following questions:

1. Is the research institution likely to be a good partner?
2. Is the nature of the research and its purpose clear to the tribe?
3. What are the specific benefits of the study for the tribe?
4. What are the potential risks of the study for the tribe? How will those risks be minimized?
5. Will genetic information collected in the study be handled in a secure manner?
6. Who will have access to the data? Will the genetic data be shared with anyone?
7. How will the tribe maintain control over how the data are used? Is there a need to control the data? Are there any secondary uses of data planned? Who “owns” the data and resulting products? Will results of the research study be returned to the tribe?
8. Is a written agreement in place to protect the tribe’s interests in the study?
9. Is there an appropriate process for obtaining informed consent from individual tribal members that might participate in the study, and from the tribe as a whole?
10. Does the informed consent form include language about how biological specimens and genetic data will be used? Do tribal participants have the option of choosing what they wish to have happen with their biological specimens and genetic data?
11. What kinds of incentives will be provided to individuals participating in the research study? Are these incentives or payment amounts ethical and appropriate for this community’s context?

### **What is a research agreement? How can research agreements help tribes to protect their interests in research?**

Research agreements can help tribes maximize potential benefits and minimize possible harms of research studies. Research agreements are signed by tribes and their research partners. Written research agreements provide a formal manner of laying out the rights and responsibilities of all partners in a research study, including the terms of how biological specimens and data will be used.

Suggested components of a research agreement include:

1. The purpose of the data collection and why it is important to the tribe.
2. The expected outcome of the project.
3. The data that will be collected and why.
4. Who (e.g., tribe, researcher, federal agency) will have access to the data and for what purposes.
5. How the data will be managed? Where will the data be stored and how long will it be stored?, How will it be secured? Is the tribe comfortable with sharing the data? Does the tribe want the data returned to them or destroyed?
6. How data will be stored or handled according to US governmental regulations which apply

(e.g., the Freedom of Information Act and amendments relating to federally funded research; HIPAA regulations)

7. How the results will be shared and who will approve the documents to be shared.

A suggested outline for a research agreement is below:

- Introduction including the relevance of the project; why tribal involvement is important; potential risks, burdens, and benefits of research; the impact of research and data collection on the tribe; and any compensation for participants involved in the study or project.
- Clear description of study design including timing, materials to be used, where the study will occur and study procedures that are mutually understood.
- Potential risks and benefits of the study including anticipated benefit to tribal community; steps taken to minimize risks and maximize benefits; and assessment of balance of risks and benefits which will be continual and on-going.
- How problems or adverse events will be handled.
- Confidentiality of research data.
- Plans for data analysis.
- Anticipated reporting of data and publications.
- Process for resolving conflicts between research partners (e.g., arbitration).

### **Are there available templates for research agreements?**

Tribes may wish to use a template research agreement when developing their own. These template agreements should be reviewed by tribal legal counsel prior to being signed. There are a number of available templates, including a [data sharing agreement from the Northwest Portland Area Indian Health Board](#) that is in this resource guide.

Other template agreements are available from:

- [The American Indian Law Center, Inc.](#)
- [The Indigenous Peoples' Council on Biocolonialism](#)
- [Canadian Aboriginal AIDS Network](#)
- [Indigenous Wellness Research Institute \(IWRI\) at the University of Washington](#)

### **What is informed consent? How can informed consent help to protect research participants?**

“Informed consent” means that potential participants have received enough information (they are “informed”) to make a thoughtful and voluntary decision about whether or not to join a study (give “consent”). Informed consent is a process involving discussions between the research team and potential participants. The *informed consent form* is an important part of this process.

Informed consent forms are signed by individuals who agree to participate in a research study. There are a number of required elements of informed consent according to federal regulations (45 CFR 46). The National Human Genome Research Institute (NHGRI) (an institute within the National Institutes of Health (NIH)), has developed a list of recommended elements of informed consent for genetics and genomics research. These are:

- Purpose of the research project
- Description of the research procedures
- Financial compensation, costs, and commercialization
- Potential benefits of participating in the project

- Potential risks of participating in the project
- Confidentiality
- Returning results to research participants
- Withdrawal
- Alternatives to participating in the project
- Voluntary participation
- Contact information

### **Are there templates or models for informed consent forms?**

The NHGRI has provided explanations of concepts in informed consent and sample informed consent language on their website. Examples of informed consent forms for different types of genetics research are also available on the [NHGRI website](#).

Informed consent forms can also include options about issues such as whether biological specimens and data can be used for other studies outside of the original research project. For example, an informed consent form could include language such as:

When my specimen is no longer needed for this study, I would like the specimen:

Disposed of by the research team

Returned to my tribe

Stored for use in future research

This type of language would have to be consistent with the research agreement signed between the tribe and its research partner(s). For example, if the tribal government decided that it would not allow any storage of specimens for future research, then the informed consent form for individual research participants would need to reflect that decision. Further examples of [informed consent language](#) are provided in the resource guide.

### **Who can we contact with additional questions about genetics research?**

For more information about the development of this resource guide, please contact the [NCAI Policy Research Center](#). Experts in the area of genetics research and AI/AN communities, including the contributing authors for the resource guide, are also available to answer questions. A [list of organizations and individuals to contact](#) has been compiled as part of the resource guide.