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TRESPASS TO CULTURE: THE BIOETHICS OF INDIGENOUS POPULATIONS' INFORMED CONSENT IN MAINSTREAM GENETIC RESEARCH PARADIGMS

Alexandra Winters*

I. Introduction

Today, genetic research is considered of vital importance in the fight against many diseases.¹ Researchers use genes to study diseases such as diabetes, asthma, and leukemia.² The indigenous populations of the world are often identified as ideal sample populations for these studies because of their isolation and the effect that isolation has on their genetic structure.³ The benefits of this research are significant, but new questions have arisen regarding the rights of DNA donors, particularly in light of the case of Henrietta Lacks and her HeLa cells, which were harvested without her knowledge or consent and are now mass produced—an “immortal cell line”.⁴

Such questions are difficult at the best of times, but doubly so in the case of indigenous participants.⁵ Standard frameworks of research and informed consent in the United States were not designed to accommodate indigenous

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1. See Charles Weijer & James A. Anderson, *A Critical Appraisal of Protections for Aboriginal Communities in Biomedical Research*, 42 *JURIMETRICS J.* 187, 187 (2002); see also Bette Jacobs, Jason Roffenbender, Jeff Collmann, Kate Cherry, LeManuel L. Bitsoi, Kim Bassett & Charles H. Evans, Jr., *Bridging the Divide Between Genomic Science and Indigenous Peoples*, 38 *J. L., MED. & ETHICS* 684, 684 (2010) (discussing the history of biomedical research among indigenous populations).

2. See Weijer & Anderson, *supra* note 1, at 187.

3. See Charles Pensabene, *A Canyon Full of Woes: The Havasupai Tribe Illustrates the Need for Cultural Competency in Genetic Research*, 7 *ALB. GOV'T. L. REV.* 637, 649-50 (2014).

4. See Joan L. McGregor, *Genome Justice: Genetics and Group Rights: Population Genomics and Research Ethics with Socially Identifiable Groups*, 35 *J. L., MED. & ETHICS* 356, 356-57 (2007); see also Deleso A. Alford, *HeLa Cells and Unjust Enrichment in the Human Body*, 21 *ANN. HEALTH L.* 223, 223-36 (2012) (discussing unjust enrichment and debated property rights in the body).

5. For the purposes of this paper, I will focus primarily on the difficulties faced by the Native American tribes of the United States, but I will use the term “indigenous” to include both Native Americans and international native populations.

peoples, and as a result, the field of bioethics has so far allowed their cases to slip through the cracks.⁶ In the United States, the history of oppression that has followed the Native American tribes has now been compounded with instances of misuse of tribal DNA donated for research.⁷ If researchers' goal is to continue genetic research in the pursuit of improved medical knowledge, the alienation of potential allies is a flawed approach.

This paper discusses bioethics as applied to indigenous communities and advocates for culturally competent informed consent procedures in genetic research. Section II will discuss the field of bioethics and the foundation for the current system. Section III will focus on relevant examples of failed informed consent with indigenous tribes. Section IV will address tribal sovereignty as the foundation for future paradigms of informed consent. Section V provides suggested methods for correcting the deficiencies in the current informed consent procedures by applying principles of tribal sovereignty.

II. Background

Bioethics, specifically informed consent, has its modern origins in the Belmont Report.⁸ The Nuremberg Code, stemming from principles stated in the Hippocratic Oath, was developed in response to the human experimentation performed under the Nazi regime in World War II.⁹ The Code provides fundamental rights to research subjects and requires voluntary consent from the subjects, as well as the subjects' ability to choose freely whether or not to participate in research.¹⁰ The Code also calls for details of potential risks and benefits, avoiding unnecessary pain

6. See McGregor, *supra* note 4, at 361; see also Weijer & Anderson, *supra* note 1, at 188.

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

8. See Pensabene, *supra* note 3, at 646.

9. See Adam H. Laughton, *Somewhere to Run, Somewhere to Hide?: International Regulation of Human Subject Experimentation*, 18 DUKE J. COMP. & INT'L. L. 181, 183-84 (2007).

10. See McGregor, *supra* note 4, at 360 ("The Code states subjects 'should have sufficient knowledge and comprehension of the elements of the subject matter involved so he can make an informed and enlightened decision.'"); see also Laughton, *supra* note 9, at 192 ("[T]he Common Rule requires that researchers secure the informed consent of the subject by providing subjects with a statements that the study involves research, the purpose(s) of the research, and the procedure(s) involved in the research.").

and suffering, qualified researchers, and the ability to withdraw from the project whenever the participant chooses.¹¹

The Belmont Report was released in 1979¹² after the Tuskegee study scandal. The Report was premised on researcher respect when designing a project concerning genetic research.¹³ The foundation of respect led to the formation of the “Common Rule.”¹⁴ The Common Rule demands informed consent from research participants through statements that specify that the study involves research, identifies the purpose of the research, and details any risks or benefits.¹⁵

The participants are also supposed to be provided with a statement of confidentiality, information about how any records are made during the course of the research, and information regarding means of identifying the participant.¹⁶ The researcher is obligated to inform the participants of any significant findings that may bear on the participants’ willingness to continue in the study.¹⁷ Despite these protections, the Common Rule was only designed to protect living human beings, not any genetic materials that have been separated from their hosts.¹⁸

A. *The Traditional Approach Under Moore*

The question of protecting genetic materials has now created much discussion. Debate arose in light of *Moore v. Regents of the University of California*¹⁹ as many states follow the rule of law established in that case, while the rest adopt the genetic research approach that supports the principles developed in both the Nuremberg Code and the Belmont Report.

While this debate continues, it is undeniable that the majority of states follow *Moore*. Although approaches to donor rights over their DNA are slowly changing, the traditional perspective in mainstream research

11. See McGregor, *supra* note 4, at 360.

12. See Laughton, *supra* note 9, at 187.

13. See Pensabene, *supra* note 3, at 646.

14. *Id.* at 646-47.

15. See Pensabene, *supra* note 3, at 647; see also 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 & BIOMEDICAL L. 175, 198 (2010) (discussing the collection framework for human biological materials).

16. See Pensabene, *supra* note 3, at 647.

17. *Id.*

18. See Drabiak-Syed, *supra* note 15, at 199.

19. *Moore v. Regents of the Univ. of Cal.*, 51 Cal. 3d 120 (Cal. 1990), *cert. denied*, 499 U.S. 936 (1991).

assumes that donors have no property rights over genetic materials given for research.²⁰ No rights signifies no compensation and no recognition.²¹ In fact, it is all too easy to ignore the DNA contribution altogether, leaving pharmaceutical companies and research firms to pocket the revenues, the respect, and the limelight.

In *Moore*, the plaintiff (John Moore) was diagnosed with hairy-cell leukemia and in the course of treatment had his spleen removed.²² Following his surgery, researchers used his diseased spleen to create and patent a cell line without his consent.²³ Outraged, Moore claimed he never gave permission for his tissues to be used in this fashion and believed that the researchers had deceived him in his treatment so they could gain financially.²⁴

The California Supreme Court, however, disagreed that Moore had a property interest in his tissues and held that recognizing such interests would stunt medical progress.²⁵ Consequently, *Moore* has become the dominant legal standard regarding ownership of genetic materials,²⁶ solidifying that intellectual property law supports the practice of denying donor ownership and patent rights.

It is also noteworthy that the court held that the researchers had not obtained informed consent and they should have disclosed their plans for financial gain through use of Moore's tissues.²⁷ Others have called for better communication, including informed consent agreements with donors, so that donors understand how their materials will be used and what their rights are at all stages.²⁸ Such a practice would be consistent with the mandates of the Nuremberg Code and the Belmont Report.²⁹

20. See Gary E. Marchant, *Property Rights and Benefit-Sharing for DNA Donors?*, 45 JURIMETRICS J. 153, 155 (2005).

21. See *id.*

22. *Moore*, 51 Cal. at 124-27; see also Marchant, *supra* note 20, at 156.

23. *Moore*, 51 Cal. at 124-27; see also Marchant, *supra* note 20, at 156.

24. *Moore v. Regents of the Univ. of Cal.*, 51 Cal. 3d 120 (Cal. 1990); see also Marchant, *supra* note 20, at 157.

25. *Moore*, 51 Cal. at 146-47; see also Marchant, *supra* note 20, at 157.

26. See Marchant, *supra* note 20, at 157.

Ernie is entitled to the value he put in into the land.chase price he had already p

27. *Moore*, 51 Cal. at 148; see also Marchant, *supra* note 20, at 157 ("The court did . . . hold in favor of Moore that he had plead a valid cause of action on his alternative claim that the researchers failed to obtain adequate informed consent . . . by not disclosing their potential financial interest in Moore's cells.").

28. See Marchant, *supra* note 20, at 163 ("Genetic researchers will hopefully . . . provide better communication and express agreements with DNA donors about how their

Informed consent is comprised of both individual self-determination and respect.³⁰ In terms of human research and participants, informed consent occurs “when it is given by a person who understands the purpose and nature of the study, what participation in the study requires the person to do and to risk, and what benefits are intended to result from the study.”³¹ This definition, however widely recognized, does not adequately address indigenous populations³² because it takes an individualistic approach, whereas many indigenous cultures operate on a community-based approach.³³

B. The Property Rights Approach

The traditional paradigm of genetic ownership is slowly changing and proponents of donor rights in a growing number of jurisdictions have made some headway in gaining recognition. The Human Genome Diversity Project, for example, acknowledges and supports a duty to share benefits with DNA donors.³⁴ The Human Genome Organization has also adopted a “Statement on Benefit-Sharing” which advocates for sharing benefits of research with the research participants.³⁵

Certain states, such as Colorado, Florida, Georgia, Alaska, and Louisiana, have enacted laws that define genetic information as personal property.³⁶ In those states, a plaintiff can file a conversion claim because their genetic material would be considered personal property, whereas John Moore was barred from a conversion claim because the Court ruled he had no ownership right in his genetic materials.³⁷

genetic material will be used in research, including any potential plans to claim intellectual property rights.”)

29. See discussion *supra* Part II.

30. See Constance MacIntosh, *Indigenous Self-Determination and Research on Human Genetic Material: A Consideration of the Relevance of Debates on Patents and Informed Consent, and the Political Demands on Researchers*, 13 HEALTH L.J. 213, 236 (2005).

31. *Id.* (quoting *1991 International Guidelines for Ethical Review of Epidemiological Studies*, COUNCIL FOR INT’L ORGS. OF MED. SCI., http://www.cioms.ch/publications/guidelines/1991_texts_of_guidelines.htm).

32. See MacIntosh, *supra* note 30, at 236.

33. See *id.*; see also Drabiak-Syed, *supra* note 15, at 209.

34. See Marchant, *supra* note 20, at 159.

35. See *id.*

36. See *id.* at 160-61; see also *Genetic Privacy Laws*, NAT’L CONF. OF ST. LEGISLATURES, <http://www.ncsl.org/research/health/genetic-privacy-laws.aspx> (last visited June 24, 2015).

37. See *Moore v. Regents of Univ. of Cal.*, 51 Cal. 3d 120, 136-37 (Cal. 1990).

The clash between the traditional individual approach and the property rights approach has always been about donor rights versus scientific progress, and the “blind promotion of scientific research.”³⁸ As mentioned above, genetic research has become incredibly important in the fight against certain diseases, but restrictions on scientific development are prevalent.³⁹ Budgets are limited, as is time, and it is understandable that further restrictions are a frustration to researchers.⁴⁰ Some researchers argue that diverting limited funds to compensate DNA donors would be yet another restriction.⁴¹

Unfortunate as delays may be, they are necessary because they conform to the Nuremberg Code and the Belmont Report by ensuring both participants’ fundamental rights and that voluntary consent stems from a thorough understanding of the research.⁴² DNA donors should be able to understand why researchers, companies, and educational institutions need their tissues and why it is going to grant those researchers and companies so much money. As researchers argue, it is true that donors will share the benefits of any discoveries made, but they also bear a significant risk for invasion of privacy and misuse of their DNA.⁴³

Proponents of a property rights approach note that if DNA were considered property, donors could pursue redress under the tort of conversion since a researcher’s use of the genetic material could be inconsistent with the owner’s property rights.⁴⁴ The threat of a tort would provide an incentive for a more collaborative approach with donors, and in the case of indigenous populations, would provide some protection for their cultural beliefs and practices.⁴⁵ One scholar, however, believes that a more effective means of achieving that goal is through a culturally competent informed consent process.⁴⁶ The informed consent process, he states, allows for contractual remedies that would protect the donor’s interests.⁴⁷

38. Drabiak-Syed, *supra* note 15, at 210; *see also* Marchant, *supra* note 20, at 166.

39. *See* Marchant, *supra* note 20, at 166.

40. *See id.*

41. *See id.*

42. *See* discussion *supra* Part II.

43. *See* Marchant, *supra* note 20, at 166; *see also* Pensabene, *supra* note 3, at 642 (“Providing human subjects with adequate protections is crucial because genetic material contains the most personal data regarding an individual’s physical identity.”); Drabiak-Syed, *supra* note 15, at 216.

44. *See* Pensabene, *supra* note 3, at 642-44.

45. *See id.*

46. *See id.*

47. *See id.* at 647.

III. Informed Consent Among Indigenous Populations

When it comes to many indigenous populations, the problem with the individual approach is that it emphasizes a split of the biological material from the person as soon as it is removed and therefore gives the person no rights in the now separate material.⁴⁸ That separation often affects indigenous populations' rights over something that they still consider to be part of themselves, even if it is no longer technically part of their body.⁴⁹ In the end, then, this separation is a form of alienation of both the self and the community because it takes a part of their very essence away from them with no regard for how such an action can impact their sense of personal and communal completeness.⁵⁰ Perhaps a better definition of informed consent is one recognizing that cultural sensitivity is an important piece of the cultural competency aspect of informed consent.

Fergus MacKay, Senior Counsel for the Legal and Human Rights Programme at the Forest Peoples' Programme, suggests defining "informed consent" as "the consensus/consent of indigenous people determined in accordance with their customary laws and practices."⁵¹

MacKay's definition might help address misuse of indigenous genetic materials, a problem that is neither insignificant nor localized. Misuse has happened throughout the world, particularly in the area of patents that includes the mapping of populations' genomes around the world.⁵² Native American tribes have also been affected domestically, which culminated in the widely debated *Havasupai* decision.⁵³ This decision illustrates the lack of informed consent applied to indigenous research participants and the cultural misunderstandings behind it.

A. Pre-Havasupai Cases

In 1958, the federal government devoted significant energy to the field of genetics in its effort to advance atomic research during the Cold War, and considered Native Americans ideal research subjects.⁵⁴ "Project

48. See Drabiak-Syed, *supra* note 15, at 221.

49. See *id.* at 221-22.

50. See *id.* at 224.

51. Fergus MacKay, *Indigenous Peoples' Right to Free, Prior and Informed Consent and the World Bank's Extractive Industries Review*, 4 SUSTAINABLE DEV. L. & POL'Y 43, 49 (2004) (discussing the meaning of free, prior informed consent).

52. See Jacobs et al., *supra* note 1, at 684.

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

54. See Ron J. Whitener, *Research in Native American Communities in the Genetics Age: Can the Federal Data Sharing Statute of General Applicability and Tribal Control of*

Chariot” was designed to create a seaport near the Inupiat town of Point Hope, Alaska.⁵⁵ The United States government engaged in environmental experiments with radiation by releasing radioactive substances near the town.⁵⁶ The purpose was to see how the indigenous population reacted to the radiation; specifically, to see if they had genetically higher metabolisms that would help them in adverse weather conditions.⁵⁷ The Inupiat, however, were not told about the study, did not give consent, and did not find out about the research until 1992.⁵⁸

The case of the Nuu-Chah-Nulth of British Columbia is also worth noting. There, indigenous participants gave blood samples to a researcher so that he could study rheumatoid arthritis.⁵⁹ The researcher moved to the University of Utah and then to Oxford University, taking the blood samples with him.⁶⁰ He then used the blood samples for his own purposes and loaned them out to other researchers—none of which was addressed in the informed consent agreements that the indigenous participants signed.⁶¹ “When the Nuu-Chah-Nulth discovered” what had happened, “they demanded” the return of their samples, but the tribe did not look favorably on genetic research again.⁶² Canada later revised its policy concerning informed consent for future uses of data samples.⁶³

A similar situation occurred in Papua New Guinea, where a cell line from a Hagahai man was patented in the United States.⁶⁴ The Hagahai were in the middle of a malaria outbreak and sought medical assistance from an anthropologist, who collected extensive data including blood samples.⁶⁵ The blood samples showed that the Hagahai carried a benign T-cell leukemia lymphoma virus.⁶⁶ The U.S. Patent and Trademark Office issued the patent to the American government three years later.⁶⁷ In response to

Research Be Reconciled?, 15 J. TECH. L. & POL’Y 217, 229 (2010) (noting research abuses among Native American and Alaskan Native communities).

55. *See id.*

56. *See id.* at 229-30.

57. *See id.*

58. *See id.*

59. *See id.* at 234-35.

60. *See id.* at 235.

61. *See id.*

62. *Id.*

63. *See id.*

64. *See MacIntosh, supra* note 30, at 227.

65. *See id.*

66. *See id.*

67. *See id.* at 228.

the public outcry that followed, the National Health Institute claimed that the patent had met all the requirements and that the Hagahai did not own their donated materials.⁶⁸

There was a similar case in Panama, where the National Health Institute filed a patent application for a T-cell line developed from a Guaymi woman.⁶⁹ U.S. officials claimed that the woman had given her consent to the taking of her DNA.⁷⁰ However, the question is not whether she gave consent, but whether she gave *informed* consent, because consent without a full understanding and disclosure of what she consented to in that research is not truly informed consent. The international condemnation led to the withdrawal of the patent application.⁷¹ Nevertheless, the DNA was not returned to its people.⁷²

The Guaymi woman's case, and many others, establish that there is a significant history of misuse when it comes to indigenous populations' genetic materials. Most of these cases appear to have gone relatively unnoticed, as did the misuse, until the Havasupai brought it to public attention.

B. The Havasupai Decision

A leading complaint in the lack of indigenous populations' informed consent is the issue of stigma.⁷³ Genetic research places tribal DNA under close scrutiny, and anything found has the power to reflect on tribal populations themselves.⁷⁴ This stigma is highly pertinent for Native American tribes when considered in the context of their long history of discrimination.⁷⁵ Native Americans may not view blood the same way as our research or patent systems do. Many consider blood to be "a sacred link to the tribe's ancestors that retains its sacred status well after removal from the body."⁷⁶

68. *See id.*

69. *See* Nancy Kremers, *Speaking with a Forked Tongue in the Global Debate on Traditional Knowledge and Genetic Resources: Are U.S. Intellectual Property Law and Policy Really Aimed at Meaningful Protection for Native American Cultures?*, 15 *FORDHAM INTEL. PROP. MEDIA & ENT. L.J.* 1, 32 (2004) (discussing patent dilemmas in indigenous populations' genetic materials).

70. *See id.*

71. *See id.* at 32-33.

72. *See id.* at 33.

73. *See* Pensabene, *supra* note 3, at 650.

74. *See id.*

75. *See id.*

76. *Id.* at 653.

In effect, blood and DNA contain the very essence of the tribe.⁷⁷ Mishandling and misusing it is a disruption to more than just one person—it is a disruption to the entire community and its spiritual well-being.⁷⁸

*Havasupai Tribe v. Arizona Board of Regents*⁷⁹ is the best illustration of the disruption misuse can have. *The case* probably demonstrates the most famous example of failed informed consent within an indigenous population. There, the Havasupai tribe gave blood samples voluntarily to Arizona State University (ASU), but specified that the samples were only to be used for research on diabetes.⁸⁰ They later discovered that ASU researchers also used the samples in studies on “schizophrenia, inbreeding, and theories about ancient-human population migrations”⁸¹ This last area of study is particularly offensive to the Havasupai because they believe that their people came from the Grand Canyon.⁸² The Havasupai claimed that the University had broken its vow of confidentiality and had given their private genetic information to third parties, including more than one doctoral candidate for their dissertations.⁸³

Havasupai warrants further investigation of the informed consent process involved. The Tribal Council received a letter from the lead researcher that described the project as relating to diabetes and that purpose was emphasized in person as well.⁸⁴ When the researchers began to take blood samples, they again explained that the purpose of the project was to study diabetes.⁸⁵ They also provided consent forms to the participants, and the participants all indicated that they understood, but what they signed identified the purpose of the research as “to study the causes of behavioral/medical disorders.”⁸⁶ Behavioral disorders were not mentioned orally, but those forms initiated the unauthorized use of the samples for purposes other than diabetes.⁸⁷ Furthermore, the Havasupai must have believed that the samples would be returned to them because, given their beliefs about genetic material and its connection to themselves, they would

77. See Drabiak-Syed, *supra* note 15, at 213.

78. See *id.* at 214.

79. 204 P.3d 1063 (Ariz. Ct. App. 2008).

80. See *Havasupai v. Ariz. Bd. of Regents*, 204 P.3d 1063, 1066 (Ariz. Ct. App. 2008).

81. See *id.* at 1067.

82. See *id.*

83. See *id.* at 1067-68.

84. See Drabiak-Syed, *supra* note 15, at 180.

85. See *id.*

86. *Id.* (quoting STEPHEN HART, INVESTIGATIVE REPORT CONCERNING THE MEDICAL GENETICS PROJECT AT HAVASUPAI, app. A at 23 (2003)).

87. See Drabiak-Syed, *supra* note 15, at 181.

not have agreed to part with it otherwise. Yet no evidence supports that the topic of their return was raised—probably because neither party thought it was necessary. The misunderstanding on that one topic alone further affirms the need for culturally competent informed consent.

When the project was handed over to another researcher, he did not know that written consent was needed and followed only an oral consent process.⁸⁸ There, too, he identified the purpose as a study focusing only on diabetes.⁸⁹ Other discrepancies in the research process have come to light as well. As it happened, another researcher who was interested in schizophrenia began to study the blood samples for that purpose, and began collecting samples from the tribe a full summer before the Institutional Review Board (IRB) approved a project on schizophrenia.⁹⁰

A key piece of informed consent is that it is obtained in advance of official authorization.⁹¹ This timeframe assures that the process also provides indigenous participants enough time to consider the relevant information and request more if needed.⁹² Sometimes it will be necessary to negotiate an agreement that is acceptable to both researchers and participants, and give the indigenous population the right to participate as they choose and obtain any information or advice that they require.⁹³ That process was bypassed here. Furthermore, the information was supposed to be private, and the participants were assured that it would be—yet the researcher provided open access to the samples to ASU and non-affiliated researchers who were studying a myriad of topics.⁹⁴

In analyzing the district court's decision against the plaintiff tribe, Professor Katherine Drabiak-Syed claims that the court entirely failed to consider what blood and genetic research mean to the Havasupai tribe.⁹⁵ She noted that while the tribal participants signed the consent as the court concluded, the researcher defendants used fraudulent statements to get the samples.⁹⁶

88. *See id.*

89. *See id.*

90. *See id.* at 181-82.

91. *See MacKay, supra* note 51, at 56.

92. *See id.*

93. *See id.* at 57.

94. Drabiak-Syed, *supra* note 15, at 183.

95. *Id.* at 186.

96. *Id.* at 188.

The court did place a significant amount of weight on that consent, but the question is whether it was *informed* consent.⁹⁷ The researchers did not communicate to the participants the full extent of what would be done with their samples, and so the participants did not have the information they needed to give consent.⁹⁸ They would likely not have consented to the complete disregard of tribal privacy rights that came from sharing the samples with third parties.

The parties eventually reached a settlement agreement, which included damages and the return of the blood samples and all related documents.⁹⁹ The University enacted some changes to its IRB samples as well, including consideration of ongoing research that uses blood samples, and they now provide a list to the tribe of anyone who received their samples.¹⁰⁰

C. Cultural Misunderstandings

It is telling to examine the researchers' reactions to the *Havasupai* controversy. In interviews with one of the researchers, the tribe was described as "hysterical" in the face of "doing good science."¹⁰¹ Recognition for indigenous beliefs is conspicuously absent in those comments—as is respect. Many indigenous populations simply do not hold their blood and genetic information as items of scientific value, but rather as part of themselves and their people.¹⁰² The *Havasupai* case and medical researchers' initial reaction to it have brought to light the need for a revised framework.

Secondary research—when biological materials are used subsequent to the primary research—is a particular problem in current informed consent procedures.¹⁰³ IRBs do not assess harm if the information collected is private and provides no opportunity to match the data to its donor.¹⁰⁴ If the samples are completely anonymized the secondary research on them does

97. *See id.* at 190.

98. *Id.* at 191.

99. *Id.* at 195.

100. *See id.*

101. *Id.* at 196 (quoting Howard Fischer, *Havasupai Blood Lawsuit Reinstated*, ARIZ. DAILY SUN (Nov. 28, 2008), http://azdailysun.com/news/havasupai-blood-lawsuit-reinstated/article_2921c286-4454-57eb-926b-11e795134f8f.html; David Osborne, *Blood Feud in the Grand Canyon*, INDEPENDENT (London) (Apr. 22, 2010), <http://www.independent.co.uk/news/world/americas/blood-feud-in-the-grand-canyon-1951972.html>).

102. Drabiak-Syed, *supra* note 15, at 196.

103. *Id.* at 199.

104. *Id.* at 200.

not violate current human genetic research standards, which occurred with the Havasupai.¹⁰⁵

The data is at risk of being identifiable because researchers can make sweeping generalizations about a population based on those samples that affect an entire tribe.¹⁰⁶ For example, the researcher in *Havasupai* claimed that the samples were anonymized, but she did label them all with the prefix “HAV”—which effectively identified the Havasupai tribe.¹⁰⁷ Even when identifiers are removed, participants can still feel stigmatization and spiritual harm because their genetic material can still be used to attribute characteristics or genetic history to their the tribe as a whole, even without a personal identifier, and that affects more than just the individual participant.¹⁰⁸

There is also an inherent problem when a participant is denied the right to discontinue participation in research. When the Havasupai realized their DNA was being misused, they sought to withdraw from the study and were denied that right.¹⁰⁹

Such a denial can have lasting effects to the tribal culture. Cultural harm is such a significant lasting effect, and to indigenous populations, the risks of harm include any practice that “disparage[s] their spiritual traditions, historical narratives, or traditional beliefs.”¹¹⁰ It is possible that researchers and IRBs omitted a concern for cultural harm because it is not a harm they themselves would conceptualize as real.¹¹¹

For example, researchers from a university might not hold a community-centered view of property as do many indigenous populations. Indigenous views of property may not be individual-centered, as American law favors.¹¹² Moreover, indigenous property systems may contain specific

105. *Id.*

106. *See id.* at 202.

107. *Id.* at 203.

108. *See id.* at 207; *see also* Richard R. Sharp & Morris W. Foster, *An Analysis of Research Guidelines on the Collection and Use of Human Biological Materials from American Indian and Alaskan Native Communities*, 42 JURIMETRICS J. 165, 167 (2002) (discussing the pros and cons of research for social groups).

105a. *See* Drabiak-Syed, *supra* note 15, at 207.

109. *Id.* at 206.

110. McGregor, *supra* note 4, at 363.

111. *See id.*

112. *See* Rebecca Tsosie, *Cultural Challenges to Biotechnology: Native American Genetic Resources and the Concept of Cultural Harm*, 35 J. L., MED. & ETHICS 396, 397-98 (2007); *see also* Debra Harry & Le’a Malia Kanehe, *Asserting Tribal Sovereignty over Cultural Property: Moving Towards Protection of Genetic Material and Indigenous*

perspectives about resources that have a sacred spirituality.¹¹³ Indigenous populations often have a different view of the relationship between human beings and the environment, which differs from the Western system of property that asserts individual rights and actions against other individuals.¹¹⁴

Indigenous populations also tend to have a communal approach of family and social ties in their property frameworks.¹¹⁵ Cultural harm is considered a direct attack on cultural survival.¹¹⁶ That harm is impermissible because “Native peoples have political and cultural rights in association with their distinctive status and relationship with their traditional lands.”¹¹⁷ It goes without saying that indigenous peoples also have the right to preserve that relationship from harm.¹¹⁸

Indigenous populations frequently consider themselves shepherds of the land and responsible for various spiritual duties.¹¹⁹ Their duties include responsibilities to their “cultural property,” which has been defined as “‘everything that belongs to the distinct identity of a people,’ which ‘includes inheritances from the past and from nature, such as human remains, the natural features of the landscape, and naturally-occurring species of plants and animals with which a people has long been connected.’”¹²⁰

Harming that knowledge or way of life has lasting consequences on their cultural survival; cultural harm and concepts of “sacred,” however, have not been considered a viable basis for damages in American courts.¹²¹ Indeed, intellectual property paradigms are traditionally lacking in any consideration of cultural harm,¹²² and indigenous cultural property is not

Knowledge, 5 SEATTLE J. FOR SOC. JUST. 27, 32 (2006) (addressing indigenous populations’ view of property ownership).

113. See Tsosie, *supra* note 112, at 398.

114. See *id.*

115. See *id.*

116. *Id.* at 402.

117. *Id.* at 403.

118. *Id.*

119. See *id.* at 404.

120. Harry & Kanehe, *supra* note 112, at 31.

121. See Tsosie, *supra* note 112, at 404; see also Mary Daniel, *Tribal DNA: Does It Exist, and Can It Be Protected?*, 30 OKLA. CITY U. L. REV. 431, 459-60 (2005) (discussing the difficulty of using the patent system to protect tribal DNA).

122. See Tsosie, *supra* note 112, at 405.

safe from misappropriation.¹²³ For these reasons, indigenous peoples are often distrustful of biomedical research.¹²⁴

This distrust was more than apparent in the Havasupai tribe. Havasupai teachings say that all genetic and biological materials must be intact in order for a tribal member to cross into the next world.¹²⁵ Imagine how it affected the tribe when five Havasupais died from diabetes while the case was being argued;¹²⁶ the tribe believed that those people could not cross into the next world unless their blood samples were returned.¹²⁷ That belief was not likely one that a non-Havasupai researcher considered, which explains why the university researchers did not address it in their informed consent procedure. *Havasupai* as well as the other aforementioned cases demonstrate a fundamental misunderstanding of both culturally competent informed consent and many indigenous belief systems.

IV. Tribal Sovereignty in the Context of Informed Consent

The above concerns arise primarily because researchers do not take into account the doctrine of tribal sovereignty. There are 566 federally recognized tribes in the United States.¹²⁸ The status of these tribes was determined in three seminal cases: *Johnson v. Macintosh*, *Cherokee Nation v. Georgia*, and *Worcester v. Georgia*.¹²⁹ In these cases, Chief Justice Marshall established that tribes are separate, but dependent, nations, limited only in their ability to convey land and transact with foreign governments.¹³⁰ The state that hosts a tribal nation is not permitted to interfere with tribal affairs in any other respect.¹³¹ In *Cherokee Nation v. Georgia*, Justice Marshall relegated the tribes to “domestic dependent nations”, but he also granted them some recognition as “states”.¹³²

123. See Harry & Kanehe, *supra* note 112, at 27.

124. Tsosie, *supra* note 112, at 405. See generally *Havasupai Tribe v. Ariz. Bd. of Regents*, 204 P.3d 1063 (Ariz. Ct. App. 2008) (researchers’ use of tribal blood samples did not match the uses authorized by donors in the university’s informed consent process).

125. Drabiak-Syed, *supra* note 15, at 214.

126. See *id.*

127. See *id.*

128. *Federal and State Recognized Tribes*, NAT’L CONF. OF ST. LEGISLATURES, <http://www.ncsl.org/research/state-tribal-institute/list-of-federal-and-state-recognized-tribes.aspx> (last visited Aug. 17, 2016).

129. See WILLIAM C. CANBY JR., *AMERICAN INDIAN LAW IN A NUTSHELL* 73-75 (6th ed. 2014).

130. See *id.* at 75.

131. See *id.*

132. *Cherokee Nation v. Georgia*, 30 U.S. (5 Pet.) 1, 16 (1831).

Even that recognition, however, soon began to fail. An additional limitation on tribal sovereignty presented itself in *Oliphant v. Suquamish Indian Tribe*, where the Supreme Court held that tribes have no criminal jurisdiction over non-Indians, basing its decision entirely on the domestic dependent status of the tribes.¹³³ This case marked the beginning of the end for any recognition as a state previously held by the tribes. The line of judicial opinions following includes *Montana v. United States*, in which the Court held that tribes do not have the power to regulate fish and wildlife on their own reservations and which limited tribal jurisdiction to “internal relations”.¹³⁴ In the end, the tribes have sovereignty at the discretion of Congress, and the veneer of tribal sovereignty is quite thin in American jurisprudence.¹³⁵

The veneer may be thin, but it exists nonetheless. Federal Indian policy promotes government-to-government cooperation between tribal and federal governments.¹³⁶ Any undertakings that could potentially affect tribal rights or resources should be subjected to standards of tribal sovereignty and respect.¹³⁷ Generally, the federal government and its departments are expected to consult tribal authorities before taking any action that could affect the tribes, assess the impact of any proposed programs or activities, and present viable solutions to address the needs of the tribes.¹³⁸ Federal agencies are also asked to encourage the tribes to design and implement their own policies in order to maintain tribal authority and objectives.¹³⁹

The question that has not been sufficiently addressed by either tribal or American courts, in any framework, concerns tribal sovereignty over intangible rights, like intellectual property rights in biotechnology. The federal government’s policy, however, is consistent with accommodating indigenous beliefs and needs in modern research paradigms. Many scholars, including Professor Rebecca Tsosie and Professor Katherine Drabiak-Syed,

133. See 435 U.S. 191, 211 (1978).

134. 450 U.S. 544, 564 (1981).

135. See CANBY, *supra* note 129, at 88-89; see also *White v. Univ. of Cal.*, 765 F.3d 1010 (9th Cir. 2014) (discussing ownership of ancient remains under the Native American Graves Protection and Repatriation Act).

136. See Colleen M. Diener, *Natural Resources Management and Species Protection in Indian Country: Alternatives to Imposing Federal and State Enforcement upon Tribal Governments and Native Americans*, 41 IDAHO L. REV. 211, 216 (2004) (reviewing the federal-tribal relationship).

137. See *id.* at 217 (citing *Government-to-Government Relations with Native American Tribal Governments*, 59 Fed. Reg. 22,951 (Apr. 29, 1994)).

138. See *id.*

139. See *id.* at 217-18.

have discussed the disparity. Even though established principles of tribal sovereignty specifically recognize independent tribal decision-making and mandate consultation with the tribes for anything that might affect them—such as their participation in biomedical research—culturally competent informed consent remains unaddressed.

V. Obtaining Culturally Competent Informed Consent

Indeed, it would be difficult for anyone to argue that participation in biomedical research and obtaining genetic information from an indigenous population do not affect that population and/or that donor. Therefore, it is difficult to deny the importance of informed consent since it protects indigenous interests while minimizing harm.¹⁴⁰ Moreover, it provides indigenous participants with a means of protecting their ability to realize the benefits of the research project impacting them.¹⁴¹

Unfortunately, obtaining informed consent in the first place can be difficult because some risks cannot be accurately foreseen or described even if they are known.¹⁴² It is more difficult to predict intangible harms that are particularly relevant to indigenous populations, such as dignitary harms and cultural harms.¹⁴³ Several scholars have provided recommendations that present sound opportunities for increasing cultural awareness of informed consent with indigenous populations. The following recommendations represent a basic synthesized framework of the most plausible and effective recommendations from scholars such as Professors Joan McGregor, Morris Foster, Bette Jacobs, Ron Whitener, and Debra Harry, as well as from biomedical ethicist Richard Sharp and attorney Le'a Malia Kanehe. What follows is the author's interpretation of an effective methodology for a culturally competent informed consent processes.

(1) *Community Participation and Control.* Progress requires cooperation, and the best way to ensure community cooperation is to make them an active part of the research.¹⁴⁴ Community representatives, for example, are much better suited to identify potential harms than an outsider to the community would be.¹⁴⁵ This is a measure that takes cultural differences

140. See MacKay, *supra* note 51, at 50.

141. See *id.*

142. See Sharp & Foster, *supra* note 108, at 171.

143. See *id.*

144. See McGregor, *supra* note 4, at 366.

145. See Sharp & Foster, *supra* note 108, at 174.

into account and conveys respect for those differences by allowing indigenous perspectives to be heard.¹⁴⁶

Community participation will also make informed consent a more holistically *informed* process. For instance, secondary research should be addressed with the indigenous community members. If the research is sought for renewal or a secondary purpose, indigenous consultation is important.¹⁴⁷ Part of the informed consent process should also deal with mechanisms for reporting findings to participants.¹⁴⁸ Certainly, participants deserve to be kept up to date on the research that they are hoping will benefit them. And certainly, the participants should be able to view the findings and discuss possible dissemination to the public *before* the results are actually disseminated to the public.¹⁴⁹

Community participation and consent has the benefit of protecting indigenous cultures and helping to ensure their survival.¹⁵⁰ It also has the benefit of giving researchers a sure path to successful projects—after all, indigenous populations know themselves and their communities better than anyone else ever will, and their help and knowledge are vital to making progress.¹⁵¹

(2) *Indigenous Institutional Review Boards and Research Codes.* Indigenous control and understanding of their resources is what makes having their own IRBs important. Professor Ron Whitener argues that indigenous peoples should create their own research systems and include indigenous participation in them.¹⁵² He notes that indigenous research codes should assert a property right over the data collected, and therefore a right to regulate how it is used.¹⁵³ Researchers seeking to work with indigenous populations should also sign documents indicating that they understand the data belongs to the participant community.¹⁵⁴

Currently, the U.S. Indian Health Service has its own IRBs for any research that one of its facilities plans to undertake, but they also extend

146. *See id.* at 175.

147. *See id.* at 176.

148. *See id.* at 180.

149. *See id.*

150. Jacobs et al., *supra* note 1, at 689 (citing *CIHR Guidelines for Health Research Involving Aboriginal People*, CANADIAN INSTS. OF HEALTH RESEARCH, <http://www.cihr-irsc.gc.ca/e/29134.html> (last modified June 27, 2013)).

151. *See id.*

152. *See* Whitener, *supra* note 54, at 271.

153. *Id.* at 272.

154. *Id.*

their research services, including IRBS, to Native American tribes.¹⁵⁵ The Indian Health Service may be better equipped to understand indigenous research concerns than many other government organizations, but they are still not as close to the community issues as the community members themselves.

In 1996, the Navajo Nation set up its own IRB, called the Navajo Nation Human Research Review Board (NNHRRB).¹⁵⁶ The Board implemented a twelve-step process that investigators must undergo, including community participation, review of data before publication, disclosure of results to the tribe, and granting of data possession to the tribe.¹⁵⁷ The Navajo have also specified that they intend to retain jurisdiction over their own intellectual property and any researchers within their borders.¹⁵⁸ No researcher is permitted to begin working unless s/he has acknowledged that fact.¹⁵⁹

The Cherokee Nation has also established an IRB, and other tribes have taken similar measures.¹⁶⁰ Some tribes have also tried to regulate genetic research on their own lands.¹⁶¹ For example, the Hopi have a Cultural Preservation Office, and the Confederated Salish and Kootenai Tribes enacted a Cultural Resource Protection Ordinance in 1995.¹⁶²

Community participation should include training indigenous peoples in genetic research, not only to help with the research, but also to ensure that they fully understand the science and why it is being performed in their community.¹⁶³ This training will increase the effectiveness of all informed consent measures and will foster a two-way street of communication between science and culture.¹⁶⁴ In effect, indigenous researchers should make sure that the research will benefit the indigenous community and should explain to the community what the science and the data will mean for them.¹⁶⁵

Of course, non-native scientists must participate in the two-way street as well, and that requires some training on working with indigenous

155. See Jacobs et al., *supra* note 1, at 690.

156. See *id.*

157. See *id.*

158. See Harry & Kanehe, *supra* note 112, at 45.

159. See *id.*

160. See *id.*

161. See *id.*

162. See *id.* at 52-53.

163. See Jacobs et al., *supra* note 1, at 690.

164. See *id.* at 692; see also McGregor, *supra* note 4, at 366 (discussing conducting research in a way that “avoid[s] harms to the group” that is being researched).

165. See Jacobs et al., *supra* note 1, at 693.

participants. Professor Bette Jacobs and her colleagues suggest five critical areas that should be conveyed to researchers working with indigenous participants: (1) accountability to the indigenous population, (2) allowing the indigenous population to have control, (3) recognizing that the indigenous population has an interest in the data and the genetic materials used in the research, (4) encouraging indigenous community members to participate as researchers themselves, and (5) remembering that this is going to be a long-term cross-cultural relationship with people who have the same right to self-determination as does anyone else.¹⁶⁶

(3) *Data Repositories*. Professor Whitener suggests that creating an indigenous data repository will vest control over research samples in indigenous peoples.¹⁶⁷ Such a repository will require that any data collected would remain housed with the population who donated it, which will also effectively restrict access to it.¹⁶⁸ Through such a repository, anyone who wanted to gain access to the data contained within will have to go directly to the indigenous community who hosts it for permission.

(4) *Compliance*. Researchers need to understand what compliance with indigenous research codes and other requirements entails, and they need to understand the consequences of a violation. Including a statement of compliance in any research agreement may also provide contractual remedies if deliberately structured to do so. A similar statement should be included in any published works that are based on the research.¹⁶⁹ That statement will provide editors and the entire peer review process with a standard for enforcement and will protect both research participants and their communities.¹⁷⁰

In conclusion, these four recommendations are a summation of the most workable recommendations from scholars in this area of research. In one combined system, they provide a strong foundation for supplying indigenous research participants with more control over their own genetic materials. Additionally, they provide the beginnings of a new relationship between researchers and indigenous research participants, one that will put them on equal ground and mandate respectful treatment in all informed consent agreements.

166. *See id.*

167. *See* Whitener, *supra* note 54, at 273.

168. *See id.*

169. *See* Weijer & Anderson, *supra* note 1, at 197.

170. *See id.* at 197-98.

VI. Conclusion

As genetic research gains importance and momentum, the role of indigenous populations in that research will also rise. Until now, it has been easy to operate in our traditional framework of research and informed consent, and our case law has supported it.¹⁷¹ This framework, however, has been proven time and time again to be incompatible with many indigenous peoples' belief systems.¹⁷² The Havasupai's case illustrates the failure of mainstream informed consent when applied to an indigenous research population, and the general lack of case law indicates all too clearly that recognition of the disparity in American jurisprudence is slow.

Havasupai also demonstrates the decline of recognition for Native American tribal sovereignty and tribal rights. This is a state of affairs that not only undermines a key principle of our jurisprudence regarding tribal relations, but simultaneously defeats the purpose of bioethics and collapses potentially beneficial research relationships—which, in the end, nullifies any progress that could be made in genetic research involving these indigenous populations.

The most effective way of redressing the problem is to invest indigenous research populations with more control over their own genetic materials through means such as indigenous research liaisons and indigenous research codes. To do that, principles of tribal sovereignty must first be renewed, followed, and respected. Genetic research has proven benefits, but it will not progress with indigenous research participants if those participants—and their way of life—are not treated with respect.

171. See, e.g., *Moore v. Regents of Univ. of Cal.*, 51 Cal. 3d 120 (Cal. 1990).

172. See discussion *supra* Part III.