

**A CANYON FULL OF WOES: THE
HAVASUPAI TRIBE ILLUSTRATES THE
NEED FOR CULTURAL COMPETENCY IN
GENETIC RESEARCH**

*Charles Pensabene**

INTRODUCTION: THE LATEST RAPID IN A RIVER OF SORROW 638
I.FROM THE CANYON TO THE COURTROOM—THE IMPETUS FOR
THE CONTROVERSY 639
II.LEGAL RECOURSE FOR NATIVE AMERICAN GENETIC
RESEARCH SUBJECTS..... 642
A. Limited Extent of a Property Right in Genetic
Information 642
B. Limited Extent of Privacy Interest for Native
Americans’ Genetic Material 644
C. Informed Consent Procedures Are The Strongest
Protection For Native American Research Subjects.. 646
III.THE UNDERLYING BASIS FOR CULTURAL COMPETENCY FOR
NATIVE AMERICAN RESEARCH SUBJECTS SPECIFICALLY .. 651
CONCLUSION 655

* J.D. Candidate, Albany Law School 2015; B.A., English, Siena College 2012. Special thanks to Professor Michelle N. Meyer for all of her support and guidance throughout the process. I would also like to thank my family and friends for their love and support.

INTRODUCTION: THE LATEST RAPID IN A RIVER OF SORROW

The grand, sweeping topography of the American Southwest evokes the splendor of the American landscape. From the seemingly endless deserts to the sky-scraping Rocky Mountains, this corner of the country reflects some of the most breathtaking vantage points that embody the nation's collective love affair with picturesque and unique vistas. Of all the entrancing sites in this astonishing area, the Grand Canyon constitutes the most sublime natural feature of the Southwest. Yet, the reality of the situation is that the natural beauty of this area hides the tragedy of the first people to settle this magnificent land. Tucked away in a cluster of small villages near the Grand Canyon, the Havasupai Indian Tribe carved out its small niche in the splendid landscape as a means of protecting the locale they believed to be the birthplace of civilization.¹ After enduring repeated intrusions by Anglo-American interlopers into their harmonious society, the Havasupai tribe strove to live as a peaceful and relatively undisturbed community as outsiders continued to make pilgrimages to view the stunning landscape in which they had carved their quaint existence. Even decades after the relationship with Native Americans and other Americans improved markedly, the Havasupai were subject to invasive and exploitive practices when genetic researchers used the tribe's genome for anthropological and medical research, antithetical to the culture and beliefs of the tribe.² While the suffering of most Native American tribes occurred in pursuit of population eradication and land conquest, the pain that the Havasupai endured at the end of the Twentieth Century influenced the tribe at a cellular level: the exploitation of their sequenced genomes for unauthorized research.³ In addition to reflecting on the continued mistreatment of Native American populations, the Havasupai controversy, and ensuing legal battle, underscore the bioethics issue surrounding the limits of genomic research on Native American research subjects. In the wake of the Havasupai tribe

¹ Kimberly Self, Comment, *Self-Interested: Protecting the Cultural and Religious Privacy of Native Americans Through the Promotion of Property Rights in Biological Materials*, 35 AM. INDIAN L. REV. 729, 729 (2010).

² See *id.*

³ See Katherine Drabiak-Syed, *Lessons From Havasupai Tribe v. Arizona State University Board of Regents: Recognizing Group, Cultural, and Dignitary Harms as Legitimate Risks Warranting Integration into Research Practice*, 6 J. HEALTH & BIOMED. L. 175, 180–81, 184 (2010).

controversy, researchers who undertake genetic research on Native American communities must exercise heightened cultural competency in drafting the scope of the genetic research to protect the Native American subject's autonomy, which is explicitly linked to tribal identity.

Part I provides an overview of the Havasupai controversy. Part II addresses the limitations of two legal concepts: property and privacy interests in genetic materials. These are interests that Native American test subjects may attempt to claim in securing redress for unauthorized uses of genetic materials. It also highlights how the doctrine of informed consent remains a stronger alternative to protect Native American test subjects. Finally, Part III shows why cultural competency is a necessary tool in the genetic researcher's toolbox when using Native American genetic materials. A two-prong protocol of informed consent documents, specifically for Native Americans, and cultural competency that considers the factors that distinguish Native Americans from other groups who undergo genetic research, will foster a more trustworthy and productive relationship between genetic researchers and Native American subjects.

I. FROM THE CANYON TO THE COURTROOM—THE IMPETUS FOR THE CONTROVERSY

The events leading to the Havasupai controversy unfolded in a seemingly harmless and progressive manner. In 1989, a Havasupai tribe member approached an Arizona State University (ASU) anthropologist with concerns about heightened diabetes levels among tribe members.⁴ The ASU anthropologist contacted an ASU genetic expert, Dr. Therese Markow, to initiate the research, and Dr. Markow expressed interest in studying the prevalence of genetic markers of schizophrenia in the tribe's isolated gene pool.⁵ Debate surrounds whether Markow was told that the tribe would not partake in such mental disorder research because of the social stigma attached to mental disorders.⁶ In 1990, before having blood samples drawn, tribe members signed a

⁴ *Id.* at 178.

⁵ *Id.* at 178–79.

⁶ See Ricki Lewis, *Is the Havasupai Indian Case a Fairy Tale?*, PLOS BLOGS (Aug. 15, 2013), <http://blogs.plos.org/dnascience/2013/08/15/is-the-havasupai-indian-case-a-fairy-tale/>.

consent form that stated in general terms that blood would be used “to study the causes of behavioral/medical disorders[,]” and then researchers shifted to oral consent from 1991–1994 after observing the hesitation that tribal subjects expressed after learning that they were required to sign informed consent forms.⁷ These consent forms served as the basis for researchers to expand beyond the boundaries of diabetes research into the historical patterns of consanguinity as a basis for schizophrenia,⁸ despite the tribe’s belief that association with mental disorders contributed to social stigma for Native Americans.⁹ Also, the blood samples were given to researchers not affiliated with ASU¹⁰ for use as evidence of the Bering Strait migration theory, which holds that all Native Americans are related to ancestors who crossed that landmass when immigrating to North America—this theory directly contradicts the tribe’s origin story of a global flood resulting in the human race emerging from the Grand Canyon.¹¹

Although the blood samples were taken over the course of four years—1990 through 1994¹²—the extent of the unauthorized research surfaced in 2003 when Carletta Tilousi, a tribe member and ASU student, attended a doctoral dissertation on population migration, a use for which the tribe had not consented.¹³ The tribe filed a state civil suit, which was later precluded on procedural grounds for lack of sufficiency.¹⁴ Tilousi and other tribal members, joined by the Havasupai tribe, filed a state civil suit against the researchers and the ASU Board of Regents that was later removed to Federal Court.¹⁵ The federal suit alleged breach of fiduciary duty, lack of informed consent, unreasonable disclosure of private facts, and intentional intrusion upon seclusion, among other causes of action.¹⁶

The District Court dismissed the lack of informed consent claim without considering the applicability of 45 C.F.R. § 46.116

⁷ Drabiak-Syed, *supra* note 3, at 180–81.

⁸ See Kim TallBear, *Narratives of Race and Indigeneity in the Genographic Project*, 35 J.L. MED. & ETHICS 412, 413 (2007).

⁹ See Drabiak-Syed, *supra* note 3, at 217.

¹⁰ Tallbear, *supra* note 8, at 413.

¹¹ See Drabiak-Syed, *supra* note 3, at 218–19.

¹² *Id.* at 180–81.

¹³ *Id.* at 184.

¹⁴ See *Havasupai Tribe v. Ariz. Bd. of Regents*, 204 P.3d 1063, 1071 (Ariz. Ct. App. 2008).

¹⁵ Drabiak-Syed, *supra* note 3, at 186, nn. 55–56.

¹⁶ *Id.* at 187.

et seq.,¹⁷ the Common Rule, a federal regulation that governs how research institutions receiving federal funds must secure informed consent for human subjects research.¹⁸ The Court avoided using the Common Rule and relied on the Restatement (Second) of Torts because the Common Rule does not create a private cause of action against researchers; rather, the Common Rule is silent on causes of action.¹⁹ The District Court reasoned that when the subjects consented to have their blood drawn, they consented to the scope of the research, even if the representations as to the use were fraudulent.²⁰ The District Court focused on the consent, instead of on how well informed the subjects were of the uses of their genetic materials, as a means of avoiding consideration of the controversy from the Native American subjects' perspectives, and of the significance of blood, the vessel in which the genetic information is stored.²¹ If the District Court had considered the Common Rule, there may have been a different outcome because the Common Rule specifically mentions that researchers must provide human subjects with information on the scope and purpose of the research,²² and since the District Court required the private cause of action to be enumerated in the Common Rule to consider such a cause of action, such explicit enumeration of the scope of the research could have led the District Court to find there was no informed consent if the Common Rule was considered.

The District Court also rejected the notion that the plaintiffs had a privacy interest in the genetic information derived from their blood that allowed for recovery when ASU researchers shared the blood samples with other research institutions, holding that the tribe members' consent to the broad research described in the informed consent documents, or mentioned in the oral informed consent conversations, waived any privacy interest in their genetic material.²³ Additionally, the District Court held that the articles containing the fruits of unauthorized research did not constitute an intrusion on seclusion because the subjects

¹⁷ *Id.* at 188.

¹⁸ Marshall B. Kapp, *A Legal Approach to the Use of Human Biological Materials For Research Purposes*, 10 RUTGERS J.L. & PUB. POL'Y 1, 5, n.8 (2013).

¹⁹ Drabiak-Syed, *supra* note 3, at 188 n. 64 (citing *Tilousi v. Ariz. State Univ.*, No. 04-CV-1290-PCT-FJM, 2005 WL 6199562 at *2 (D. Ariz. Mar. 3, 2005)).

²⁰ *Id.* at 188.

²¹ *See id.* at 188, 190.

²² 45 C.F.R. § 46.116(a)(1) (2005).

²³ *See* Drabiak-Syed, *supra* note 3, at 189.

consented to having blood drawn for the diabetes research.²⁴

The District Court remanded the remaining claims back to state court.²⁵ The tribe's case was then consolidated with Tilousi's case.²⁶ In 2010, the cases were disposed of by a settlement agreement requiring ASU to pay the Havasupai \$700,000, return all blood samples in its possession and all documents containing research derived from the blood samples, terminate IRB approvals for any research using the samples, and provide the tribe with a list of all entities to which it had previously transferred the samples.²⁷ While the Havasupai tribe was able to secure redress by ending the use of their blood samples in unauthorized research areas, the compensation for the tribe's collective dehumanization rings hollow for those tribal members who simply desire to live in accordance with the cultural practices the Havasupai have held sacred for centuries, including the ability to practice their community-oriented cultural customs.²⁸ The pain the tribe experienced by enduring public exposure of their most personal and sacred symbol, the blood that runs through the veins of the tribal members, suggests the need for change in the operation of genetic research when the subjects of human research are among Native American populations.

II. LEGAL RECOURSE FOR NATIVE AMERICAN GENETIC RESEARCH SUBJECTS

A. *Limited Extent of a Property Right in Genetic Information*

As the technological advancements in the field of genetic research allow previously unparalleled access by researchers keen on discovering more about human subjects through genetic investigations, the importance of establishing protections for the genetic research subjects has never been greater. Providing human subjects with adequate protections is crucial because genetic material contains the most personal data regarding an individual's physical identity, and there is a distinct possibility

²⁴ *Id.*; *Tilousi v. Ariz. State Univ.*, No. 04-CV-1290-PCT-FJM, 2005 WL 6199562 at *2 (D. Ariz. Mar. 3, 2005).

²⁵ *Havasupai Tribe v. Ariz. Bd. of Regents*, 204 P.3d 1063, 1070 (Ariz. Ct. App. 2008).

²⁶ *Drabiak-Syed*, *supra* note 3, at 195.

²⁷ *Id.*

²⁸ Debra Harry, *Indigenous Peoples and Gene Disputes*, 84 CHI.-KENT L. REV. 147, 150-51 (2009).

that the researchers or third parties may expand the uses of genetic information culled for research beyond those authorized by the subjects, as the Havasupai controversy depicts.²⁹

One proposed option to protect genetic research subjects is to create a property right in genetic material, but such an option fails to protect the genetic information contained in the genetic material, and a property interest is silenced once an individual voluntarily discloses or transfers the material to another.³⁰ A property right includes the ability to use, possess, enjoy, exclude, and/or dispose of an item.³¹ A person is free to use, enjoy, and dispose of the pieces of the body, organs, and tissues as he or she sees fit.³² Common examples include posthumous organ donation for medical education or *inter vivos* donation for a family member who needs the organ to live.³³ Similarly, individuals can donate blood, which courts view as either a commercial transaction or a service rendered, but both concepts underscore the notion that individuals have a property interest in blood because they can use and dispose of it if they choose.³⁴ A property interest in a research subject's genetic material is insufficient to protect the most unique expression of that person's individuality unless the genetic information is covertly acquired from research subjects because they voluntarily transfer their genetic material to researchers—a process governed by contract law—and courts are remiss to grant special treatment for genetic material compared to other forms of biological materials.³⁵

If wronged Native American research subjects possessed a property interest in their genetic information, they could claim the tort of conversion as a cause of action because the researcher's exercise of control over the genetic information is inconsistent with the owner's rights, as demonstrated by the Havasupai's experience.³⁶ This alleged property interest in genetic material reflects Native American property constructs, including the

²⁹ Self, *supra* note 1, at 729–30.

³⁰ See Albert R. Serrano IV, *Pieces of Me: The Immoral and Unjust Appropriation of Genetic Material*, 16 MICH. ST. J. MED. & L. 95, 96–97 (2011).

³¹ See Rebecca Tsosie, *Cultural Challenges to Biotechnology: Native American Genetic Resources and the Concept of Cultural Harm*, 35 J.L. MED. & ETHICS 396, 397 (2007).

³² Self, *supra* note 1, at 734.

³³ See *id.*

³⁴ *Id.* at 740.

³⁵ See Richard S. Saver, *Medical Research and Intangible Harm*, 74 U. CIN. L. REV. 941, 972–73 (2006).

³⁶ Self, *supra* note 1, at 762–63.

inalienability of property rights and the prominent notion that property rights are collective for the entire tribe,³⁷ and aligns with previous developments of federal legislation concerning Native American property rights, including a property interest in the human remains of their ancestors and proper respect for cultural artifacts.³⁸ Proponents of a property interest for Native American genetic research subjects believe that instead of subjecting tribal member research subjects to social scorn and the continuing stereotypes about Native Americans' genetic health conditions, researchers would have an incentive to work in conjunction with Native American research subjects to ensure that the property interest in the subjects' genetic information—their microscopic yet significant link to their culture and heritage—would be respected.³⁹ However, principles of contract law and, more specifically, culturally competent informed consent documents, would provide redress for arms-length relations between the tribe, the individual research subjects, and researchers.⁴⁰

*B. Limited Extent of Privacy Interest for Native Americans'
Genetic Material*

Proponents of heightened legal interests for Native American research subjects have suggested that genetic researchers must exercise heightened care and ensure that the privacy of the subjects whose genetic material they are studying is protected in such a way as to prevent exploitation, ridicule, and dehumanization of the very substance that makes a person unique.⁴¹ The potential protection that a privacy interest may afford genetic research subjects, namely reinforcing personal autonomy during genetic research, stands in marked contrast with the value that society can gain from insights into their genetic information from such experiments⁴² because privacy from

³⁷ Debra Harry & Le'a Malia Kanehe, *Asserting Tribal Sovereignty Over Cultural Property: Moving Towards Protection of Genetic Material and Indigenous Knowledge*, 5 SEATTLE J. FOR SOC. JUST. 27, 32 (2006).

³⁸ Rebecca Tsosie, *Indigenous Peoples and Epistemic Injustice: Science, Ethics, and Human Rights*, 87 WASH. L. REV. 1133, 1182 (2012).

³⁹ See generally Self, *supra* note 1, at 748.

⁴⁰ Harry & Kanehe, *supra* note 37, at 40.

⁴¹ See generally Stephanie A. Alessi, *The Return of Results in Genetic Testing: Who Owes What to Whom, When, and Why?*, 64 HASTINGS L.J. 1697, 1700–01, 1716 (2013).

⁴² *Id.* at 1701.

use of the genetic material precludes researchers from exercising their discretion for fear of offending the Native American subjects' cultural practices and chill avenues of research for fear of litigation.

The torts often associated with rectifying a breach of an individual's privacy interest, including unreasonable public disclosure of private facts and intrusion upon seclusion, are avenues through which Native American research subjects would attempt to seek redress.⁴³ For a claim of public disclosure of private facts, the research subject:

must show that the fact disclosed was private, that it was disclosed to the public, that the disclosure was one that would be considered highly offensive to a reasonable person, that the fact was not an issue of public concern, and that the person disclosing did so with reckless disregard for the privacy of the wronged individual.⁴⁴

In the context of wrongful genetic research on Native American subjects, the reasonable person standard fails to consider that what offends Native American populations may not be offensive to a reasonable person in American jurisprudence because the average juror in an American court may not know that Native American research subjects and their tribes value spiritual and cultural tenets that a Westerner does not value,⁴⁵ such as the preeminence of blood in certain tribes or the importance of an origin story for a particular tribe.⁴⁶

Another privacy tort that wronged Native American research subjects may claim, but which may prove difficult to recover under, intrusion upon seclusion, "requires that someone intentionally intrude upon the solitude of the [research subject] and that the intrusion be considered offensive to the reasonable person."⁴⁷ Again, proving that a reasonable person, who by American jurisprudential standards is more likely a non-Native American Westerner, would be challenging because Native American tribes center on communal standards as opposed to individual or at most family-centered standards of reasonableness.⁴⁸ A similar issue would arise when the tribe

⁴³ Self, *supra* note 1, at 757.

⁴⁴ *Id.*

⁴⁵ *Id.* at 758.

⁴⁶ See *id.* at 729, 756–57; Leslie E. Wolf, *Advancing Research on Stored Biological Materials: Reconciling Law, Ethics, and Practice*, 11 MINN. J.L. SCI. & TECH. 99, 123 (2010).

⁴⁷ Self, *supra* note 1, at 758.

⁴⁸ See *id.*

itself, as opposed to individual members of the tribe who participated in the research, files a suit on such basis because the reasonable person standard is difficult for juries to comprehend when Westerners have an individual-centric perspective compared to Native American tribes that emphasize the collective values of the communal tribe.⁴⁹

C. Informed Consent Procedures Are The Strongest Protection For Native American Research Subjects

The notion of informed consent is a creation of Twentieth Century jurisprudence.⁵⁰ In a 1914 New York State Court of Appeals case, then-Judge Benjamin Cardozo stated the bedrock principle of informed consent: “Every human being of adult years and sound mind has a right to determine what shall be done with his own body[.]”⁵¹ In fashioning this concept, he intended to provide patients with unprecedented “autonomy and bodily integrity.”⁵² By the last quarter of the Twentieth Century, the Federal Government recognized the need for informed consent in research of human subjects under the financial auspices of the federal agencies and codified it in “the Common Rule.”⁵³

The Common Rule was developed in response to The Belmont Report,⁵⁴ a cornerstone of ethical human subject research that propels the concept of respect to the forefront of the researcher’s perspective when he or she is creating a protocol for genetic research.⁵⁵ The tenet of respect underscores the preeminence of the subject’s autonomy in the research event, urging researchers to refrain from treating subjects as a dehumanized means to secure the desired results of a study.⁵⁶ In keeping with the notion

⁴⁹ *Id.*

⁵⁰ See Catherine K. Dunn, *Protecting the Silent Third Party: The Need for Legislative Reform with Respect to Informed Consent and Research on Human Biological Materials*, 6 CHARLESTON L. REV. 635, 666 (2012). See also *Schloendorff v. Soc’y of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914).

⁵¹ *Schloendorff*, 105 N.E. at 129.

⁵² Laura B. Rowe, Note & Comment, *You Don’t Own Me: Recommendations to Protect Human Contributors of Biological Material After Washington University v. Catalonia*, 84 CHI.-KENT L. REV. 227, 234 (2009).

⁵³ *Id.* at n. 51. See 45 C.F.R. § 46.116(a)(1) (2005).

⁵⁴ *Federal Policy for the Protection of Human Subjects (“Common Rule”)*, U.S. DEPT OF HEALTH & HUMAN SERVS., <http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html> (last visited Feb. 20, 2014).

⁵⁵ *Id.*; Rowe, *supra* note 52, at 234.

⁵⁶ Saver, *supra* note 35, at 957.

of respect for the research subject, the Common Rule requires that researchers secure the informed consent of the subject by providing subjects with a statement that the study involves research, the purpose(s) of the research, and the procedure(s) involved in the research.⁵⁷ Also, the researcher must inform the subject of the reasonably foreseeable risks, benefits, and alternatives to the research,⁵⁸ a description of the confidentiality procedure for records that identify the subject,⁵⁹ and that the researcher will inform the subject of significant new findings during the research that pertain to the subject's willingness to participate in the continuation of that research.⁶⁰ Courts—when hearing allegations of failures of medical professionals to secure the informed consent of patients or research subjects—have viewed the informed consent as extending a quasi-contract to otherwise vulnerable subjects.⁶¹ By grounding the failure to secure informed consent in contract law,⁶² courts have provided human subject research participants with a means of employing a legal theory that can be comprehended easily by judges or juries unfamiliar with overarching bioethical principles and how such principles apply to a given ethnic group.⁶³ The use of informed consent is a better option than crafting a property or privacy interest when research subjects knowingly provide their genetic material to researchers because the informed consent doctrine recognizes that subjects may value their self-determination in the period leading up to the donation of their genetic material for research purposes.⁶⁴ Native American research subjects who feel wronged by the subsequent, unauthorized use(s) of their genetic material can turn to the contractual basis for informed consent to claim legal basis for their disapproval of that unauthorized scope and the individual and communal pain they shoulder as a result.⁶⁵

⁵⁷ 45 C.F.R. § 46.116(a)(1) (2009).

⁵⁸ 45 C.F.R. §§ 46.116(a)(2)–(4) (2009).

⁵⁹ 45 C.F.R. § 46.116(a)(5) (2009).

⁶⁰ 45 C.F.R. § 46.116(b)(5) (2009).

⁶¹ Gail Javitt, *Why Not Take All of Me?: Reflections on the Immortal Life of Henrietta Lacks and the Status of Participants in Research Using Human Specimens*, 11 MINN. J.L. SCI. & TECH. 713, 735–36 (2010).

⁶² Paula Walter, *The Doctrine of Informed Consent: To Inform or Not To Inform?*, 71 ST. JOHN'S L. REV. 543, 543–44 (1997).

⁶³ Dayna Bowen Matthew, *Race, Religion, and Informed Consent—Lessons From Social Science*, 36 J.L. MED. & ETHICS 150, 158 (2008).

⁶⁴ *Id.*

⁶⁵ Larry I. Palmer, *Should Liability Play a Role in Social Control of*

In the context of the Havasupai controversy, the process of securing informed consent for the blood samples failed to meet Common Rule standards⁶⁶ because the ASU researchers did not inform the participating tribal members of the full extent to which their genetic material would be used and therefore breached confidentiality by providing the genetic information to non-ASU researchers.⁶⁷ The unauthorized use of the tribal subjects' genetic materials for research purposes beyond diabetes research, including schizophrenia and Bering Strait migration theory,⁶⁸ stand in stark contrast to the autonomy that the framers of the Common Rule intended because instead of being aware of the uses of their material and being able to leave the study, had they known of the uses of their genetic material antithetical to their cultural beliefs, they would not have proceeded with the research.⁶⁹ The Havasupai research subjects did not have all the information needed to make informed consent for the research⁷⁰ when researchers withheld the possibility of using the genetic material for other research avenues,⁷¹ and the researchers exerted undue influence over the participating tribal members⁷² because they recognized the Havasupai were wary of potential unauthorized uses of their genetic material.⁷³

Additionally, the researchers failed to recognize the psychosocial harms that could burden the research subjects.⁷⁴ The Havasupai—like many other Native American tribes—view risks to the tribe's social standing—such as the schizophrenia research, and threats to tribe's unique cultural perspective—such as the origin story that conflicts directly with the Bering Strait migration theory, as risks to the individual and the tribe jointly. This is because Native Americans who live on tribal reservations often do not distinguish between the individual and tribe since

Biobanks?, 33 J.L. MED. & ETHICS 70, 76 (2005).

⁶⁶ *Id.*

⁶⁷ Drabiak-Syed, *supra* note 3, at 182–83.

⁶⁸ Joan L. McGregor, *Population Genomics and Research Ethics with Socially Identifiable Groups*, 35 J.L. MED. & ETHICS 356, 364 (2007).

⁶⁹ *Id.*

⁷⁰ See Lindsey Singeo, *The Patentability of the Native Hawaiian Genome*, 33 AM. J.L. & MED. 119, 131 (2007).

⁷¹ Rowe, *supra* note 52, at 250; Drabiak-Syed, *supra* note 3, at 182.

⁷² See generally Gerald Carr, *Protecting Intangible Cultural Resources: Alternatives to Intellectual Property Law*, 18 MICH. J. RACE & L. 363, 372 (2013).

⁷³ See Drabiak-Syed, *supra* note 3, at 182.

⁷⁴ *Id.* at 206.

their values are co-extensive.⁷⁵ To provide for any disparities in values between individual tribe members and the tribe as a communal unit, researchers should secure individual informed consent documents from the individual research subjects and from the tribal representatives, including notifications about developments in the research and the ability to withdraw from the research at any time.⁷⁶ This dualistic approach to securing informed consent embodies the subjective patient standard of informed consent⁷⁷ because considering both the tribe's and the individual subject's interests allows researchers to respect the autonomy and bodily integrity—the core of informed consent—since the many tribal members are entwined with the tribe and its cultural heritage compared to non-Native American research subjects.⁷⁸

Providing Native American research subjects with informed consent documents that respect cultural principles of the subject's tribe is an effective means of preventing disrespect and psychosocial harm.⁷⁹ While informed consent documents grant participants in human subjects research, including those who participate in genetic research, greater protections for their autonomy, the Common Rule, a prominent means of ensuring informed consent in many American human subject research projects, is far from comprehensive and has received much criticism from those who believe protections afforded to research subjects by informed consent should be greatly expanded,⁸⁰ especially in the context of Native American research subjects.⁸¹

In an effort to clarify the Common Rule in the face of rapidly expanding human subjects research, the U.S. Department of Health and Human Services issued an Advanced Notice of Proposed Rulemaking (ANPRM) because many research projects that seemed to be human subjects research fell within one of the exceptions to the Common Rule, thus allowing researchers to circumvent the requirement to secure informed consent from the research participants.⁸² The ANPRM proposed prescribing more

⁷⁵ See McGregor, *supra* note 69, at 358.

⁷⁶ *Id.* at 366.

⁷⁷ See Dunn, *supra* note 49, at 671.

⁷⁸ McGregor, *supra* note 69, at 358.

⁷⁹ See Carr, *supra* note 72, at 371, 376, 389.

⁸⁰ See Rowe, *supra* note 52, at 247 n. 144.

⁸¹ *Id.* at 250.

⁸² Brett A. Williams & Leslie E. Wolf, *Biobanking, Consent, and Certificates of Confidentiality: Does the ANPRM Muddy the Water?*, 41 J.L. MED. & ETHICS

specific content to be included in consent forms, limiting the length of sections in informed consent documents, prescribing the structure and presentation of information in the documents, reducing boilerplate language that protects institutions while failing to inform subjects, and providing standardized consent form templates.⁸³ The ANPRM simplifies increasingly lengthy informed consent documents and allows for subjects to more easily comprehend the information that researchers provide them, thus providing for greater respect for the research subjects.⁸⁴ Genetic researchers treasure Native American populations as a “gold mine” because the tribes studied are often isolated geographically and culturally from other ethnic groups,⁸⁵ thereby allowing researchers to attribute conclusions about the research data they cull from the Native American tribe under investigation without considering the influence of genetic stimuli from other ethnic groups who have bred with the subject’s ancestors. Since some diseases occur in disparate rates in Native American populations, researchers believe genetic research on tribal members’ genes will shed light on how genetic diseases evolve through a bloodline, although a growing number of critics have been chastising researchers for oversimplifying the context in which medical maladies arise by focusing exclusively on genetics without considering environmental or social influences that contribute to the spikes in these diseases in Native American populations.⁸⁶

Genetic research on Native Americans holds significant importance to the tribe members who expose themselves to investigations at the molecular level because such research scrutinizes the Native American subject’s personal connection to the tribe and affects social perceptions of the health of Native American populations in the wake of centuries of discrimination.⁸⁷ If mishandled, the results of genetic research can subject Native American populations to more ridicule and discrimination, including the proliferation of stereotypes that Native American populations are flawed at the most intrinsic levels of existence.⁸⁸

440, 440 (2013).

⁸³ *Id.* at 445–46.

⁸⁴ *Id.*

⁸⁵ Harry, *supra* note 28, at 151.

⁸⁶ *See id.* at 154.

⁸⁷ *See id.* at 147.

⁸⁸ *Id.* at 154.

Native Americans can attempt to secure legal redress, such as filing civil actions like the Havasupai did, for the harms of genetic research that tribal members consider antithetical to their collective beliefs. However, such lawsuits may result in judicial indifference to the painful past and current sufferings that Native Americans endure as an ethnic group because judges, as non-Native Americans, may fail to recognize the impact of the cultural harm that has transpired upon the individual tribal members.⁸⁹ This pain is magnified because the genetic research results from exposing the health problems against which Native Americans struggle and are secured at the cost of corrupting sacred symbols of personhood, such as the district court's lack of concern for the Havasupai tribe's sacred treatment of blood in their cultural practices.⁹⁰

It is possible for genetic research involving Native American subjects to yield beneficial results for society, which is a positive change to the longstanding social perception that Native Americans are inferior and worthless.⁹¹ Genetic materials gleaned from research on Native American populations have a broader meaning and value for the subjects of the research. Although genetic information and the tissue from which it is derived may not trigger property and privacy interests for the subjects who have provided the samples, Native American subjects may still have a more active role in decisions leading up to and surrounding the fruits of genetic research involving their personal information if the informed consent process involves more cultural competency.

III. THE UNDERLYING BASIS FOR CULTURAL COMPETENCY FOR NATIVE AMERICAN RESEARCH SUBJECTS SPECIFICALLY

The argument that a research subject's culture or ethnicity, both of which are social constructs, is a necessary component that researchers should consider is often criticized for fear of dehumanizing the individuals who fit into a given cultural or ethnic group without considering the individual preferences of the research subject, especially in the area of genetic research.⁹²

⁸⁹ Tsosie, *supra* note 31, at 408.

⁹⁰ See Drabiak-Syed, *supra* note 3, at 175–76, 186–87, 193, 197.

⁹¹ Alexander Tsesis, *The Empirical Shortcomings of First Amendment Jurisprudence: A Historical Perspective on the Power of Hate Speech*, 40 SANTA CLARA L. REV. 729, 747–51 (2000). See Whitener, *supra* note 49, at 218–21.

⁹² See Michael J. Malinowski, *Dealing with the Realities of Race and*

However, this criticism is misplaced when the cultural group is a Native American tribe because the notion of abandoning cultural or ethnic boundaries, while helpful in separating underlying racism toward Western minorities from the goals of genetic research, fails to consider that Native American communities operate differently from those of other Western minorities. These minority groups, such as African Americans or Asian Americans, resemble Western society at large because, while members of those groups are often subjugated, they still adhere to the prevailing Western cultural norms of individual autonomy, instead of the dualism of individual autonomy and the collective structure of the tribal community. Instead of excluding the cultural identity of Native American research subjects from the parameters of the genetic research,⁹³ genetic scientists should weigh heavily, and responsibly consider, the importance of Native American cultural tenets on the scope of the research protocols so as to mitigate the instances in which the research subjects will voice problems with the research and preclude future genetic research on that tribe's genome,⁹⁴ such as the Havasupai did in the aftermath of their legal battle with ASU.⁹⁵

Native Americans maintain their cultural identity as a means of keeping their communities alive despite centuries of Western corrosion on the sacred traditions through continued attempts at assimilation and domination.⁹⁶ Members of Native American tribes often resist calls to join the pluralistic cultural landscape dominating the Western social landscape because they are wary of losing what distinguishes their tribes from all other ethnic groups and provides them with a necessary perspective by which they run their lives individually and collectively.⁹⁷ Allowing Native American culture to be swallowed up by a multicultural movement disregards the unique sovereignty that tribes enjoy compared to other ethnic sects in America's melting pot; this also makes Native Americans suffer further victimization at the

Ethnicity: A Ethics-Centered Argument in Favor of Race-Based Genetics Research, 45 HOUS. L. REV. 1415, 1417–19, 1433–35, 1462. (2009).

⁹³ *Id.* at 1462–63.

⁹⁴ *See id.* at 1463, 1472–73; *Havasupai Case Turns Spotlight on Tissue Banking*, THOMPSON'S FDA COMPLIANCE EXPERT (July 1, 2010) available at <http://prod-admin1.tmg.atex.cniweb.net:8080/preview/www/2.3427/2.3465/1.93259> (last visited Feb. 10, 2014).

⁹⁵ THOMPSON'S FDA COMPLIANCE EXPERT, *supra* note 94.

⁹⁶ Tsosie, *supra* note 31, at 402.

⁹⁷ *Id.*

hands of Westerners who claim to recognize Native American culture yet ironically antagonize the tribe, just as previous Western rulers and society at large had done for centuries.⁹⁸ Since Native American research subjects serve as a “gold mine”⁹⁹ to Western genetic researchers, failing to recognize the cultural factors that Native American tribal members value highly can result in further painful experiences for Native American research subjects or the foreclosure of future research opportunities; both of these effects have been highlighted by the litigation and resulting moratorium on participation in genetic research by the Havasupai tribe.¹⁰⁰

Researchers must employ cultural sensitivity when brokering research protocols with Native American tribes. While most Western subjects feel that giving blood is merely a minor hassle, the extent of which is a needle prick, many Native American subjects hail from tribes that consider blood to be a sacred link to the tribe’s ancestors that retains its sacred status well after removal from the body.¹⁰¹ A failure to consider the value of blood and the unique genetic information encased within it creates a disrespectful affront to the subjects whom researchers seek chiefly because they have maintained such strong cultural traditions that have resulted in genetic isolation.

Another instance where the privacy interest in the Native American genomes counterbalances the risk of cultural exploitation is the size of the subject pool. Because some tribes have a small number of members or a small number of genetic lineages, identification of a medical malady in any given member of a tribe subject to research is more likely than in research ventures on other Western ethnicities.¹⁰² If Western researchers were to consider the cultural values and norms on which Native American subjects would likely disagree with the scope of a given genetic research investigation, Native Americans would be fully informed and more likely to consent to future research; this would be more beneficial because then tribal members would know that their unique genetic code is not going to be exploited for profit by others or for proliferation of concepts antithetical to what the tribe to which belongs objects.

⁹⁸ *Id.*

⁹⁹ Harry, *supra* note 28, at 151.

¹⁰⁰ THOMPSON’S FDA COMPLIANCE EXPERT, *supra* note 94.

¹⁰¹ See Tsosie, *supra* note 31, at 405.

¹⁰² *Id.* at 405–06.

Genetic researchers cannot detach Native American subjects from their culture because such subjects see themselves as part of the communal tribe, so researchers need to consider the impacts of the research on the subject and the tribe as a whole.¹⁰³ This dual consideration of the individual research subject and the tribe, including its cultural norms, sacred practices, and origin story, showcases the necessity of comprehending the broader context in which Native American subjects view the tribe, such as the ASU researchers should have done instead of using broad consent forms that failed to address research avenues that conflicted with the known or easily discoverable cultural practices of the tribe.¹⁰⁴ Since society stands to benefit from medical advances stemming from research on Native American genomes, researchers should secure the approval of the individual and a representative body that serves as a proxy for the tribe because, unlike with other ethnic minorities, Native Americans who live on reservations are often deeply entwined with their tribe.¹⁰⁵ Such tribal approval can vary based on the tribe whose genome is under review because each tribe, in exercising tribal sovereignty, can elect a system of governance it deems fit.¹⁰⁶ Just as researchers seek approval from an institutional review board for an experiment, researchers can appeal to the tribal council or other governing body of a tribe to ensure that the community, as directly represented by these leaders, agrees to the scope of the experimentation.¹⁰⁷ Researchers and tribal leaders can craft a clear plan outlining the bounds to which the tribe will agree and ensure that individual subjects know that the tribe is satisfied with how the individual's genome will be used because the individual subjects highly value what the tribe maintains in conjunction with tradition and prevailing cultural norms.¹⁰⁸ This procedure will compel researchers to consider the cultural considerations that have shaped Native American tribes since before the creation of American society; this will also foster a more progressive symbiosis between researcher and research subject at a time when genetic research has reached unparalleled levels and depends now more than ever on having Native

¹⁰³ See Carr, *supra* note 72, at 390.

¹⁰⁴ Drabiak-Syed, *supra* note 3, at 180–81.

¹⁰⁵ Harry & Kanehe, *supra* note 37, at 47–48.

¹⁰⁶ See McGregor, *supra* note 68, at 366.

¹⁰⁷ *Id.* at 366–67.

¹⁰⁸ *Id.*

Americans participate for the benefit of the nation's health.

CONCLUSION

The Grand Canyon is one of the world's most impressive natural wonders. Nestled in the seemingly infinite landscape of terra cotta rock formation, the Havasupai tribe, a small band of Native Americans, attempts to reside peacefully and in seclusion as their ancestors have for centuries. This small population of Native Americans has endured enough sorrow to fill the Grand Canyon multiple times. However, the victimization is not in vain if genetic researchers can learn from the painful experiences that the tribe has undergone. As researchers increasingly turn to genetic research to yield means to combat disease, Native Americans, whose genetic isolation provides valuable pools of research subjects, will be called upon to contribute their genetic materials for insight into medical and anthropological theories with the potential to revolutionize medicine. While these advancements are titillating, researchers must consider the cultural backgrounds of their Native American subjects.

To comport with fundamental bioethical principles, researchers should expand the preparation of Native American research subjects by securing the informed consent of the research subjects through a process that employs cultural competency. Developing research protocols to factor in Native American cultural practices will ensure a continuing symbiosis and respect for an ethnic minority deserving of special protection, in light of centuries of discrimination and attempted capitulation of their culture. A system that weighs the cultural principles of Native American research subjects will provide tribal members with a newfound means of declaring the personal and tribal autonomy that has eluded them for centuries.