Havasupai Tribe and the lawsuit settlement aftermath

In 1989, researchers from Arizona State University (ASU) embarked on a research partnership called the Diabetes Project with the Havasupai Tribe, a community with high rates of Type II Diabetes living in a remote part of the Grand Canyon. The Diabetes Project with the Havasupai included health education, collecting and testing of blood samples, and genetic association testing to search for links between genes and diabetes risk. After several years of trying, the researchers were not successful in finding a genetic link to Type II Diabetes. They then used the blood samples containing DNA for other unrelated studies such as studies on schizophrenia, migration, and inbreeding, all of which are taboo topics for the Havasupai. Carletta Tilousi, a member of the Havasupai tribe and a participant in the Diabetes Project, attended a lecture at ASU in March 2003 where she learned the samples were used for the later studies without her consent or the consent of other tribal members (Rubin 2004).

In 2004, the Havasupai Tribe filed a lawsuit against Arizona Board of Regents and ASU researchers for misuse of their DNA samples (Havasupai Tribe of the Havasupai Reservation v. Arizona Board of Regents and Therese Ann Markow 2004). The lawsuit articulated concerns about lack of informed consent, violation of civil rights through mishandling of blood samples, unapproved use of data, and violation of medical confidentiality. The initial case complaints also listed misrepresentation, infliction of emotional distress, conversion, violation of civil rights, and negligence, but it was ultimately dismissed due to a procedural error.

The Arizona Court of Appeals later reinstated the lawsuit, leading to a lengthy legal battle. Eventually, the Arizona Board of Regents v. Havasupai Tribe case reached a settlement in April 2010 in which tribal members received $700,000 for compensation, funds for a clinic and school, and return of DNA samples (Harmon 2010; Mello and Wolf 2010). Because the lawsuit ended in an out-of-court settlement, there is no legal precedent emerging from this case over how informed consent issues in research should be handled. Tribes could benefit from becoming informed of the issues that arose in the case and develop safeguards to prevent similar issues from arising in future studies.

Issues raised in the Havasupai lawsuit

Informed consent: Using samples without complete informed consent and without permission from tribal members was a major concern in the Havasupai lawsuit. Informed consent was obtained by making oral statements to the tribal members to recruit them to the research study, and then they were given informed consent documents to sign. All tribal members who gave blood were told that the samples would be used for genetic studies on diabetes. Although the consent forms mention that the samples would be used for research on “behavioral and medical disorders,” no Havasupai members were told this would include studies on schizophrenia (Hart 2003). Use of broad language in consent forms should be considered carefully. Advances in genetic research happen all the time, so it can be hard for a researcher to predict all the possible types of research that can be done with a sample. Other informed consent forms have created very specific language that allows researchers to use the samples for particular types of studies.

Human Migration studies: In genetic research, migration studies use genetic markers in people to look at how people are related to their distant relatives. The studies trace genetic markers back in time by comparing many people from different tribes, communities, and parts of the world. Scientists study these genetic markers by using statistics and make calculations using models in order to predict how closely related two or more tribes are to each other. These models take genetic information from tribes and communities that exist today, and then scientists compare them with
each other to predict how long ago distant relatives were more closely related.

Imagine a case in which one modern-day tribe is able to trace its history to being a part of another modern-day tribe. For one reason or another, some people left that other tribe to migrate, or move away, and live as a separate people. Over time, the small group of people that left grew larger, the language began to change, and this group of people became their own distinct tribe. In fact, some tribes do have old stories in their tribal history about a great migration or about branching away from another group a very long time ago. However, different tribal members might interpret these stories differently, so it is important to think carefully about how tribal migration stories or origin stories might fit in with genetic migration studies, and whether tribal members might be opposed to genetic migration studies.

Scientists who study migration patterns will take genetic information from dozens or even hundreds of different tribes to look at how all these modern-day tribes are related. In many cases, scientists use genetic information from people in Mongolia and other parts of Asia to support the Bering Strait theory that ancestors of modern-day Native Americans came across the Bering Strait.

Languages can also be studied to look at possible relationships between groups. For example, fluent Navajo speakers can understand a lot of the Apache language. Spanish speakers can understand a lot of the Portuguese language. The Navajo and Apache languages are related, and so are the Spanish and Portuguese languages. If you go back far enough in time, you can say that these two distinct groups of people used to live together and spoke the same language at one time, but at some point the two groups separated and the languages began to change and became different from each other.

Scientists have already gathered a lot of information using linguistics (from comparing different languages), anthropology (such as cultural practices and cultural beliefs), and archaeology (from bones, pottery, arrowheads, and other ancient remains). Sometimes, scientists also use genetic information to support theories and ideas of how two distant groups might be related.

Migration studies are a concern for many tribes because the scientific evidence for tribal origins may go against cultural beliefs on tribal origins or be taken as true. Tribes who are considering involvement in migration or ancestry studies should think carefully about the implications this work would have on their tribes and other related tribes. For example, if a migration study suggests that a tribe originally came across the Bering Strait from Asia, the results of the study might have political implications and challenge tribal sovereignty and land rights. Similarly, if a tribe is genetically related to other nearby tribes, involvement in research could affect those related tribes. In these ways, nearby or related tribes might be affected by the actions of one tribe who decides to participate in genetic research. To address these potential concerns, it might be important for tribes to communicate with each other to come to an understanding or agreement about what types of genetic research might be acceptable (such as understanding a disease in the community) or not as acceptable (such as research that may support negative stereotypes or that might suggest a tribe is not “Native” to the U.S.).

Stigmatization: Stigmatization of the tribe was also a risk to the Havasupai community, especially with the concern of “inbreeding.” Scientists used a statistical measurement called the “inbreeding coefficient” to estimate how similar individuals within a population are to each other genetically (Markow and Martin 1993). The “inbreeding coefficient” is high if a community is small and isolated with few outsiders coming into the community. On the other hand, the “inbreeding coefficient” is low when the community is large and in an area where there is a lot of outsiders who come into the community and intermarry. For the Havasupai, the “inbreeding coefficient” was high compared to other tribes. The way in which this information was conveyed to the Havasupai may have been insensitive, because it was interpreted as tribal members who “inbreed” with each other. That is not the case at all. For the Havasupai and for many other tribes, inbreeding is a taboo and
people who break that taboo might have problems later in life. The taboos are often very explicit; complex kinship, marriage, and other cultural protocols have been in place for centuries that prevent close coupling. Furthermore, measuring the “inbreeding coefficient” did not benefit the community; rather it may have caused harm and distress over misinterpretation of the term.

**Access to medical records:** In the Havasupai case, some researchers gained access to medical records without permission from tribal officials or clinic administrators. Obtaining medical records without permission is illegal, but safeguards should also be in place to prevent breach and unauthorized use. In some cases, it is important for researchers to have access to medical records; for example, if researchers are trying to determine how many individuals in a tribe have diabetes, they can look at medical records to determine how many people have already been diagnosed, and this can be useful to carry out a research project on diabetes. However, before researchers should be allowed to have access to medical records and other medical information, there should be clear rules and guidelines on who can have access to the information and specifically what information can be accessed and for what purpose. For example, in the case of diabetes, researchers might be allowed to have access to information related to blood sugar levels, but should not be allowed to have access to unrelated information such as mental health, cancer, or other potential diseases that a patient may have. Medical records should be secured in a safe place where only authorized users can have access. If the medical records are kept in an electronic format, such as on a computer, they should be encrypted and stored on a password-protected computer in a secure location.

Data from medical records could include a person’s genetic information in addition to information about physical characteristics (such as age, height, weight, blood pressure measurements, disease status, medical prescription information, and more). Medical records also contain names and other personal identifiers, but that information is not important for researchers to carry out a study. In cases where it is not important to have personal information about a person, researchers can “de-identify” a sample by removing or not including information such as names and addresses that would link a person to a sample. It is very important to have a system in place to prevent researchers and other unauthorized users from accessing personal identifiers.

The Privacy Rule within the Health Insurance Portability and Accountability Act (HIPAA) can offer some protection for research participants. The Privacy Rule requires that personal identifiers such as name, address, birthday, phone numbers, social security numbers, email addresses, driver license numbers, photographs, or any other identifiers be removed to protect the identity of the individual. The Privacy Rule also extends to “all geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geographical codes” (Health 2011). HIPAA only applies to “covered entities,” which include health care facilities and organizations which handle health-related data, such as insurance companies. However, if research data are shared with organizations that do not fall under HIPAA, those entities are not required to follow the Privacy Rule. In addition, genetic data specifically are covered by the [Genetic Information Nondiscrimination Act of 2008](https://www.giact.org/). This law prohibits discrimination in health coverage and employment based on an individual’s genetic information.

There may be a few other enforcement mechanisms available to tribes once research has begun, including appeals to university Institutional Review Boards or funders (e.g., the federal government) who oversee medical and other research and have requirements related to informed consent, data collection and management, data de-identification and secondary use, and dissemination. However, in order for tribes to maintain the greatest control over research that takes place on their lands and/or with their citizens, they should consider developing their own research review processes.

**Identification:** By naming the Havasupai tribe on scientific papers, there was a risk of identification to individuals. Although individual tribal members were not named, the Havasupai census was 650 around the time the project began, and samples were collected from about 400 Havasupai
individuals. For potentially stigmatizing research such as on inbreeding or schizophrenia, identification of individuals becomes a concern. In scientific publications, the tribe was described as “an isolated Native American population, Havasupai of Arizona” (Markow, Hedrick et al. 1993). Supai, AZ is such a small town in an isolated part of the Grand Canyon that it is relatively easy to identify people from that area.

**Control of samples**: When entering into a research agreement or when deciding whether to participate, tribes should consider whether they will enforce control over how samples can and should be used, and dictate what can or cannot be done with samples.

1. Some **strategies** that tribes might consider are to: 1) create policies over control of samples, 2) suggest changes in the informed consent form before researchers begin to recruit individuals to the study, 3) carefully review the policies from the researcher’s institution. For more information on model research agreements, informed consent form language, and policies, please see [Regulating Genetics Research in Your Community](#).

2. Sometimes the researcher’s institution already has a **policy** that states all samples that are obtained become property of that institution. Some tribes have their own research review boards and may have requirements already in place for control of data or a requirement to return data to the tribe at the completion of a research study. However, ownership of samples typically resides with the university where the researcher is from. Even if control remains solely with the researcher and his/her institution, tribes should take the time to understand what the ownership policies are for the institution. Sometimes tribes and universities need to negotiate the differences between the return of data and data ownership policies. For more information on tribal data control and data sharing, please see [Sharing Data and Protecting Your Community](#).

**Discussion Questions:**

1. What issues were raised in the Havasupai case? How would your tribe respond to the issues that were raised in the Havasupai case?
2. What were the risks to Havasupai individuals and to tribal members? Would these also raise issues for your tribe?
3. If your tribe decided to participate in genetic research, how would you ensure full understanding (“informed consent”) of the project goals?
4. What protections does your tribe have for tribal members who decide to enroll in a research project as a research participant?
5. What privacy protections would your tribe require?
6. Would it be okay for researchers to use your tribal affiliation (i.e., Havasupai tribe) in publications, or would you prefer that your tribe remain anonymous (i.e., an American Indian tribe)? What are the reasons for your decision?