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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

Katherine Drabiak-Syed*

In March 2010, members of the Havasupai tribe and Arizona State University Board of Regents ("ASU") entered into a settlement agreement, signaling the end of a lengthy legal battle over the research use of blood samples. Approximately twenty years ago, researchers at ASU began collecting blood from members of the tribe to conduct what the tribe thought would be diabetes research projects. Years later, however, the tribe discovered that a researcher at ASU shared their blood with other researchers and conducted research on schizophrenia, inbreeding, and human population migration theories. Upon discovering how researchers at ASU had been using their blood, tribe members asserted that consent to such research would not have been acquired had they been adequately informed, and they demanded that ASU withdraw them from the study and return their blood samples. When ASU refused, members of the tribe filed two separate lawsuits against the University, alleging that ASU's actions resulted in cultural, dignitary, and group harm to the participants. The progression of events during the course of research and subsequent litigation demonstrates how the current legal and ethical framework governing the collection of biological materials for research fails to account for assessments of risk and harm that are specific and unique to identifiable population groups and Native American tribes. For these specific populations, blood

* Katherine Drabiak-Syed, JD. Visiting Assistant Research Professor and Faculty Investigator Indiana University Center for Bioethics, 410 West 10th Street, Indianapolis, Indiana, 46202. Phone: (317) 278-4041. Email: kdrabiak@iupui.edu. Acknowledgments: Drabiak-Syed is a Visiting Assistant Research Professor and Faculty Investigator at the Indiana University Center for Bioethics. This publication was supported by a grant from the Richard M. Fairbanks Foundation to the IU Center for Bioethics, and by NIH/NCRR Grant Number RR025761. Its contents are solely the responsibility of the author and do not necessarily represent the official views of the NIH.

holds immense cultural and spiritual value. Research that fails to account for its worth and ignores its cultural significance results in harms presently unrecognized in the American legal framework. This article will describe how the meaning of blood to the Havasupai and other Native American tribes is integral to their sense of identity and cultural cohesion, and accordingly, why misuse of blood causes such significant harmful consequences to the individual subject and to the tribal groups to which they belong. Understanding genetic research, both its harms and benefits, from the perspective of tribal group members themselves is critical because the combination of health disparities among Native American tribes and the genetic homozygosity among members of the same tribe make it likely that researchers will continue to approach Native American tribal members as potential research subjects.[1] The inherent conflict over the value and meaning of blood to researchers and tribal members—scientific to the former and spiritual to the latter—calls for a new understanding of how to assess the benefits and the harms of research while using biological materials unique to Native American tribes to ensure their values are not diminished or overlooked in the research process.

This article will first describe ASU's research efforts in Supai Village, the process of blood sample collection, the scope of the Havasupai tribe's consent, and the problems with the project's overall research design. Next, the article will provide an overview of the litigation and settlement agreement relating to ASU's alleged research misconduct and more specifically, the University's improper use of blood samples in violation of the Havasupai tribe's consent. This paper suggests that ASU, as well as other researchers and institutions, may still fail to recognize how research involving Native American tribal blood samples can harm individual participants and the tribes

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[1] *See generally* Leslie Wolf, *Biology and Genetics: Advancing Research on Stored Biological Materials: Reconciling Law, Ethics & Practice*, 11 MINN. J.L. SCI. & TECH. 99 (2010) (describing disparity between regulatory requirements, research practices, and the preferences of research participant). Wolf discusses the federal regulatory framework adopted by sixteen different agencies involved in human subjects research as a floor which federally-funded universities and other research institutions are required to adopt. *Id.* at 145. Known as the Common Rule, this framework sets the standards that Institutional Review Boards ("IRB") must follow. *Id* at 128-33. Although Wolf notes that IRBs can and do set higher standards for research than required by the Common Rule, a disparity remains between protocols used and the ethical preferences of participants. *Id.* at 145-47. Where minority or vulnerable populations are concerned, this disparity is even more pronounced. *Id.* at 143-145. *See also* Arizona State University, Office of Research Integrity and Assurance, http://researchintegrity.asu.edu/humans (last visited Nov. 19, 2010). ASU policy dictates that all research involving human subjects must be approved by the Institutional Review Board. *Id.* The IRB, comprised of faculty (from both scientific and nonscientific disciplines) and community members, ensures that all subjects are treated ethically and that their rights and welfare are protected. *Id.*

themselves because of the spiritual and cultural significance of these materials. The article will conclude with recommendations as to how procedures and protocol can adhere to standards that protect the rights and welfare of its Native American participants, as well as how the current federal law governing human subjects research falls short based on its underlying value judgments related to risk, harm, and the significance of the biological material.

I. Arizona State University's Research in Supai Village

A. Disparate Rates of Diabetes Among the Havasupai

The interplay between genetic, socioeconomic, and environmental causes of health disparities among Native American tribes is an area of research that has been of growing importance over the past decade.[2] Researchers interested in examining the genetic components of disease assert that genetic research can lead to significant health benefits by identifying markers for disease risk and developing more effective treatment options for chronic conditions that disparately affect Native American populations.[3] Despite proponents for genetic research agendas, some scholars assert that dispossession from land, environmental contamination, oppression, and a lack of access to healthcare have combined to produce chronic health conditions among members of Native American tribes.[4] This ongoing debate is of particular importance to the Havasupai, who have the fourth highest prevalence of diabetes among any group in the world; in fact, diabetes affects forty-five percent of the men and fifty percent of the women in the tribe.[5] Most recently, researchers have explained the prevalence of diabetes among the Havasupai by the Thrifty Phenotype Theory, which suggests that the development of diabetes is less related to genetic predisposition than to interaction between biology and the environment.[6] More specifically, the Thrifty Phenotype Theory

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[2] *See generally* Pamela Sankar et al., *Genetic Research and Health Disparities*, 291 JAMA, June 2004 at 2984 (discussing genetic research and health disparities campaign).

[3] *See* Donald Warne, *Genetic Research in American Indian Communities: Sociocultural Considerationas and Participatory Research*, 45 JURIMETRICS J. 191, 199 (2005).

[4] *See generally* Mervlyn Tano, *Interrelationships Among Native Peoples, Genetic Research, and the Landscape: The Need for Further Research into Ethical, Legal, and Social Issues*, 34 J.L. MED. & ETHICS 301, 303-06 (2006). In fact, Tano discusses some experts who believe that the "gene chase" is actually detrimental to the health of Native American tribes because it diverts attention away from prevention programs for diabetes, lifestyle education for heart disease and hypertension, and addiction treatment programs for alcoholism. *Id.* at 303.

[5] *See* Stephen Hart, *Investigative Report Concerning the Medical Genetics Project at Havasupai*, app. A at 23, *available at* http://rosettelaw.com/HartReport.pdf.

[6] *Id.* at 23-24. The Thrifty Phenotype Theory is of the belief that the Havasupai have a "genetic

has been used to study how a mother's blood sugar level during pregnancy impacts inter-uterine development of a fetus and can change the development of the pancreas and liver, as well as insulin production and processing mechanisms of the fetus.[7]

To examine the underlying reasons for the abnormally high incidence of diabetes among the Havasupai, Arizona State University first began collecting blood samples from members of the Havasupai tribe in 1990 for what the members of the tribe believed would be research solely related to the prevalence of diabetes among them.[8] In 1989, Mabel Hanna, a member of the Havasupai tribe, had approached Dr. John Martin, an anthropologist from Arizona State University, to relay her concern about the diabetes epidemic among the tribe and to seek help in obtaining answers to the problem, specifically to help alleviate the high prevalence among tribe members.[9]

To initiate this area of study, Dr. Martin contacted Dr. Therese Markow, a zoologist and genetics expert, about developing a research agenda to study the high rates

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predisposition" to diabetes because of their diet and irregular food supply. *Id.* at 23. Such diet irregularity is due to the tribe historically being hunters and gatherers, which has led to a development and adaptation over time by the tribe's members of an ability to maintain blood sugar levels from small amounts of food. *Id.* at 24.

[7] *Id.* The Thrifty Phenotype Theory further postulates that periods of starvation in the Havasupai tribe, including starvation of pregnant tribe members, leads to protein deficient diets. *Id.* The offspring of women with protein deficient diets are often born with underperforming pancreases and overcompensating livers. *See* Hart, *supra* note 5 at 23-24. When these offspring mature and become pregnant themselves, their pancreases cannot neutralize naturally increasing blood sugars, leading to further offspring being born under hyperglycemic conditions. *Id.* Fetuses developed in hyperglycemic conditions must rely upon their pancreas to try to control blood sugar levels, and often have overactive pancreases after birthing themselves. *Id.* This supports the Thrifty Phenotype Theory's explanation for why so many Havasupai children have elevated insulin levels. *Id.*

[8] *See* Hart, *supra* note 5, at 23-24. The description of events that follows is based upon a comprehensive investigation into the research process, design, and progression of ASU research conducted by Attorney Stephen Hart, which was compiled into a single document, hereinafter referred to as the "Hart document." *Id.* The Hart document describes how ASU obtained consent from Havasupai members to collect their blood, as well as the flaws in the process through which researchers sought to obtain consent from such persons. *Id.* Further, it explains how ASU's subsequent actions deviated from the representations that researchers made to the Havasupai, expanded the scope of the proposed research, permitted research sharing not in accordance with the consent obtained, and failed to adhere to the study's promised mechanisms for privacy protection. *Id.*

[9] *See* Hart, *supra* note 5, at 40. Martin had been working in the Supai village since 1963. *Id.* At that time, Martin presumed the prevalence of diabetes among the people of the village was a result of a combination of genetics and diet. *Id.*

of diabetes among the tribal members.[10] Markow expressed to Martin that she was also interested in studying the genetic underpinnings of schizophrenia among the tribe, but Martin informed her that the tribe would not be interested in participating in that area of study, maintaining that diabetes was to be the primary focus of the research.[11] Accordingly, Martin and Markow submitted a proposal to the Vice-President of Research at ASU describing a three-component project designed solely to study diabetes among the tribe while simultaneously providing the tribe with related benefits.[12] Given the prevailing Thrifty Phenotype Theory, significant emphasis in the project design was placed upon nutrition.[13] The first component was to provide tribe members with the opportunity to attend nutrition and physiology classes, with the purpose of educating the members about the causal links and connections to diabetes.[14] The second component was to obtain blood samples and test for glycosylated hemoglobin levels, in order to identify diabetic tribe members or those at risk for developing diabetes.[15] The

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[10] *See* Hart, *supra* note 5, at 40-41. Martin believed that the opinion of a genetic and nutritional diet expert would be beneficial to his study to attempt to determine the underlying cause of the high diabetes rate within the tribe. *Id.* at 40.

[11] *See* Hart, *supra* note 5, at 41. Martin instead, expressed that there may be an opportunity to expand the research further at a later date, once the Havasupai began to understand the testing and accompanying results of the diabetes research, especially since diabetes was their primary concern and reason for consenting to the research from the outset. *Id.*

[12] *See* Hart, *supra* note 5, at 43-44 (noting the proposed compliance of the research with the tribe's wishes).

[13] *See* Hart, *supra* note 5, at 43-44. The memorandum to the Vice-President of Research, entitled "Summer Proposal for Diabetes, Education/Research in Havasupai," noted the high incidence of diabetes among tribal members and described the three proposed components for the program. *Id.* The components of the project included educating several members of the tribe regarding the causal attributes of diabetes, taking the appropriate blood samples of tribe members for genetic testing, and conducting such testing to evaluate the genetic propensities of the tribe members towards diabetes. *Id.* at 42-43. The memorandum also stated, "[t]he proposed program will cement the necessary relationship between the Supai community and the University, thus opening the door for research in genetics of diseases, cultural practices, and the relationship between nutrition and disease." *Id.* at 44-45.

[14] *See* Hart, *supra* note 5, at 42. The components of the research conformed with pertinent Arizona State University's Institutional Review Board requirements that the benefits of a research project must outweigh the risk to the subjects, and each participant must be notified of all risks and perceived benefits of that particular study. *See* Arizona State University, Procedures for the Review of Human Subjects Research 3 (2009), http://researchintegrity.asu.edu/files/IRB/IRBPolicies.pdf. In addition, researchers must include a list of anticipated benefits to the subjects when they are submitting their proposals. *Id.* at 4.

[15] *See* Hart, *supra* note 5, at 42. As defined by the IRB, a benefit is "a valued or desired outcome; an advantage." *See* Arizona State University, *supra* note 14, at 39. Detection of diabetes and those at risk of diabetes would be beneficial to any and all participants who suffer from the disease and would allow for further developments in proper treatments for the disease in the

third and last component, which Markow was slated to direct, used genetic testing to identify whether gene variants correlated to incidence of diabetes among tribe members.[16]

B. Consenting Members of the Havasupai Tribe for Research

In 1990, Martin sent a letter to the Havasupai Tribal Council ("Tribal Council") describing the project and its three-part focus related to diabetes education, screening, and research.[17] In June and July of 1990, after Martin repeatedly emphasized to the Tribal Council that diabetes was the sole purpose behind the research, the blood drawing process began.[18] Martin arranged for Dr. Kevin Zuerlein, a psychiatrist, to work with the Indian Health Service ("IHS") in Supai Village to coordinate and begin the research process. Zuerlein recalled that he explained to each subject prior to the blood draw the project and its purpose to study diabetes; in addition, he obtained written consent forms.[19] Records indicate Zuerlein obtained over one hundred written consent forms identifying the project as "Medical Genetics at Havasupai."[20] By signing the consent forms, the subjects indicated that they understood the purpose of the research to be "to study the causes of behavioral/medical disorders."[21] Accordingly, the

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future. *See* Hart, *supra* note 5, at 43. Likewise, the National Human Genome Research Institute ("NHGRI") of the National Institute of Health ("NIH") has sought to provide guidance for the "ethical, legal and social implications ("ELSI") of genome research." National Institute of Health, http://www.nih.gov/about/almanac/organization/NHGRI.htm (last visited Nov. 19, 2010). The goal of the NHGRI is to understand the "structure and function of the human genome and its role in health and disease." *Id.* Moreover, "[t]he institute supports the development of resources and technology that will accelerate genome research and its application to human health." *Id.*

[16] *See* Hart, *supra* note 5, at 42. The test would be a genetic analysis that would involve looking at "an association between the HLA-A2 allele and diabetes." *Id.* The HLA-A2 allele was not found to be associated with diabetes among the tribe. *Id.* at 53.

[17] *See* Hart, *supra* note 5, at 50.

[18] *See* Hart, *supra* note 5, at 23-24 (describing the timeline of events leading up to and continuing through the study of the Havasupai tribe).

[19] *See* Hart, *supra* note 5, at 55-57. Zuerlein noted that although he did not read the consent script verbatim, he conveyed that the project was intended to study diabetes and that "many of these diseases, such as diabetes, schizophrenia, [and] depression, are complicated[,] so we try to look at as many factors as possible." *Id.* at 56-57. Zuerlein knew the focus of the study would be diabetes, but he received a mandate from Markow to look for signs of schizophrenia. *Id.* at 56. The informed consent document introduced the participant to the researchers, as well as the project. *Id.* at 58. The document stated, "the possible benefits of my participation in the research are a better understanding and treatment of diseases in my family and tribe." *Id.*

[20] *See* Hart, *supra* note 5, at 56-58, 59-60.

[21] *See* Hart, *supra* note 5, at 58.

broad consent form that the subjects signed for approximately a year became the mechanism and foundation for the expansion of research beyond studying the prevalence of diabetes.[22] However, the totality of information provided to the subjects regarding the meaning of "medical genetics" was likely focused on, or possibly limited to, only the diabetes project.[23] In 1991, Dr. Daniel Benyshek took over the process of collecting blood samples. Early in the course of collection, Benyshek observed that subjects were hesitant to sign the written informed consent forms.[24] Without knowledge of the need for written consent, Benyshek began obtaining only oral consent prior to collecting each sample from 1991-1994.[25] Benyshek orally explained to each subject that the protocol intended to study diabetes and the project would include three components: (1) education, (2) screening/testing, and (3) research of genetic factors related to developing diabetes.[26] Benyshek knew that Markow had expressed interest in schizophrenia, but based on his discussions with Martin and members of the tribe, Benyshek did not believe that this project entailed schizophrenia research or research unrelated to diabetes.[27] Thus, from 1991-1994, Benyshek informed subjects that the research would solely focus on diabetes, and because subjects did not see written forms, they had no reason to believe the scope of consent extended beyond diabetes research.[28]

C. Emerging Problems with Protocol Research Design

Between 1990-1994, the research team collected blood samples from over two hundred subjects and transferred the samples back to ASU. During this time, aside from Markow and Zuerlein who were the principal investigators, the Tribal Council, IHS physicians and personnel, and data collectors believed, and accordingly represented, that the scope of the project and consent for participation was limited to diabetes.[29] In

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[22] *See infra* notes 29-38 and accompanying text.

[23] *See* Hart, *supra* note 5, at 63 (stating participants likely only knew of diabetes research and that is what they believed they consented to by signing).

[24] *See* Hart, *supra* note 5, at 57. Charlotte Beauty, the phlebotomist at IHS, explained to Benyshek that the members of the tribe were wary of signing written documents. *See id.*

[25] *See* Hart, *supra* note 5, at 55-57, app. A at 38. Benyshek stated that he did not obtain informed consent forms and admits he now knows this was a mistake. *Id.* at 60. There is no record that Benyshek collected written consent forms or any consent forms from 1991-1994 when Benyshek obtained oral consent from the participants. *Id.* at 56, 60-62, app. A at 137-38. Despite Benyshek's admission, Markow contends that Benyshek did collect written forms, but the forms must have been lost during her professional move from ASU to University of Arizona. *Id.* at 60-62, app. A at 137-38.

[26] *See* Hart, *supra* note 5, at 57, app. A at 28-31.

[27] *See* Hart, *supra* note 5, at 57.

[28] *See* Hart, *supra* note 5, at 57.

[29] *See* Hart, *supra* note 5, at 49-59. Principal investigators and data collectors were unaware that

dire contrast to the limited research representations made to the tribe and individual subjects, however, Markow pursued and directed additional research use of the samples.[30]

In fact, Markow's research and supervision of ASU researchers during this time period reflects a strong concentration on schizophrenia, despite conversations with Martin and representations made to Tribal Council about the project's limited focus.[31] First, in a 1991 grant application, Markow indicated she wanted to "study the role of genetic factors in schizophrenia . . . which occurs at a significantly higher rate among the Havasupai (7%) than in any other population (1%). Interestingly, all cases of schizophrenia occur in lineages tracing back to a single man (a shaman or medicine man) who lived in the 1880s."[32]

Critically, ASU's Institutional Review Board's ("IRB") initial approval for any project involving the Havasupai tribe consisted of Markow's proposal to study the genetic underpinnings of schizophrenia.[33] Second, and more problematically, however, Markow had been directing the collection of blood from the tribe for an entire summer prior to IRB approval of this schizophrenia project.[34] Indeed, as early as 1990, Markow instructed the primary data collector to review the tribe's medical charts contained in the IHS clinic building and to look for indications of schizophrenia, neither of which was approved by ASU, the IRB, or participants.[35] As a result of Markow's actions, over the course of the project, numerous graduate students at ASU and researchers outside of ASU used the samples for research related to genetic causes of schizophrenia,

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Markow was using the samples for non-diabetes projects. *Id.* at 49, 55-59. Despite that consensus, Markow maintains the project contained dual foci designed to study the incidence of diabetes and to research the genetic underpinnings of schizophrenia. *Id.* at 80.

[30] *See* Hart, *supra* note 5, at 70-79.

[31] *See* Hart, *supra* note 5, at 49-53, 80-82, 92-93.

[32] *See* Hart, *supra* note 5, at 168, 186. Despite this frequency statistic, David Morgan, a pharmacist at the Indian Health Service ("IHS") who oversaw the administration of medical services, indicated he had no idea how this statistic was ever determined because to his knowledge, there had never been a diagnostic study to establish prevalence of schizophrenia among tribal members. *Id.*

[33] *See* Hart, *supra* note 5, at 146.

[34] *See* Hart, *supra* note 5, at 146.

[35] *See* Hart, *supra* note 5, at 239-40. Zuerlein stated that Markow gave him a list of names to search in IHS records, names of people who had visions, and she told him that she secured access for him to look at the files through IHS. David Morgan, a pharmacist at IHS who oversaw the administration of medical services, indicated no one from IHS would have allowed unauthorized review of patient medical records in Supai. *See id.* at 184-85. Markow subsequently denied having instructed Zuerlein in this manner. *Id.*

inbreeding, and population migration theories, which are clearly not connected to the study of diabetes.[36] In fact, twenty-three academic papers, articles, and dissertations used the Havasupai blood as a source.[37] Of these, fifteen contained research specifically related to schizophrenia, inbreeding, or population migration, rather than diabetes.[38]

In addition to the aforementioned problems, a subsequent investigation revealed an incongruity between the consent form's provision relating to research sharing and the actual practices Markow directed.[39] The informed consent form stated that research would be conducted at ASU and "all information" would be kept private.[40] Despite this provision, Markow provided both ASU and non-ASU affiliated researchers access to samples for projects that were unrelated to diabetes research.[41] Samples with identifiers were sent to researchers located at various universities, to labs outside of ASU for further testing, and to ASU researchers who were not participants in the research project.[42] Code books allowing for re-identification of research samples, although located in a private office of the ASU campus, were accessible not only to Markow, but to other researchers as well.[43] Collectively, these facts demonstrate that a majority of the

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[36] *See* Hart, *supra* note 5, at 80, 126, 128, 147.

[37] Paul Rubin, *Indian Givers*, THE PHOENIX NEWS TIMES, May 27, 2004, *available at* http://www.phoenixnewtimes.com/2004-05-27/news/indian-givers/1/. *See* Havasupai Tribe v. Ariz. Bd. of Regents, 220 Ariz. 214, 218 (Ariz. Ct. App. 2008).

[38] Rubin, *supra* note 37. In response to accusations of breach of informed consent, Markow asserted that she and ASU were at liberty, based on the consent form's wording, to study any type of disease or behavioral health problems among the Havasupai. *See* Hart, *supra* note 5 at 84.

[39] *See* Hart, *supra* note 5, at 4, 55-62.

[40] *See* Hart, *supra* note 5, at 58, 81 (describing the mechanism by which the identity of the participants was protected and also the clauses of the informed consent document ensuring such protection).

[41] *See* Hart, *supra* note 5, at 67-79. Although it is arguable that the secondary research was related to diabetes and therefore fell under the informed consent of participants since it "allowed researchers to gain a better understanding of the variations in the genes of a population, which in turn may allow inferences to be drawn about . . . diabetes," participants were not informed that their samples would be shared for such purposes; as such, they could not consent to such use. *Id.* at 75.

[42] *See* Hart, *supra* note 5, at 112-14. Dr. Daniel Garrigan, then a doctoral student at ASU, described his research that revealed additional inconsistencies between forms submitted to the IRB and actual research practices. *Id.* According to a project IRB form, "data only" could be released without identifiers. *Id.* However, Dr. Garrigan received samples and data with identifiers and had access to Markow's office that contained the lab books with the code for re-identification. *Id.* Markow also sent samples out of ASU laboratories for further testing and sent samples to researchers located at University of California, San Francisco, Stanford University, and Roche Molecular Labs. *Id.* at 67- 84.

[43] *See* Hart, *supra* note 5, at 111-12. Garrigan stated that Markow allowed him to use her lab books containing the codes for his research, as long as he did not remove them from the lab.

security requirements described or approved by the IRB were neither practiced nor enforced because Markow shared both the samples and the data, as well as provided access to her lab books containing the codes to re-link the samples.[44]

In sum, the first project Markow submitted to the IRB intended to study schizophrenia; sample collection began prior to IRB approval for any project; Markow shared the samples and information with other ASU and external researchers for non-diabetes research; and Markow allegedly directed data collectors to violate authorization requirements to access medical records and look for patient information relating to the occurrence of schizophrenia among tribal members.[45] All of these actions were taken while Markow was allegedly aware of the limited consent procured from the Havasupai Tribe.[46]

D. Research (Mis) Conduct Revealed

In 2003, the scope of research using Havasupai samples became known to the public, which initiated a series of actions against ASU by the tribe. Martin learned that Dr. Daniel Garrigan, an ASU doctoral student, was scheduled to present his dissertation, which contained research findings related to the blood samples collected from the Havasupai.[47] Martin invited Carletta Tilousi, a member of the Havasupai tribe who was an ASU undergraduate student at the time, to attend the presentation. When Tilousi questioned Garrigan on whether he obtained permission from the tribe to use the samples for his research on population migration, he conceded he did not obtain consent because he thought Markow made sure everything was in order.[48] To remedy this finding, Martin promptly approached and explained the situation to ASU officials, urging them to return the blood to settle the dispute, but they did not follow Martin's advice.[49] Soon after, ASU and the Havasupai tribe jointly commissioned attorney

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According to Markow, by keeping codes to re-link the samples in lab books located in her office, this meant all "information" was kept at ASU. *See id.* at 84.

[44] *See* Hart, *supra* note 5, at 84, 111-12. Section VI (A) of the Hart report describes the requisite standards that researchers should have been following, but when applied to the facts as laid out from the investigation, the security requirements were not met. *Id.* at 33-40.

[45] *See* Hart, *supra* note 5, at 111-12.

[46] *See* Hart, *supra* note 5, at 56-57, app. A at 240.

[47] *See* Jana Bommersbach, *Arizona's Broken Arrow,* PHOENIX MAGAZINE, Nov. 2008, at 134-35, *available at* http://www.phoenixmag.com/lifestyle/200811/arizona-s-broken-arrow/2/.

[48] *See id.*; Hart, *supra* note 5, at 111-12.

[49] *See* Bommersbach, *supra* note 47, at 134. Following Garrigan's presentation, Martin informed ASU officials that the tribe had planned a news conference to publicly state that their blood had been misused by ASU. *Id.* In his memo informing ASU officials of the planned conference,

Stephen Hart to investigate the events surrounding the collection of blood samples and the use of research directed by ASU.[50] Tilousi shared her discovery with the tribe, and at a special Tribal Council meeting, the council issued a Banishment Order stating: "[t]he Havasupai Tribe has demanded that ASU disclose to the Tribe all of its actions regarding Havasupai blood and stop all unauthorized experimentation on Havasupai blood, but ASU has failed to disclose to the Tribe any information about where ASU distributed the blood and the purposes for all research."[51]

II. The Havasupai Tribe Seeks Legal Redress

When individuals donate human biological materials to an institution for research purposes, an un-consented use of the donors' samples may constitute grounds for a cause of action against the research institution and the researchers themselves.[52] Individuals may object when their biological materials are used for research without their consent, when used beyond the scope of consent, or when used for purposes with which the subjects do not agree.[53] Aggrieved parties, such as the members in the Havasupai companion cases, may present claims under varied tort theories or

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Martin added "I believe the charges to be true." *Id.*

[50] *See* Bommersbach, *supra* note 47, at 135; Hart, *supra* note 5, at 5-10. The Havasupai tribe and Arizona State University jointly hired Attorney Hart to find out what actually happened with the blood samples once they were transferred out of Supai Village. *See* Bommersbach, *supra* note 47, at 135. The scope of Attorney Hart's work was general in nature, as neither the tribe nor ASU knew many of the facts regarding the blood samples. *Id.*

[51] *See* Bommersbach, *supra* note 47, at 134. The Banishment Order effectively "barred ASU, its professors and employees from the reservation forever." *Id.*

[52] *See generally* Wolf, *supra* note 1, at 126-27 (providing a summary of cases involving contributors of biological materials). In the case of *Moore v. Regents of the Univ. of Cal.*, Moore brought suit against the Board of Regents after learning that his biologic materials taken without permission during his treatment for leukemia had been used for profit to create a cell line. *Moore*, 793 P.2d 479 (Cal. 1990). Similarly, in *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, the Greenbergs filed a complaint against their research physician and Miami Children's Hospital after the Greenbergs donated their biological materials in an attempt to find a genetic test for Caravan disease, and the hospital sought ways to limit access to the testing. *Greenberg*, 264 F.Supp.2d 1064 (S.D. Fla. 2003). *See also infra* notes 74-76 and accompanying text (discussing *Moore* and *Greenberg*).

[53] *See* Laura Rowe, *You Don't Own Me: Recommendations to Protect Human Contributors of Biological Material After Washington University v. Catalona*, 84 CHI.-KENT L. REV. 227, 250 (2009). The outdated law governing human subjects research was drafted "to govern research on living, breathing humans, not their disembodied tissues;" therefore, it does not protect contributors against nonphysical or psychosocial harm. *Id.* at 249. The Havasupai "tribe alleges that the schizophrenia and inbreeding research has stigmatized them, and that they never would have consented to the migration studies because they directly conflict with their religious beliefs." *Id.* at 251.

constitutional law theories related to breach of fiduciary duty, lack of informed consent, negligence, emotional distress, and privacy.[54] Members of the Havasupai tribe filed two separate claims; Carletta Tilousi led individual plaintiffs in *Tilousi v. Arizona State University Board of Regents*,[55] and the entire tribe filed a companion case, *Havasupai Tribe v. Arizona State University Board of Regents*.[56] The crux of both claims alleged that the actions of ASU researchers constituted wrongdoing, which resulted in harm to the respective plaintiffs.[57]

The *Tilousi* courts' treatment of the plaintiffs' claims and interpretation of the legal standard for each claim demonstrates an inherent limitation in the legal system. The court failed to appreciate the particular significance of blood and research findings to the Havasupai tribe and individuals within an identifiable population group. As a result, the substance of the plaintiffs' allegations necessarily fell short of the courts' bar to find that the defendants committed any wrongdoing, or significantly, satisfied the element of legal harm. Because the court in *Havasupai Tribe v. Arizona State University Board of Regents* centered on the procedural issue of whether the plaintiffs satisfied notice pleading requirements, this discussion will focus on *Tilousi* prior to consolidation and the outcome contained in the settlement agreement for the consolidated cases.[58]

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[54] *See* Wolf, *supra* note 1, at 111. In *Greenberg*, when the Greenbergs learned of the hospital limiting access to the genetic testing, which their biological materials helped to create, they brought causes of action including "lack of informed consent, breach of fiduciary duty, unjust enrichment, fraudulent concealment, conversion, and misappropriation of trade secrets." *Id.* Constitutional law claims are in the form of section 1983 actions and are premised on the receipt of federal funding. *Id.*

[55] Tilousi v. Arizona State Univ. Bd. of Regents, No. CV2005, 2006 WL 4642922 ¶1-25 (Ariz. Super. Feb. 7, 2006) (describing procedural posture of case both prior to and after removal to federal district court).

[56] Havasupai Tribe v. Arizona State Univ. Bd. of Regents, 204 P.3d 1063, 1070 (Ariz. Ct. App. 2008) (discussing claims filed by tribe prior to removal to federal district court and subsequent remand).

[57] *See Havasupai Tribe*, 204 P.3d at 1063. However, the procedural issue of whether notice was timely dominates the Havasupai tribe's claim. *Id.* at 1073-74. This procedural issue is outside the scope of this article.

[58] *Id.* at 1073-74. Despite focusing on the procedural issue in *Havasupai Tribe*, Judge Barton did in fact connect the court's perception of the legal sufficiency of a claim and the request for damages to the tribe's claim and assessment of damages. *Id.* at 1076-77. In dicta, Judge Barton supports the position that a person has an interest in his or her own blood sample and the information that may be obtained from it, describes how this implicates a strong privacy interest against use of the blood without consent, and explains how this should support "a claim . . . for intrusion upon seclusion." *Id.* at 1076-77 (quoting United States v. Comprehensive Drug Testing, Inc., 513 F.3d 1085 (9th Cir. 2008)).

A. *Tilousi v. Arizona State University Board of Regents*

In February 2004, Carletta Tilousi, joined by other members of the tribe, filed a claim in Arizona District Court against the Arizona State University Board of Regents and individually named ASU researchers as defendants.[59] The plaintiffs alleged eight counts of wrongdoing: (1) breach of fiduciary duty and lack of informed consent; (2) fraud, misrepresentation, and fraudulent concealment; (3) intentional and negligent infliction of emotional distress; (4) conversion; (5) violation of civil rights; (6) negligence, gross negligence, and negligence per se; (7) unreasonable disclosure of private facts; and (8) intentional intrusion upon seclusion.[60] The court dismissed many of the claims in part or in their entirety, finding as a matter of law that the plaintiffs' pleadings failed to assert damages and other elements of individual claims. For the claims it dismissed, the court's analysis demonstrated the legal system's limitations and structural inabilities to comprehend and recognize the existence and gravity of spiritual and cultural damages incurred by the plaintiffs.[61] The inherent conflict between existing perceptions of harm, and the meaning ascribed to blood by the traditional tort system is best demonstrated by Counts I, VII, and VIII. As such, the following discussion will focus solely on the *Tilousi* court's treatment of these individual claims.

The court's analysis for Count I focused on the tort framework alone, without integrating the federal regulations' requirements specific to research claims, and consequently, the court prematurely dismissed the plaintiffs' claim for Count I.[62] The plaintiffs claimed that the defendants failed to obtain informed consent for drawing blood and also that the defendants failed to use the care and skill exercised by

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[59] Tilousi v. Arizona State Univ. Bd. of Regents, No. 04-CV-1290, 2005 WL 6199562, at *1 (D. Ariz., Mar. 3 2005). More specifically, the defendants named included the Arizona Board of Regents; Therese Markow, an ASU biology professor; John Martin, an ASU professor; Daniel Benyshek, an anthropology master's student; and Kevin Zuerlein, a graduate student. *Id.* at *16.

[60] *Id.* at *3, *6-7, *9-12 (noting all charges brought forth against the defendants in the suit).

[61] *Id.* at *2-6. In fact, the court dismissed counts I, II, IV, VII, and VIII in their entirety. *Id.* Additionally, it is worth noting that here, the term "damages" refers to the tort framework that defendants' breach of a legal duty was the proximate and actual cause of plaintiffs' experience of harm. *See generally* BLACK'S LAW DICTIONARY 416-19 (8th ed. 2004) (defining various kinds of damages).

[62] *Tilousi*, 2005 WL 6199562, at *2-3. Claims filed under federal regulations are generally separate from private actions, meaning that they have their own remedies. *See* Alexander v. Sandoval, 532 U.S. 275, 286 (2001) (discussing that courts must decide whether regulations create both a private right and a private remedy). Here, however, the court concluded that the federal statute and regulation cited by the plaintiffs neither offers a private right of action nor evidences a goal of providing a private right of action. *See Tilousi*, 2005 WL 6199562, at *5.

researchers of ordinary prudence.[63] The court overlooked the plaintiffs' reference to 45 CFR § 46.116, a federal statute dictating the requirements for proper consent, and the court concluded that because the plaintiffs consented to have their blood drawn, the consent at issue was effective, even if the defendants allegedly made fraudulent representations to induce it.[64] Although the plaintiffs claimed, in the alternative, that the researchers breached the duty of care owed to them because they omitted information material to consent, the *Tilousi* court held that even fraudulent (mis)representations to induce consent are insufficient to invalidate consent where the plaintiffs are fully aware of "the nature of the contact."[65]

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[63] *See Tilousi,* 2005 WL 6199562, at *2, *3-5. The court analyzed the consent question from a provider's standpoint, disregarding the fact that the informed consent question should have been considered from a researcher's perspective. *See infra* notes 73-76 and accompanying text.

[64] *See Tilousi,* 2005 WL 6199562, at *2. In evaluating Count I of the claim, pertaining to lack of informed consent, the court rejected the plaintiffs' argument that the defendants violated 42 U.S.C. § 289 and 45 C.F.R. § 46.116, holding that such federal regulations created no private right of action nor an intent to create a private right of action. *Id.* These statutes provide, as an element of valid informed consent, that certain information must be provided to participants. *See* 45 C.F.R § 46.116 (2005). Instead, the court applied the Restatement, which merely requires consent "to the particular conduct, or substantially the same conduct." RESTATEMENT (SECOND) OF TORTS § 892A(2)(b) (1965). Furthermore, the court cited to a comment in the Restatement addressing consent procured through fraudulent misrepresentations. *See Tilousi,* 2005 WL 6199562, at *1. The comment states, "consent, though fraudulently procured, prevents the infliction of the contact from being itself a wrong and as such actionable." RESTATEMENT (SECOND) OF TORTS § 18 cmt. f (1965). Accordingly, the court dismissed the count, reasoning that because the plaintiffs consented to their blood being drawn and understood the character of the contact, their consent could be made effective even if procured by fraud. *See Tilousi,* 2005 WL 6199562, at *1. Moreover, Count II of the claim, pertaining to fraud and misrepresentation/fraudulent concealment, was also dismissed. *Id.* at *3. The plaintiffs alleged that Martin, Markow, Benyshek, and Zuerlein had each made false or misleading statements to procure their blood, as well as false statements relating to how the blood would be kept "locked" at ASU. *Id.* The court ultimately rejected each respective allegation, claiming the plaintiffs failed to introduce the elements of fraud for each defendant to the degree of specificity as required by Rule 9(b) of the Federal Rules of Civil Procedure. *Id.* Still, the plaintiffs, along with their complaint, put forth the Hart report, which was subsequently dismissed for lack of brevity, but it perhaps contained more detailed documentation of the specific misrepresentations made to the tribe members. *Id.* at *1, 3.

[65] *See Tilousi,* 2005 WL 6199562, at *2. The court reasoned that the plaintiffs consented to have their blood drawn and were fully aware of the type of contact necessary. *Id.* It further relied on the Restatement (Second) of Torts stating,

> the rule stated in § 892B, that a consent to a contact the particular character of which the other is fully aware, is not made ineffective by reason of the fraudulent misrepresentations which induce the other to give the consent, is of peculiar importance in determining the existence of liability for a merely

In Count VII, the plaintiffs alleged that because they held a privacy interest in their blood and the defendants transported their blood samples from "laboratory-to-laboratory and university-to-university," the defendants unreasonably disclosed private facts about them.[66] Private facts are simply facts about an individual or group that the public is not entitled to.[67] The plaintiffs alleged that the information contained in their samples amounted to private facts because the general public did not have ready access to this data prior to the researchers' disclosures.[68] The Tilousi court, in contrast, focused on the fact that the plaintiffs provided consent and contributed their samples "for research purposes," which negated the possibility of treating the blood samples as "private facts."[69]

The court likewise dismissed plaintiff's Count VIII, intrusion upon seclusion.[70] The crux of the plaintiffs' argument for this count was that the defendants conducted unauthorized research using their blood samples and published scholarly articles on population migration theories, which (1) constituted an intentional intrusion into a private matter that would be (2) highly offensive to a reasonable person.[71] The court summarily rejected this claim because the tribe voluntarily donated their blood samples.[72]

> offensive contact . . . . [T]he consent, though fraudulently procured, prevents the infliction of the contact from being itself a wrong and as such actionable.

Id. (quoting RESTATEMENT (SECOND) OF TORTS § 892A (2)(b) cmt. f (1965)).

[66] *See Tilousi*, 2005 WL 6199562, at *5.

[67] *See* RESTATEMENT (SECOND) OF TORTS §652D cmt. h (1977). Comment h to the Restatement goes on to say that "customs and conventions of the community" must be taken into account when determining what is a private fact. *Id.* Furthermore, the Restatement suggests that common decency and regard for the individual's feelings should be heavily considered in light of what harm the exposure may cause. *Id.*

[68] *See Tilousi*, 2005 WL 6199562, at *5. Conversely, the defendants argued that the blood samples did not constitute "private facts" because reasonable people would not have been offended by the dissemination of the samples and society had a great interest in advancing medical and scientific knowledge. *Id.*

[69] *See Tilousi*, 2005 WL 6199562, at *5. In the plaintiff's second amended complaint, they asserted an invasion of privacy from the transfer of the samples themselves, rather than any data or information contained within the blood, given that the blood samples were used for purposes other than those they consented to. *Id.*

[70] *See Tilousi*, 2005 WL 6199562, at *6. A claim for intentional intrusion upon seclusion requires the plaintiff to prove "(1) an intentional intrusion into a private place, conversation, or matter (2) in a manner highly offensive to a reasonable person." *See* Med. Lab. Mgmt. Consultants v. Am. Broad. Companies, Inc., 306 F.3d 806, 812 (9th Cir. 2002).

[71] *See Med. Lab. Mgmt. Consultants*, 306 F.3d at 812 (describing the elements of the tort "intrusion upon seclusion" (quoting RESTATEMENT (SECOND) OF TORTS § 652B (1959))).

[72] *See Tilousi*, 2005 WL 6199562, at *6. The court stated, "because plaintiffs voluntarily supplied

In each of these three counts, the *Tilousi* court ascribes excessive weight to the consent obtained by researchers without considering whether the consent given was truly informed; its ruling on the issues of breach of duty, privacy, and intrusion upon seclusion, predicated on the assumption of effective consent, might have come out differently had it taken into consideration the research-specific purpose of collecting the plaintiff's blood.

With respect to Count I, the *Tilousi* court should have incorporated requirements set forth in federal regulations governing research conduct, which would have made fraudulent inducement of consent a more central concern.[73] Although jurisprudence governing the collection of blood samples for research purposes was still

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the blood samples, plaintiffs have failed to state a claim that defendants intruded into a private matter of plaintiffs' in a highly offensive matter. Count VIII is dismissed in its entirety." *Id.*

[73] *See* 45 C.F.R. § 46.116 (2005). The federal regulation requires the following information be given to potential participants:

> (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental; (2) A description of any reasonably foreseeable risks or discomforts to the subject; (3) A description of any benefits to the subject or to others which may reasonably be expected from the research; (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject; (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained; (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Id. Of note, is the fact that the regulation specifies that the purposes of the research must be explained, arguably, indicating that *all* purposes should be discussed with participants. *Id.* Nonetheless, the regulation later notes that these are the elements to obtain legally effective informed consent, implying that Congress too, intended a different standard for what constitutes informed consent under the law. *Id.*

developing during *Tilousi*, both *Moore v. Regents of the Univ. of Cal.* and *Greenberg v. Miami Children's Hosp. Research Inst.* were on the radar to indicate the issue of informed consent was far from settled.[74] Moreover, although *Greenberg* classified the contributors of biological materials as "donors," rather than human subjects requiring informed consent under federal law, *Moore* stands for the proposition that obtaining biological materials for research purposes requires, at a minimum, informed consent.[75] Thus, *Moore* and *Greenberg* should have signaled to the *Tilousi* court that research using biological materials required a reconsideration of how to properly obtain informed consent based on the standards set forth in federal law, even if the federal law itself does not provide a private right of action.[76]

As to Count VII, the court ought to have considered the nature of the "contact" from the plaintiff's perspective. More specifically, contact for purposes of consent did not merely entail a simple blood draw, but it necessarily implicated the entire project. Indeed, the plaintiffs stated that had they known the manner in which data would be stored and findings shared, they would not have given their consent in the first place.[77] By failing to properly communicate details of how samples would be handled, used, and shared, researchers arguably did not provide the information participants needed to determine the purpose of the contact and to decide whether or not to give consent.[78] Because standards for informed consent in research differ from those in a medical malpractice context, where written consent vitiates a claim for battery,

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[74] *See generally* Greenberg v. Miami Children's Hosp. Research Inst., 264 F. Supp. 2d 1064 (S.D. Fla. 2003) (dealing with lack of patient consent in obtaining patent based genetic sequences that plaintiff patients presented during a study on Canavan disease); Moore v. Regents of the Univ. of Cal., 793 P.2d 479 (Cal. 1990) (dealing with physician incentive to keep a patient in care for research purposes without informing the patient of the research motive).

[75] *See Greenberg*, 264 F. Supp. 2d at 1071 (distinguishing petitioners from human subjects and reaffirming informed consent requirements for research participants); *Moore*, 793 P.2d at 483 (discussing informed consent broadly).

[76] *See Greenberg*, 264 F. Supp. 2d at 1069 (stating that the issue of informed consent for medical research, instead of medical treatment, was a novel one for the court in this case and a quite complex one as well because the Florida statute only pertains to the patient/*treating* doctor relationship). In *Greenberg*, Florida statutory law was unclear on the issue of informed consent, so the court examined the issue in the tort context to see if the researchers had a duty to obtain consent to seek a patent. *Id.* Additionally, in *Moore*, the court stated that the scope of informed consent includes any and all information that would be material to the patient's decision, even if that includes information unrelated to medical risks. *See Moore*, 793 P.2d at 483. The language of the Common Rule does not appear to set forth a private right of action, but the standards for informed consent are clearly stated. *See* 42 U.S.C. § 46, 116.

[77] *See Tilousi*, 2005 WL 6199562, at *2.

[78] *See Moore*, 793 P.2d at 483 (defining scope of consent and placing a premium on material information).

the question of whether informed consent was truly obtained was in dispute and ought not to have been dismissed so quickly.[79] A more legally sound approach to the issue of privacy would have been to examine this specific allegation in conjunction with those regarding consent.[80]

The Restatement (Second) of Torts provides an example that is analogous to this case: Person A can provide consent to share a private fact for a limited purpose to a limited audience, but if Person B shares this fact to a wider audience (or logically shares more than this fact), then this constitutes an invasion of Person A's privacy.[81] In this

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[79] *See* W. M. Moldoff, *Malpractice: Physician's Duty to Inform Patient of Nature and Hazards of Disease or Treatment*, 79 A.L.R.2d 1028 (1961) (providing a comprehensive discussion of medical malpractice and one of its vital elements, the duty of informed consent). This report was originally published in 1961, but it has been updated continually, and it lists a catalog of seminal cases interpreting the matter for each state and federal circuit. *Id.* A physician has a duty to inform a patient of the nature and hazards of the disease or treatment. *Id. But see supra* note 73 and accompanying text (providing the federal guidelines for medical research requiring informed consent). *Cf. Greenberg*, 264 F. Supp. 2d at 1070-71. In *Greenberg*, the court declined to extend the duty of informed consent to economic interests, asserting that the standard would be unworkable and would have a chilling effect on medical research, as it would require that researchers constantly evaluate whether a "discloseable" event has occurred. *Id.* at 1070. The court was also wary of providing research subjects with a "dead-hand" control, the ability to influence and direct how medical research could be conducted upon their donated materials. *Id.* at 1070-71. The court also distinguished the plaintiffs as donors, as compared to those having medical research conducted upon them, thus altering how informed consent should be analyzed. *Id.* at 1071. *Cf. Moore*, 793 P.2d at 483. The California court held that a physician must disclose personal interests unrelated to the patient's health that may affect the physician's professional judgment, whether they are research related or economically driven, and a failure to disclose such interests may give rise to a cause of action for performing medical procedures without the patient's informed consent, or in the alternative, may constitute a breach of fiduciary duty. *Id.* In *Moore*, the conflict arose because the physician continued to ask for genetic material from Moore that was unrelated to his treatment, and which only served to benefit the physician's economic interests in patenting a certain cell line. *See id.* at 481-82.

[80] In fact, the only circumstances creating exceptions to obtaining informed consent, which were not present here, are if:

> (1) The research involves no more than minimal risk to the subjects; (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) The research could not practicably be carried out without the waiver or alteration; and (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

45 C.F.R. § 46.116 (2005). The regulation, however, does not expressly invalidate situations where consent exceeded its scope. *Id.*

[81] *See* RESTATEMENT (SECOND) OF TORTS § 652D cmt. a, illus. 11 (1977) (providing example of

instance, the defendants provided samples to other ASU researchers and graduate students to use for research purposes outside of the scope of consent, thus disclosing information contained in the samples that was not otherwise publicly available and revealing additional private information related to schizophrenia, inbreeding, and ancient population migration about the group as a whole.[82] The *Tilousi* court's dismissal of this count, therefore, was not only questionable as a matter of law, but it also failed to distinguish the significance of blood as a raw material for research and the amount of deeply private information contained therein. In addition, ASU researchers presented, shared, and published their research to the public, which further disclosed information about the plaintiffs' group related to these three topics of research.[83]

The *Tilousi* court also failed to consider relevant legal standards as to how consent operates in the context of an intrusion upon seclusion claim—plaintiff's Count VIII. The Restatement (Second) on Torts provides the following examples with respect to this specific issue: Person A opening Person B's mail without permission or Person A examining Person B's private bank accounts without permission.[84] For these examples, if Person A gives permission to Person B to open private mail X, this does not mean that Person B also has permission to open Person A's other private mail, nor does Person B have permission to show the contents of private mail X to any interested

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situation in which information used outside scope of consent).

[82] *See* Bommersbach, *supra* note 47, at 137-38, 140. Martin was an anthropologist who lived in Supai in the 1960s and studied the Havasupai Indian tribe to map their complete lineage. *Id.* at 137. In 1989, diabetes became an epidemic in the Havasupai Indian village, and at the time, Martin was teaching at ASU. *Id.* The Havasupai Indian tribe approached Martin to see if he and ASU could help them overcome the diabetes outbreak in their village. *Id.* The Havasupai Indian tribe made it clear that they would donate blood for diabetes research only. *Id.* Martin recruited Markow, a biology professor, to assist him in the research. *Id.* Markow expressed her desire to expand the research to also test for schizophrenia, but Martin told her that the Havasupai tribe would not be interested. *See* Bommersbach, *supra* note 47, at 137. Markow, however, applied for a grant to search for schizophrenia among the Havasupai tribe members, and the grant was awarded. *Id.* Markow then had a graduate student search through medical records for signs of schizophrenia in specific tribal members. *Id.* Markow maintained that she had permission to test for other things besides diabetes, as evidenced by the consent forms that some of the Havasupai tribal members signed. *Id.* at 138. However, the Havasupai tribe members understood this project to be a diabetes project only. *Id.* Also, in 2003, Martin became upset when he learned that a graduate student used Havasupai blood samples for a dissertation on migration patterns that had nothing to do with diabetes, and the student used Martin's lineage research without his permission. *Id.* at 140. *See also* John McGregor, *Population Genomics and Research Ethics with Socially Identifiable Groups*, 35 J.L. MED. & ETHICS 356, 364 (2007).

[83] *See* Bommersbach, *supra note* 47, at 142-44 (explaining that the tribe learned of the additional uses of their blood by attending a public ASU dissertation presentation).

[84] *See* RESTATEMENT (SECOND) OF TORTS § 652B cmt. b (1977).

party.[85] For the plaintiffs, this same logic demonstrates that the plaintiffs only gave certain researchers permission to use their blood for specific diabetes related research projects.[86] Critically, the court, in failing to find an inclusion upon seclusion claim, did not recognize that each additional category of contentious research disclosed otherwise private information about the plaintiffs because the plaintiffs are part of the identifiable group studied.[87]

Furthermore, because the court found that the plaintiffs' blood samples and the information derived from them did not constitute private facts, the court did not address whether sharing the blood samples and information would be offensive to a reasonable person. If the court examined whether publishing research on a population migration theory is offensive to a reasonable person, it should have separated this analysis from the dominant religious ideology and instead analyzed how a reasonable person in similar circumstances (an insular, identifiable, Native American tribe) would react.[88] The defendants' theories of population migration publicly, set forth as solid scientific theory, implied that the plaintiffs' sacred beliefs of creation, identity, and purpose were wrong.[89] Thus, the court should have recognized that a reasonable person could object to having researchers use genetic samples and medical information given for a different purpose to study and disseminate information that devalues and dishonors this person's way of living and belief system.

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[85] *See* Birnbaum v. U.S., 436 F. Supp. 967, 977 (E.D.N.Y. 1977).

[86] *See* Hart, *supra* note 5, at 1 (describing the focus of the project as "finding an association within the Havasupai population between diabetes and certain gene variants").

[87] *See* Havasupai Tribe v. Arizona State Univ. Bd. of Regents, 204 P.3d 1063, 1067 (Ariz. Ct. App. 2008) (stating researchers continued to perform research and publish articles after project ended). The tribe contends that the defendants "conducted genetic research using tribal members' blood samples, published papers that disclosed tribal members' private genetic data and other private information derived from the blood samples, and transferred blood samples to third parties without consent." *Id.* at 1074. "To prove actionable intrusion, the plaintiff must show the defendant penetrated some zone of physical or sensory privacy surrounding, or obtained unwanted access to data about, the plaintiff." *See* Shulman v. Group W Productions, Inc., 955 P.2d 469, 490 (Cal. 1998). Since plaintiffs' privacy was disrupted by the unauthorized and intrusive use of identifiable information, the inclusion upon seclusion claim meets this standard. *See Havasupai Tribe v. Ariz. Bd. of Regents*, 204 P.3d at 1067.

[88] *See* Rubin, *supra* note 37. The tribe's allegation of being "duped" into giving blood "raises questions about the complex intersection of modern science and the cultures of indigenous peoples." *See id.*

[89] *See* Rubin, *supra* note 37. To understand the centrality of this belief to the Havasupai, one story aptly suggested it would be similar to a researcher asking Christians living in Nazareth to provide a blood sample for diabetes research, using this blood for unauthorized research into their history, and telling them that Jesus never existed. *Id.*

B. *Havasupai Tribe v. Arizona State University Board of Regents* Settlement Agreement

After several procedural volleys, the two cases were consolidated and continued through the court system until the parties arrived at a settlement agreement in March 2010.[90] The settlement contains several provisions to protect the Havasupai tribe's privacy, and it details Arizona State University Board of Regents' performance obligations. First, ASU is required to pay the Havasupai $700,000.[91] Second, ASU must return all blood samples in its possession.[92] Third, ASU shall return all documents containing research derived from the blood samples.[93] Fourth, ASU is obligated to terminate IRB approvals for any ongoing or new research using the samples. Finally, ASU is required to provide the tribe with a list of all entities to which it had previously transferred the samples.[94]

While the request for damages merely concretized the degree of dignitary, cultural, and other harm the members of tribe and the tribe itself had suffered, statements made by ASU representatives suggest the University's continued failure to appreciate the extent of harm done.[95] According to one of the plaintiffs' attorneys,

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[90] *See Havasupai Tribe v. Ariz. Bd. of Regents*, 204 P.3d at 1067 (summarizing facts and procedure).

[91] Settlement Agreement, Havasupai Tribe v. Arizona State Univ. Bd. of Regents, Mar. 6, 2010 (Settlement) (on file with author).

[92] *See id.*

[93] *See id.*

[94] *See id.* Additionally, the settlement agreement set forth a creative five-year collaborative between ASU and the tribe, ostensibly to re-bridge the vast chasm that occurred as a result of the research conduct and ongoing litigation. *Id.* The joint agreement was designed to address the tribe's needs in the areas of education, health and nutrition, economic development, architecture, engineering, and legal governance. *Id.* Several of these provisions included pursuing funding opportunities to build a high school near the reservation, partnering ASU nursing students to provide clinical care in Supai village, and working with the tribe to develop business plans related to its tourism programs. *See* Settlement Agreement, Havasupai Tribe v. Arizona State Univ. Bd. of Regents, Mar. 6, 2010 (Settlement) (on file with author).

[95] *See* Bommersbach, *supra* note 47. The tort remedy of replevin returns misappropriated property to a plaintiff, but this remedy is generally unsuitable in matters pertaining to human body products because of public health considerations. *See also* Judith D. Fischer, *Misappropriation of Human Eggs and Embryos and the Tort of Conversion: A Relational View*, 32 LOY. L.A. L. REV. 381, 418 (1999). "Redress for the harm through the tort system is an important means of both recognizing the relational concerns and attempting to make the aggrieved patients whole." *See id.* at 402. The need expressed by the Havasupai for the return of the blood samples is akin to that felt by soldiers' families whose loved ones were killed abroad – it reflects a desire to bury or cremate the remains in order to allow the souls of those passed to move on. *Id.* Public health concerns therefore play a smaller role in determining whether tort remedies are indeed

Robert Rosette, officials at ASU told him during mediation that there had been "no broken bones—[the tribe had not] been harmed."[96] Similarly, Markow classified the plaintiffs' claims as "hysterical," insisting she was only "doing good science."[97] Both comments echo the sentiment that the tribe's claims and request for damages merely represented an extreme irrational or anti-science sentiment, rather than a genuine attempt to signify the harm they incurred.

Despite this potential shortcoming of the settlement, the provision specifying that ASU must return the samples and research materials highlights several important issues relating to the current standards and assumptions governing research using human biological materials.[98] The physical transfer of samples indicates recognition that they are not merely items holding immense scientific value, but rather, they are also an important part of an individual's identity and that of a tribal group, which continues to play a vital spiritual and cultural role once excised from the physical being.[99] By

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appropriate. *Id.*

[96] *See* Bommersbach, *supra* note 47. ASU's transfer of $700,000 (split among the forty-one plaintiffs) seems nominal compared to plaintiffs' request for $25 million in compensatory damages and $25 million in punitive damages. *See* Lori Andrews, *Havasupai Tribe Sues Genetic Researchers*, LAW AND BIOETHICS REPORT, Winter 2004, 10, 11, *available at* http://www.kentlaw.edu/islat/pdf/HavasupaiTribeSues.pdf. However, money was arguably not the central concern in these cases and would never alone be sufficient to remedy the plaintiffs' alleged damages without addressing the use and possession of the blood samples. *See id.* at 10, 11. Moreover, the numerical amount ASU must provide the plaintiffs raises the question whether, even after all of the litigation, it fully comprehends the amount of harm experienced by the plaintiffs. *See id.* at 10, 11.

[97] *See* Howard Fischer, *Havasupai Blood Lawsuit Reinstated*, ARIZONA DAILY SUN, Nov. 28, 2008, *available at* http://azdailysun.com/news/article_2921c286-4454-57eb-926b-11e795134f8f.html (last visited Nov. 19, 2010); David Usborne, *Blood Feud in the Grand Canyon*, THE INDEPENDENT, Apr. 23, 2010, available at http://www.independent.co.uk/news/world/americas/blood-feud-in-the-grand-canyon-1951972.html (last visited Nov. 19, 2010).

[98] *See* Julie A. Burger, *What is Owed Participants in Biotechnology Research?* 84 CHI.-KENT L. REV. 55, 56 (2009). Due to advancements in methods and techniques in genetics research, more information is known about people who submit to such research, and as a result, recently, there has been a "reanalysis of duties owed to human subjects." *Id.* Research participants have the right to withdraw from further research, but questions remain regarding the legitimacy of research when it "is performed on blood or other tissue that has been removed from the body." *Id.*

[99] *See* Robert Heidt, *Maintaining Incentives for Bioprospecting: The Occasional Need for a Right to Lie*, 13 BERKELEY TECH. L.J. 667, 707 (1998) (noting that research participants may seek to nullify previously given consent when "the subject assigned the researcher the right to use the cells" and "the court can use its equitable powers to effect that result"). The equitable remedy used here is arguably equivalent to nullifying a participant's previously given consent; therefore, the provision of the settlement agreement providing for the samples return is indicative of the importance the

providing for a return of the samples, the settlement demonstrates that our framework can and must recognize that for some individuals and groups, blood is so integral to a sense of identity and cultural cohesion, that its significance demands a separate evaluation and category of harm. In this instance, the return of the samples signaled a forced recognition of its value as defined by the tribe.[100]

III. Assessing Shortcomings in Current Federal Law to Inform Future

A. Research Using Biological Materials

The unfortunate incidents in the Havasupai case offer several points about the future of genetic research involving vulnerable, tribal populations. Since Native American populations experience significant health disparities, there is an incentive to involve them in research that may provide them with health care benefits both in the short term and in the long run. Additionally, the disparate rate that Native Americans experience chronic conditions makes is quite likely that such populations will continue to be approached as potential research participants.[101] However, in light of the apparent

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participants, themselves, ascribed to the materials. *Id.*

[100] *See* Michael Kiefer, *Havasupai Tribe Ends Regents Lawsuit with Burial*, THE ARIZONA REPUBLIC, Apr. 22, 2010, *available at* http://www.azcentral.com/arizonarepublic/local/articles/2010/04/22/20100422arizona-havasupai-tribe-regents-lawsuit.html (last visited Nov. 19, 2010). Having the blood samples returned was the most important element of the settlement for the tribe, and since thirty-two of the blood donors have died since their blood was drawn, it was crucial that this blood was returned and buried. *See id.*

[101] *See* McGregor, *supra* note 82, at 357 (explaining minority groups suffer from a disproportionate amount of health problems in respective populations). As a population group, Native Americans in the United States suffer the highest mortality rates from preventable diseases. *Id.* According to the Indian Health Service, the average life expectancy for Native American males is 6.2 years less than the national average, and for females, the average life expectancy is 5.2 years less than the national average. *See* Warne, *supra* note 3, at 193. Diabetes, alcohol-related deaths, injuries, and suicide all adversely affect Native American populations at disparate rates. *Id.* Diabetes and alcohol related health issues have been studied extensively by researchers because these diseases may contain significant genetic components. *Id.* at 195. The propensity to develop such diseases within a Native American group is further compounded by disparities in socioeconomic status, access and utilization of health services, and cultural factors. *Id.* Despite these statistics, several scholars question whether genetic research should even constitute a research agenda, asserting that current health disparities are a product of social and environmental causes. *See* McGregor, *supra* note 82, at 357; *see also* Debra Harry, *Indigenous Peoples and Gene Disputes*, 84 CHI.-KENT L. REV. 147, 154 (2009) (explaining groups may be stigmatized as "inherently flawed" by emphasis on linking disease to genes); *see generally* Tano, *supra* note 4, at 303-06 (discussing how lifestyle education is the best prevention strategy and removing environmental contaminants would lessen

disconnect between researchers and tribal participants about what constitutes risk, it is imperative to re-examine the regulatory framework that governs the collection of human biological materials. If the rights of participants are to be protected and research institutions are to be trusted, we must examine the underlying value judgments the current framework makes about risk and harm, as well as analyze the assumptions regarding the significance of the biological materials.

B. Current Federal Framework Governing the Collection of Biological Materials

1. Overview of the Common Rule and OHRP Guidance

The Common Rule provides the federal regulatory standards for the protection of human subjects involved in research conducted or supported by federal agencies or departments.[102] Under the Common Rule, "individuals are considered human research subjects if an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private health information."[103] Federally funded entities wishing to conduct human subjects research must therefore institute procedures and protocol that adhere to federal standards aimed at protecting the rights and welfare of prospective participants.[104] As the collection of biological materials results from the interaction with an individual and involves the collection of identifiable private health information, research involving blood sampling falls within the scope of the Common Rule's requirements.[105]

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manifestation of diseases even if they contain a genetic component).

[102] *See* 45 C.F.R. § 46 (2009).

[103] *See* Protection of Human Subjects: Definitions, 45 C.F.R. § 46.102 (2009).

[104] *See* U.S. Dep't of Health & Human Servs., Office for Human Research Protections ("OHRP"), http://www.hhs.gov/ohrp/IRBfaq.html (last visited Nov. 19, 2010). An Institutional Review Board must be registered with the United States Department of Health & Human Services ("HHS") "if they will review human subjects research conducted or supported by HHS." *Id.* The OHRP's oversight compliance procedures allow the agency to conduct for-cause and not-for-cause compliance oversight evaluations, may recommend improvements to be made to the protection policies and procedures, may require corrective actions, and may restrict, suspend, or even permanently remove an institution's participation in specific projects. *See* U.S. Dep't of Health & Human Servs. Office for Human Research Prot., *OHRP's Compliance Oversight Procedures for Evaluating Institutions,* 2-7 (2009), *available at* http://www.hhs.gov/ohrp/compliance/ohrpcomp.pdf.

[105] *See* Human Research Protection Program/Institutional Review Board, Activities Subject to IRB Review 1-2 (2010), https://irb.llnl.gov/pdfs/SOP_7.pdf (last visited Nov. 19, 2010). Performing "noninvasive or invasive procedures for research," which includes drawing blood or collecting other biological samples, suffices as human subject research by obtaining "(1) data

Although the donation of biological materials is accordingly covered by the requirements set forth under the Common Rule, scholars have recently noted that the current federal regulatory framework falls short of fully protecting individuals who donate their blood for research.[106] Even if applied correctly, these regulations are inadequate to protect human subjects in the research process because the Office for Human Research Protection's ("OHRP") guidance for applying the regulations relies on the identifiability of the sample and does not strictly pertain to additional research uses under sharing agreements between institutions.[107] As such, gaps exist when researchers use subjects' biological materials for secondary research and in a de-identified manner outside the scope of the Common Rule.[108]

The requirements set forth in the Common Rule were designed to protect "living, breathing human subjects, not their disembodied tissues."[109] While subjects may no longer encounter physical harm during the later stages of a project, it is possible to still experience significant nonphysical or psychosocial harms that researchers and institutions may not have considered when determining whether research complies with the rule's requirements.[110] As a result, institutions' IRBs may not consider psychosocial risks of harm when approving research uses of samples, and thus, researchers may not inform subjects of these risks during the consenting process.

The tenuousness of the OHRP guidelines, which act as the de facto reference point for interpretation of the Common Rule, is central to this concern.[111] As OHRP

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through intervention or interaction, or (2) identifiable private information." *Id.* at https://irb.llnl.gov/pdfs/SOP_7.pdf.

[106] *See* McGregor, *supra* note 82, at 367 (discussing that federal rules do not protect samples if stripped of identifying information or coded by original lab and sent out for secondary research use); Rowe, *supra* note 53, at 249-50 (Common Rule protects living individuals as test subjects but does not cover extracted tissue samples and their contributors from nonphysical psychosocial harm); Wolf, *supra* note 1, at 132 (researchers may be exempt from the federal law if they code samples rather than label with personal identifiers).

[107] *See* McGregor, *supra* note 82, at 367 (explaining federal regulations exempt IRB approval where investigators do not have access to identifiable private sample source information); Rowe, *supra* note 53, at 250-51 (stating OHRB does not consider coded non-identifiable samples to involve human subjects, and therefore, exempts it under the Common Rule).

[108] *See* McGregor, *supra* note 82, at 367.

[109] *See* Rebecca Skloot, *Taking the Least of You*, N.Y. TIMES MAGAZINE, Apr. 16, 2006, at 36. The Common Rule "was written to govern research on living, breathing humans, not their disembodied tissues;" there have been no updates to the rule since it was adopted in 1981, and thus "much of tissue research is not governed by the Common Rule." *Id.*

[110] *See* Rowe, *supra* note 53, at 249.

[111] *See* U.S. Dep't of Health & Human Servs., Office for Human Research Prot., *Guidance on*

does not consider "research involving *only* coded private information or specimens" to involve human subjects as defined under 45 C.F.R. § 46.102(f), IRBs are not required to assess harm when the proposed research does not involve the collection of private information and investigators are unable to link the individualized data to its source.[112] Accordingly, coded or anonymized samples used for secondary research, as used by ASU in the Havasupai case, are not subject to federal regulation governing human subjects research.[113] Conversely, back in 1999, before the proliferation of secondary research, the National Bioethics Advisory Commission ("NBAC") recommended that research with coded or identified samples be considered human subjects research and that it be governed by the Common Rule.[114] As Congress has not yet acted on this recommendation, the distinctions between data collection and analysis, codified in the OHRP's Guidance, and the assumptions associated with the various stages of research, govern the current research design and implementation process.[115]

Research Involving Coded Private Information or Specimens (2008) [hereinafter OHRP Guidance], *available at* http://www.dhhs.gov/ohrp/humansubjects/guidance/cdebiol.htm (clarifying the scope of OHRP jurisdiction). According to the OHRP Guidance, it is the interactions that generate the data in question and the degree of anonymity involved that are determinative of whether HHS supported research using human biological samples will fall under the Office's jurisdiction. *Id.*

[112] *See* OHRP Guidance, *supra* note 111 (explaining when private information or specimens are considered individually identifiable under 45 C.F.R § 46.102). The OHRP Guidance states that when the following two conditions are met, research using coded data does not qualify as human subjects research and is thus beyond the purview of § 46.102: "(1) the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and (2) the investigator(s) cannot readily ascertain the identity of the individual to whom the coded private information or specimens pertain." *Id.*

[113] *See* Amy L. McGuire & Richard A. Gibbs, *No Longer De-Identified*, SCIENCE, Apr. 26, 2006, 370, 370, *available at* http://www.sciencemag.org/cgi/reprint/312/5772/370.pdf (noting limited Federal oversight of research not considered to involve human subjects). MgGuire and Gibbs point out that while informed consent and IRB oversight are required for the collection and sampling of genetic material, limited protection is afforded to participants with respect to the sequencing and data analysis phases of genetic research. *Id. See generally* OHRP Guidance, *supra* note 111 (differentiating between collection and secondary research involving coded, de-identified samples).

[114] *See* NAT'L BIOETHICS ADVISORY COMM'N, ETHICAL AND POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS, at 4-8 (2001), *available at* http://bioethics.georgetown.edu/nbac/human/overvol1.pdf (outlining 1999 recommendations regarding coded data and research oversight). Since all coded data are identifiable regardless of the difficulty of linking the data to identifying information, the National Bioethics Advisory Commission recommended an approach to oversight that allowed for varying levels of IRB review based on the difficulty of linking data to its source. *See id.*

[115] *See id.* at 117-124 (outlining history of current regulatory framework).

2. Identifiability and Research Sharing: Shifting Evaluations of Risk and Harm

Both the Common Rule and the OHRP's Guidance hinge upon these two assumptions: (1) coding or anonymization mitigates or prevents the sample from being re-identified; and (2) re-identification is what poses the risk to subjects.[116] Recently, however, discoveries in biostatistics have challenged the assumption that samples cannot be re-identified.[117] For instance, it is now known that researchers working with genetic databases can link coded and stored data to an individual donor using only seventy-five single nucleotide polymorphisms ("SNPs") from that individual and a reference sample, a finding that calls into question the value of de-identification procedures.[118] Changing assumptions about identifiability has been the topic of discussion for samples intended for use in genome-wide association studies ("GWAS") because these studies generate thousands of SNPs for an individual.[119] In response to these discoveries, in 2008, the National Institutes of Health ("NIH") swiftly removed aggregate genotype data for GWAS from public access pending further study of mechanisms for release to mitigate re-identification.[120]

The fact that there is now widespread discussion about the sufficiency of

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[116] *See* Wolf, *supra* note 1, at 131-33 (detailing regulatory framework for human subjects research).

[117] *See, e.g.*, Nils Homer et al., *Resolving Individuals Contributing Trace Amounts of DNA to Highly Complex Mixtures Using High-Density SNP Genotyping Microarrays*, PLOS GENETICS, Aug. 2008, at 1, 7-9 (relating results of study aimed at identifying an individual's presence in a complex genomic DNA mixture); Kevin B. Jacobs et al., *A New Statistic and its Power to Infer Membership in a Genome Wide Association Study Using Genotype Frequencies*, NATURE GENETICS, Oct. 2009, at 1253 (testing application of forensic methods of identifying individual presence in DNA mixtures developed by Homer et al. to aggregate GWAS data).

[118] *See* McGuire & Gibbs, *supra* note 113, at 370 (describing study identifying individual DNA sequences and privacy risks associated with public access to identified DNA).

[119] *See* Stephanie Fullerton et al., *Meeting the Governance Challenges of Next-Generation Biorepository Research*, SCIENCE TRANSLATIONAL MEDICINE, Jan. 2010, at 15; *see also* Catherine Heeney et al., *Assessing the Privacy Risks of Data Sharing in Genomics,* PUBLIC HEALTH GENOMICS, Mar. 2010, at 1, 5-6, *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2872768/pdf/phg0000-0000.pdf (discussing risks of genomic identification); Jane Kaye et al., *Ethical Implications of the Use of the Whole Genome Methods in Medical Research*, EUROPEAN JOURNAL OF HUMAN GENETICS, Apr. 2010, at 398 (discussing privacy and confidentiality of research participants); Jeantine E. Lunshof et al., *From Genetic Privacy to Open Consent*, NATURE REV. GENETICS, May 2008, at 406, 407-09 (discussing privacy, confidentiality, disclosure, and consent issues with genomic science).

[120] *See* NAT'L INSTITUTES OF HEALTH, MODIFICATIONS TO GENOME-WIDE ASSOCIATION STUDIES (GWAS) DATA ACCESS (2008) [hereinafter NIH GWAS MODIFICATIONS], *available at* http://grants.nih.gov/grants/gwas/data_sharing_policy_modifications_20080828.pdf. NIH stated its intention to possibly make this data available through the controlled access DAR/DAC process. *Id.* at 1.

methods to prevent re-identification warrants additional analysis for several reasons. First, this discussion assumes that re-identification of the sample is the prominent risk to participants and that potential re-identification is a necessary prerequisite to experience other harms such as discrimination, stigma, or psychological stress.[121] Secondly, it speaks to the weight ascribed to the risks of genetic research as against potential benefits to participants, and it focuses on a top-down calculus, as opposed to one at the group or community level.[122] Lastly, and most problematically, the discussion reifies an understanding that what constitutes a risk is based on whether the scientific community considers the risk in question to be *legitimate*.[123] An alternative approach to the risk-benefit calculus would have investigators analyze whether the proposed research involves harm to the subjects in the study population, with the potential for re-identification and subsequent revelation of private facts magnifying any harms identified. From the perspective of Native American tribes, therefore, the risk of participating in genetic research includes psychosocial risks from the misuse of biological materials, as well as the risks of re-identification associated with coded sample aggregation and storage.

3. Identifiability and Research Sharing

It is always possible to infer an individual's presence in a dataset when group attributes are disclosed to the public, but sample size and a unique data source magnifies this particular danger to research participants.[124] Researchers may likewise make non-distributive generalizations about a subject based on study outcomes, concluding that for any given participant, a specific health trait is shared with the group. Although this risk is inherent to population-based research, it is heightened in the context of genetic research involving participation rates nearing a third of the group in question.[125]

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[121] *See* Lunshof et al., *supra* note 119, at 407-09 (discussing link between privacy breaches and informed consent); *see also* Heeney et al., *supra* note 119, at 5-6 (identifying involuntary disclosures resulting from re-identification by intruders as a risk to participants in GWAS studies).

[122] *See* NIH GWAS MODIFICATIONS, *supra* note 120 (noting example of risk-benefit analysis seen in NIH's decision to suspend public access to GWAS data pending resolution of potential threat). An alternate approach to limiting access would be to use group or tiered consents highlighting these specific risks.

[123] *See* NIH GWAS MODIFICATIONS, *supra* note 120. Although GWAS studies have been underway since 2005, it was not until fears of re-identification were validated that precautionary measures were taken to limit public access to these data. *Id.*

[124] *See* Heeney et al., *supra* note 119, at 3 (discussing inferential attribute disclosure risks).

[125] *See* Lunshof et al., *supra* note 119, at 407-09 (explaining non-distributive generalizations and risks to participants).

For the Havasupai, the investigation into ASU's alleged misconduct, now known as the Hart Report, illustrated these heightened risks associated with population-based secondary research falling outside the purview of the Common Rule. As documented in the report, Markow sent samples to researchers at University of California at San Francisco, Stanford, and Roche.[126] According to Markow and the recipient researchers, the samples did not contain identifiers, but some samples were coded or were labeled with the "HAV" prefix.[127] Markow admitted that the "HAV" prefix compromised the identity of the group, but she countered that the prefix did not specifically identify individuals, implying that the use of coding negated the allegations of harm advanced by the Havasupai.[128] However, because of the small population size of the Havasupai (approximately 650) and the number of individuals who donated samples (approximately 200), one could argue that additional care with respect communicating research findings ought to have been taken.

Problematically, Markow's position assumed that identifying the group's characteristics through secondary research is necessarily separated from the individual and poses minimal or no risk of harm to the subjects. Yet key to the Havasupai tribe's argument was that secondary research is harmful to the group because of the stigmatization that can result even without re-identification. It is important to note that a significant minority of professionals involved in human subjects research still echo Markow's sentiment that coded samples neither constitute human subjects research, nor pose a risk of re-identification, so subjects would not be harmed even if they were identified.[129] Despite advances in bioethics and technology, this persistent attitude towards research fails to capture the actual harms experienced by the Havasupai, and it is a clear call for reforming the standards that govern research protocols.[130]

4. Institutional Review Boards (IRBs): Standardization and Review for Compliance

Scholars argue that research using biological materials should be subject to

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[126] *See* Hart, *supra* note 5, at 70.

[127] *See* Hart, *supra* note 5, at 84.

[128] *See* Hart, *supra* note 5, at 70.

[129] *See* Amy A. Lemke et al., *Attitudes Toward Genetic Research Review: Results from a National Survey of Professionals Involved in Human Subjects Protection*, 5 J. OF EMPIRICAL RES. ON HUM. RES. ETHICS 83, 87 (2010) (examining whether various functions of IRBs should differ for genetic research).

[130] *See id.* at 87. A total of 208 human subject protection professionals ("HSPs") completed a web-based survey. *Id.* at 85. The results indicated that 34% of the HSPs believed that harm would result if study participants were personally identified in a study involving coded genetic data. *Id.* at 87.

stringent and continuous IRB review.[131] However, for IRBs to serve as an effective

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[131] *See* Wolf, *supra* note 1, at 147; *see also* Leslie E. Wolf et al., *IRB Chairs' Perspectives on Genomics Research Involving Stored Biological Materials: Ethical Concerns and Proposed Solutions*, 3 J. EMPIRICAL RES. ON HUM. RES. ETHICS 99, 107 (2008) (outlining three primary challenges for obtaining necessary IRB review). Federal regulations govern research involving human participants. *Id.* The Federal Policy for the Protection of Human Subjects, also known as the Common Rule, applies to human subjects research conducted or supported by any of the sixteen federal departments and agencies that have adopted the Common Rule. *Id.* As such, institutions engaged in human research that is subject to the Common Rule must certify that the research complies with the Office of Human Research Protections ("OHRP") and also has been approved by an IRB prior to commencing any research. *Id. See also* 45 C.F.R. § 46.111 (2010) (establishing minimum standards of oversight that IRBs must follow). 45 C.F.R. § 46.111(a) and (b) reads in pertinent parts:

> (a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:
>
> (1) Risks to subjects are minimized: (i) [b]y using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
>
> (2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the important of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
>
> (3) Selection of subject is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
>
> (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by § 46.116.
>
> (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
>
> (b) When some or all of the subjects are likely to be vulnerable to coercion or

oversight mechanism, they must reassess and standardize their approval process.[132] Wolf and colleagues recently examined how investigators and IRBs addressed ethical issues within a consent form related to genetic research of stored biological materials.[133] Their study indicated a lack of information in the consent forms related to non-physical harm and an inability to withdraw the materials from the research.[134] Wolf's study of 139 consent forms found significant variation and gaps of information provided to subjects in IRB approved forms.[135] Notably, although almost all protocols referred to physical risks associated with donating biological materials for storage, less than half of the procedures discussed some type of psychosocial risks, such as discrimination (29%), stress (11%), or stigmatization (1%).[136] Further, 66.9% of the protocols stated that materials would be shared, and around 55% of protocols specified with whom the samples would be shared.[137] Additionally, Wolf and colleagues found a gap regarding how many of the protocols discussed the right to withdraw from research. Approximately 9% of protocols clarified that researchers would remove identifiers from a sample if a subject requested to withdraw, but they would not actually withdraw the

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> undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Id.

[132] *See* Wolf, *supra* note 1, at 147 (discussing the need to balance continuing interests and countervailing interests for biological materials used for research).

[133] *See* Wolf, *supra* note 1, at 140-41.

[134] *See* Wolf, *supra* note 1, at 140-41; Leslie E. Wolf et al., *Genetic Research with Stored Biological Materials: Ethics and Practice*, 32 IRB: ETHICS & HUM. SUBJECTS RES. 7 (2010) (discussing challenges that practice-based research networks face with respect to the regulatory requirements for IRB review and the protection of human subjects in research); *see also* 45 C.F.R. § 46.111(a)-(b) (2010) (articulating some of the protections in place to assure compliance with the ethical regulations on human research).

[135] *See* Wolf, *supra* note 1, at 140-42 (articulating results ultimately derived from 139 studies). Wolf found that investigators overwhelmingly relied on consent when using biological materials for research. *Id.* Additionally, when collecting new specimens, 75% of investigators used consent forms that allowed participants to select among different options regarding future use of their specimens, and the majority of investigators limited future research to certain conditions or uses in their consent forms. *Id.* at 141; *see also* Wolf et al., *supra* note 134 (detailing results of the study).

[136] *See generally* Wolf et al., *supra* note 134 (examining physical risks associated with donating biological materials for storage).

[137] *See* Wolf et al., *supra* note 134, at 11; *see also* Wolf, *supra* note 1, at 138 (discussing how some of these chairs were familiar with the regulatory exceptions that permit some uses of biological materials without consent).

sample to properly discontinue participation.[138] Around 18% of these proposals placed some type of restrictions on withdrawal and would not withdraw the sample if it had been de-identified, already shared, or if it was necessary for the integrity of the project.[139] This study demonstrates that many IRBs fall short of ensuring that their institution's protocols include pertinent information necessary to inform a subject's decision to participate in donating biological materials for research—a finding that calls into question the suggestion that IRBs are an effective mechanism for the mitigation of these particular problems.[140] If research protocols continue to operate without fully informing subjects of the psychosocial risks of research and the limitations on withdrawing their participation, then this will only perpetuate the disconnect between the subjects' understanding of their participation and the potential harms they may encounter, notably including cultural and spiritual harms.[141] Furthermore, these results suggest that IRBs must critically examine their internal practices, ensure accountability that protocols adhere to federal regulations governing human subjects research, and comply with the ethical purpose of human subjects protections.[142]

Applying these principles to the instant case, the sharing of the participants' coded materials for research projects unrelated to diabetes produced significant psychosocial harm in the form of stress and stigmatization.[143] When the tribe realized how their samples were being used and requested to withdraw, ASU refused.[144]

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[138] *See* Wolf et al., *supra* note 134, at 12; *see also* Wolf, *supra* note 1, at 141-42 (stating that researchers found nine studies that permitted investigators to continue to use biological materials in research after a participant requested to withdraw from the study, provided the researchers removed identifiers). Not only is this ethically problematic, but participants have a legal right to withdraw their study participation, which itself is indicative of the need for reform. *Id.* at 141; 45 C.F.R. § 46.116(a)(8) (2005).

[139] *See* Wolf et al., *supra* note 134, at 12.

[140] *See* Wolf, *supra* note 1, at 145 (suggesting studies reflect reluctance within research community to embrace the federal regulations governing research with biological samples).

[141] *See supra* note 49 and accompanying text (discussing how Havasupai tribe demanded the blood samples back); *see also infra*, notes 187-217 and accompanying text (discussing the significant cultural and dignitary harms that result from misuse of blood samples).

[142] *See* Wolf, *supra* note 1, at 145-56 (recommending several ways in which IRBs can critically examine their internal practices and further protect human biological materials for research).

[143] *See* Rubin, *supra* note 37. Rubin further noted that schizophrenia is a stigmatizing condition, as well as the fact that "no one wants to be known as the . . . crazy tribe." *Id.* (quoting Bill Freeman).

[144] *See* Rubin, *supra* note 37. When the project started in 1989, standard ethical practices for the collection and use of human biological materials was arguably not well known or understood. *Id.* However, Carletta Tilousi, the Havasupai Tribe, and Martin requested that ASU return the samples in 2003, after the passage of NBAC's guidance that stated the collection of biological samples for research should be governed under the Common Rule that requires the right to

Denying the right to withdraw creates additional legal and ethical shortcomings in the current framework.[145] Moreover, the process of de-identifying or stripping identifiers from a sample, as the mechanism to discontinue participation, also incorrectly assumes that the subjects' motivation to withdraw only stems from the identifiability of their individual sample.[146] Henry Greely, who has researched the practice of refusing to honor these withdrawal requests, has asserted that it is plainly unethical to not follow the express wishes of the subjects, but rather, override their wishes and continue using the sample.[147] Declaring that stripping identifiers properly mitigates or erases harm to subjects fails to consider potential intangible harms from the subjects' perspective, such as the stigmatization that can be associated with research participation despite researchers' use of coding.[148] Biological materials for some subjects may hold substantial intrinsic value and continuing to use the sample after a request for withdrawal would violate strongly held moral or religious beliefs.[149] To the Havasupai,

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withdraw participation from research. *Id.*

[145] *See* Rubin, *supra* note 37. ASU's interaction with the Havasupai demonstrated this institution-tribe clash of retaining samples despite subjects' wishes to discontinue participation. *See* Wolf, *supra* note 1, at 155 (noting limitations with the current legal framework following her independent studies). In 2003, when the Havasupai learned how Markow had shared their samples for projects unrelated to diabetes, they asked ASU to withdraw their participation and return their samples. *See* Bommersbach, *supra* note 47, at 134-35. ASU's refusal to withdraw the samples after the Havasupai's request in 2003 demonstrated the inherent failure to recognize how the use of the samples in these other research projects caused harm to the tribe and how continuing to use them would cause further harm. *See infra*, notes 187-217 (discussing the various cultural and dignitary harms the Havasupai tribe suffered as a result of the misuse of the blood samples).

[146] *See* Wolf, *supra* note 1, at 142, 155. Moreover, "[t]he approach to withdrawal that allows research to continue on de-identified specimens misconstrues the regulatory requirements and mistakenly understands the only potential objections to continued use to be ones of confidentiality." *Id.* at 142. Ultimately, however, "[t]o use the materials after a participant requests to withdraw violates the participant's wishes and thus also violates both the ethical principles governing human subjects research and the federal regulations that incorporate those principles." *Id.*

[147] *See* Rowe, *supra* note 53, at 265 (citing to Henry Greely, *The Uneasy Ethical and Legal Underpinnings of Large-Scale Genomic Biobanks*, 8 ANN. REV. GENOMICS & HUM. GENETICS 343, 352-53 (2007) (discussing the unethical practice of refusing to honor participants' requests to withdraw their biological materials)).

[148] *See* Wolf, *supra* note 1, at 155-56. In addition, the Havasupai were not critically concerned with confidentiality; rather, the significance the materials held and the effect of their improper use, was the primary issue at contention. *Id.*

[149] *See* Rowe, *supra* note 53, at 266. Rowe specifically states that regardless of whether it is linked to them, "using a sample for certain research purposes after its withdrawal or destruction has been requested may still violate the personal preferences, morals, or religious beliefs of its human source." *Id.*

their blood samples contained significant spiritual value, the loss of which was only capable of redress through their actual return.[150]

In addition, the Hart Report revealed egregious lapses in the IRB's oversight when Markow first sought IRB approval for the initial research involving the Havasupai.[151] The record for IRB approvals revealed that ASU's IRB first approved a protocol to collect samples from the Havasupai for schizophrenia research in January of 1991.[152] While the IRB was likely unaware that Markow's research team had been collecting blood for an entire summer prior to any IRB approval and that the subjects provided consent because they believed the ASU team was solely conducting diabetes research, the Hart Report also found several inconsistencies between the research proposal and the actual data collection.[153] Even though the application for expedited review stated that the researcher would only use information without identifiers, it was later found that he used both information and samples.[154] Moreover, although the samples were not accompanied by identifiers, the researcher not only had access to Markow's lab books with the codes to re-link the samples, but he also used these lab books for his research.[155] These lapses in oversight and adherence to IRB procedures

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[150] *See* Wolf, *supra* note 1, at 123. The tribe stated that in keeping with its beliefs, the tribe needed the samples returned so that it could properly bury the blood samples. *Id.* In addition, the Havasupai tribe alleged that "ASU's actions have invaded the personal privacy of Havasupai tribal members and the cultural and religious privacy of the Havasupai tribe." *Id. See also* Usborne, *supra* note 97 (explaining deceased tribal member souls' cannot rest if parts of their physical being are absent at burial).

[151] *See generally* Wolf, *supra* note 1, at 120-22 (discussing the errors and faults in ASU's research and consent process).

[152] *See* Hart, *supra* note 5, at 146. "The log pertaining to IRB approvals of projects identifying Therese Markow as a principal investigator, reflected that the first IRB approval date was January 18, 1991, for 'schizophrenia: a genetic model,' under file no. R0166-91." *Id.*

[153] *See* Hart, *supra* note 5, at 63, 146. The presentations by Martin to the Tribal Council reflected that diabetes was the focus and that schizophrenia was not even a "secondary consideration[]." *Id.* at 63. The summer proposal for the Havasupai research stated, "[d]iabetes in Havasupai is just the beginning: we envision the development of a major research program to include additional tribes and diseases." *Id.* at 45.

[154] *See* Hart, *supra* note 5, at 112. Garrigan admitted that this was his first human subjects research project. *Id.* In order to receive a grant from the National Science Foundation ("NSF"), IRB approval was necessary; therefore, Markow submitted the application to the IRB on Garrigan's behalf and faxed the document to NSF. *Id.* Markow later called Garrigan to inform him what she did and Garrigan assumed that "if the documentation was good enough for the NSF everything must be in order." *Id.*

[155] *See* Hart, *supra* note 5, at 112. Although Garrigan claimed there was no way to convert the identification numbers into names, the access to Markow's lab and books gave him a means to obtain genealogies. *Id.*

highlight the importance of considering the development of new research standards; the remainder of this piece will address how one might take initial steps in this direction.

IV. Re-Envisioning Research Standards From the Perspective of the Subjects

A. Recognizing Group Rights

The varied application of the federal framework governing human subjects research has distinct implications in the context of research involving Native American individuals and groups. Scholars have noted that federal law and current research standards overlook the possibility and importance of group rights when interacting with Native American tribes; in light of the conflict between ASU and the Havasupai, one may conclude that the manner in which research is currently conducted is fundamentally incompatible with a Native American viewpoint of what constitutes harm.[156] Given this potential for conflict, researchers and institutions ought to re-evaluate the consenting process, giving more weight to group perspectives as a means to reduce barriers to participation and create a more trusting relationship with future research participants.

The entire informed consent process is built around the concept of individual rights, rather than the rights of collective groups. However, Debra Harry, an expert on issues of indigenous rights, suggests that the notion of group consent arises in part from the fact that research on individuals within Native American tribes naturally impacts all members because they form an identifiable group.[157] In addition to constituting separate identifiable groups with distinct cultural values, Native American tribes are unlike other identifiable groups because they also represent separate political entities.[158] Tribes constitute sovereign political units designated under United States law as "domestic, dependent nations;" furthermore, the law classifies them as political, rather than racial, groups for equal protection purposes.[159] Thus, to properly conceptualize how to approach members of a Native American tribe requires: (1) approaching a tribe as a sovereign and independent entity with priorities deserving respectful consideration, and

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[156] *See* Harry, *supra* note 101, at 150-52 (explaining how using Havasupai tribe members' blood samples to perform unauthorized genetic research without subjects' informed consent and against their spiritual beliefs led to mistrust and, ultimately, lawsuits); Rebecca Tsosie, *Cultural Challenges to Biotechnology: Native American Genetic Resources and the Concept of Cultural Harm*, 35 J.L. MED. & ETHICS 396, 396-97 (2007).

[157] *See* Harry, *supra* note 101, at 154 (discussing how searching for genetic, racial causes of traits, especially behavioral traits that are not necessary innate, can lead to stigmatization of entire groups).

[158] *See* Tsosie, *supra* note 156, at 402.

[159] *See* Tsosie, *supra* note 156, at 402.

(2) incorporating tribal interpretations of federal regulations pertaining to human subjects into the consent process.[160]

B. Questioning Implicit Value Judgments

Approaching research with Native American tribes from a group perspective would in turn shift current value judgments related to participation and classification of harm away from those currently institutionalized in IRB processes to those of potential research subjects. As seen in the case of the Havasupai, researchers, as well as respected scientific journals, grossly mischaracterized the complainants' reaction as "hysterical" and "hypersensitive" and portrayed the case as groundless.[161] This response problematically exemplified the notion that opposition to a particular use of samples, such as those at issue, necessarily stems from an anti-science attitude without rational merit, rather than a legitimate, albeit different, standpoint. Current federal regulatory practices implicitly adopt this same attitude in its promotion of a hierarchy of concerns that assume scientific research should always trump other intangible priorities.[162] This blind promotion of scientific research may also arise from a highly offensive sense of paternalism to "help" a population that does not "understand."[163] As one commentator on this case noted, "[a]ssertions of 'good science,' however are not the end of the discussion, but a prerequisite for the start. Full disclosure does not guarantee

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[160] *See* Tsosie, *supra* note 156, at 408 (discussing how to restructure the legal relationship between tribes and institutions to incorporate the tribe's values and norms into research protocol); *see also* McGregor, *supra* note 82, at 366 (discussing methods of group consent for research).

[161] *See* Usborne, *supra* note 97 (describing Markow's view of the plaintiffs' claim as 'hysterical' and defending herself stating that she was only acting in furtherance of scientific research); *see also* Fischer, *supra* note 95, at 418-20 (discussing generally tort-based remedies for conversion or misappropriation of property intended for medical research only). The use of replevin or conversion as remedies is inappropriate to punish parties who misappropriate human eggs and embryos. Fischer, *supra* note 95, at 418-20. *See also* Rowe, *supra* note 53, at 250 (discussing outdated law governing use of disembodied human tissues), *supra* notes 61-89 and accompanying text (critiquing outcome of Havasupai litigation).

[162] *See generally* Kristen Carpenter, *Real Property and Personhood*, 27 STAN. ENVTL. L. J. 313, 380 (2008) (examining prioritization of fungible versus non-fungible interests in context of environmental issues and analyzing how majority interests in policy-making are often automatically classified in hierarchy above tribal interests).

[163] *See* Rubin, *supra* note 37 (noting blatant disregard of some researchers with respect to rights of tribe members). Chris Armstrong, a graduate student who was working under Markow, stated that Markow told him the members of the Havasupai tribe did not understand what schizophrenia was, and by lying about the research they were doing, they would be serving the "higher good." *Id.* Despite the many individuals involved in the project that did not know about Markow's schizophrenia research, Markow insists that she did not ask Armstrong to lie, although Armstrong has publicly maintained the contrary. *Id.*

acceptance, and rejection is not necessarily a sign of ignorance."[164] Thus, to fully respect the individuals within a Native American tribe as potential research subjects and to recognize that their assertions of harm do not pertain to the mere opposition of samples used for scientific purposes, researchers must begin with a critical examination of their own implicit value judgments.

C. Benefits and Direct Harms from the Perspective of Native American Tribes

Partnering with interested and willing Native American communities could lead to potentially significant health benefits for the Native American groups specifically, as well as generally for society as a whole.[165] Genetic research using biological samples could uncover: (1) markers to identify disease risk, (2) new and more effective treatment options, and (3) data to measure the efficacy of treatment options.[166] The results of this research could also provide information regarding secondary preventive measures for diseases such as diabetes and help to identify individuals at risk for developing such diseases, most specifically through offering appropriate monitoring resources prior to onset or diagnosis.[167] However, specifically donating biological samples for the "good of humankind" requires agreeing and consenting to how our current system processes genetic research advancements through the patent system.[168] Rather than merely interacting with potential subjects with the goal of procuring consent, researchers should critically and actually analyze the risk-benefit ratio to the individual subjects in the tribe and how the research would affect the tribe as a group.[169]

While these potential benefits exist, however, it is important to remember that

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[164] Pete Shanks, *When Cultures Collide, Genetic Crossroads*, PSYCHOLOGY TODAY, May 2, 2010, http://www.psychologytoday.com/blog/genetic-crossroads/201005/when-cultures-collide (noting the opinion of a member of the Center for Genetics and Society who is of the belief that cultural, social, and scientific viewpoints in this arena must work together in an effort to coincide).

[165] *See* Charlotte Harrison, *Neither Moore Nor the Market: Alternative Models for Compensating Contributors of Human Tissue*, 28 AM. J.L. & MEDICINE. 77, 83-84 (2002) (discussing health care benefits of aggregated blood sample research). Despite offering benefits to tribal communities, however, injustices due to unfair bargaining and disclosure may continue absent proper and adequate regulation and supervision. *Id.* at 84-85.

[166] *See* Warne, *supra* note 3, at 199-200 (identifying the benefits of genetic research in tribal communities).

[167] *See* Warne, *supra* note 3, at 199-200 (noting additional benefits for the mentioned assessment techniques and in performing genetic research in tribal communities as a whole).

[168] *See* Harry, *supra* note 101, at 189.

[169] *See* Harry, *supra* note 101, at 157.

not all research can deliver a timely tangible benefit as an outcome. It is also difficult to determine what research areas are important and would provide benefit to Native American communities because of the distinction among the tribes in defining benefits and harms. One critic characterized this arrangement by summarizing, "traditionally it has been the scientists defining the research questions, with indigenous peoples as passive pincushions."[170] When there is no direct benefit to the subjects, then the researcher must recalculate and *truthfully* represent this information to the subjects. Scholars have criticized representations that researchers have made to subjects at this juncture, arguing that researchers have approached the notion of benefit from how the research would impact the general public or scientific advancement in the field, which may run contrary to other principles held by the tribe.[171]

Failing to adequately assess this risk-benefit ratio can have tangible consequences on the trust between members of the tribe and researchers, whether or not the individuals actually participated in the research.[172] Accordingly, this level of trust influences an individual's interaction with the medical profession and participation in future research.[173] In the case of the Havasupai, members of the tribe described how they were fearful of going back to IHS for any medical care and were distrustful of receiving medical attention because they did not want to be subjected again to research without their knowledge or consent.[174] In fact, to support their claims, the *Tilousi* plaintiffs averred that they feared both visiting their IHS clinic and seeking medical attention.[175] Viewing this hesitation in conjunction with the frequency and severity of the tribe's health issues means that the breach of trust dissuades members from seeking potentially life-prolonging care for diseases like diabetes.[176]

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[170] *See* Harry, *supra* note 101, at 189.

[171] *See* Harry, *supra* note 101, at 189; *see also* Lindsay Singeo, *The Patentability of the Native Hawaiian Genome*, 33 AM. J.L. & MED. 119, 122 (2007) (discussing Native Hawaiian opposition to patenting and licensing their genome); *see generally* Warne, *supra* note 3.

[172] *See* Warne, *supra* note 3, at 191. Trust can be the most significant barrier to genetic research within the American Indian population. *Id.* at 200.

[173] *See* Harry, *supra* note 101, at 193-96 (explaining tribes have a right and ability to control research that impacts their community by adopting codes and protocols to govern human subject research); *see also* Tsosie, *supra* note 156, at 405-06 (discussing Native American distrust with participating in medical research).

[174] *See* Bommersbach, *supra* note 47, at 134. If researchers operate through the IHS clinic and the tribal members feel that the researchers betrayed their trust, then tribal members may also impute this feeling to the IHS clinic based on a notion of uncertainty or complicity. *Id.*

[175] Brief for Plaintiff, Tilousi v. Arizona State Univ. Bd. of Regents, No. CV2005-013190, 2008 WL 618736 (Ariz. App. Ct. Jan. 31, 2008).

[176] *See* Bommersbach, *supra* note 47, at 134. According to Havasupai Tribal Chairman Don Watahomigie, approximately twenty people are on dialysis for their diabetes because they sought

Professor Rebecca Tsosie, a legal scholar whose work centers on cultural resources and pluralism, describes potential harms arising from genetic research: (1) failing to recognize and honor the meaning of biological materials, (2) worrying that the samples or data will be used for unauthorized purposes, and (3) fearing that information derived from the samples will reveal information about the rest of the tribe and breach the privacy of the tribe and its members.[177] To assess the risk of these first three harms and understand their significance prior to initiating any new research projects, researchers and institutions must examine the significance of biological materials and the implication that their misuse would have both to the individual subject and the entire tribe, including as the case was here, the misuse of the blood samples.

D. Blood: An Interconnected Web of Existence

There has been widespread discussion relating to the notion that blood and bodily materials contain a special significance to many tribes, including the Havasupai.[178] First, blood contains the substance of social identity connecting an individual to relatives and ancestors.[179] Ruth Liloqua, a Solomon Islander, noted that because blood connects people to family members, her tribe traditionally places immense value in knowing and protecting their biological materials and related genealogy.[180] Similarly, Ahora Mead, of the Ngati Awa and Ngati Porou lineage, explains that "a physical gene is imbued with a life spirit handed down from the ancestors."[181] Likewise, according to another woman of Native American lineage, this life spirit "was given [to me] to use and it belongs to the Great Spirit."[182] Thus, biological material and DNA tie the individual to everyone else

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care too late into the progression of their disease. *Id.*

[177] *See* Tsosie, *supra* note 156, at 405-06. As a result of these perceived breaches of privacy, many Native Americans are distrustful of biomedical researchers. *Id.*

[178] *See* Harry, *supra* note 101, at 189-90; Tsosie, *supra* note 156, at 406-07; Singeo, *supra* note 171, at 122.

[179] *See* Harry, *supra* 101, at 190 (discussing how many indigenous peoples have identified a cultural and spiritual relationship with genetic materials).

[180] *See* Harry, *supra* 101, at 190. Indigenous Solomon Islanders also place similar value in protecting other body parts "whether blood, hair, nails, saliva, or placenta." *Id.* "Indigenous peoples have a relationship with DNA akin to that which we have without ancestors – one of reverence, respect and responsibility." *Id.*

[181] *See* Harry, *supra* 101, at 189. "Ngati Aw and Ngati Poror tribes also place great emphasis on physical genes being passed on to future generations." *Id.*

[182] *See* Harry, *supra* 101, at 181. When asked if she would "approve of someone taking a genetic sample from her, claiming ownership through patent, and then possibly making some money from her DNA" the same woman replied, "[i]t would be all right if they took the sample. But as far as owning it, no, I don't think that's right . . . because they can't own a part of my body. I don't even own my body." *Id.*

in the community, ancestors, and a higher power.[183] This means that the tribe views biological materials within an interconnected web of meaning, and that as a result, mishandling one person's blood causes significant damages and disrupts the community, the family, and that person's spiritual welfare.[184]

There is also a close connection between the sacredness of blood in this life and one's welfare in the afterlife.[185] Tsosie describes that "according to Hawaiian custom, human remains are spiritual beings that possess all the traits of a living person."[186] As seen in the context of attempting to retain or repatriate remains, disruption to these remains is viewed as a physical injury to the person who was once living.[187] Similarly, the Havasupai tribe believes that biological materials must be intact to cross from the physical world to the spirit world.[188] If a person is missing part of the physical body at the time of death, then the Havasupai believe the person is "doomed" because this person's spirit cannot travel to the afterlife.[189] To note, after the plaintiffs filed the suit in the Havasupai cases, five of the plaintiffs passed away of diabetes related complications.[190] Consequently, and according to Havasupai belief, the spiritual afterlife of those individuals hinged on the outcome of the litigation and whether ASU physically returned the blood samples.[191] The portion of the Havasupai settlement agreement that dictated the return of blood therefore meant that the tribe could properly bury the blood with the deceased individuals, so the deceased could finally enter the spirit world.[192] Thus, appropriation or misuse of biological materials and DNA has grave cultural implications that in this case could *only* be remedied by the physical return of the blood samples.[193]

The National Congress of American Indians ("NCAI") declaration aptly

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[183] *See Harry*, *supra* note 101, at 181.

[184] *See Harry*, *supra* note 101, at 190 (explaining the collection of DNA through blood samples goes against the Native American's view of the body as sacred).

[185] *See* Tsosie, *supra* note 156, at 406-07; Bommersbach, *supra* note 47; Usborne, *supra* note 97.

[186] *See* Tsosie, *supra* note 156, at 407 (discussing biological materials in the context of human remains, spiritual harm, and repatriation).

[187] *See* Tsosie, *supra* note 156, at 407.

[188] *See* Usborne, *supra* note 97 ("the souls of the dead cannot rest with the spirits if any part of the physical body is absent at the time of the burial"); Bommersbach, *supra* note 47 (members of the tribe who died after giving their blood were "seen as being doomed and prevented from traveling to the Spirit World because their blood was lost").

[189] *See* Bommersbach, *supra* note 47, at 134-35.

[190] *See* Bommersbach, *supra* note 47, at 134-35.

[191] *See* Usborne, *supra* note 97.

[192] *See* Usborne, *supra* note 97.

[193] *See* Usborne, *supra* note 97.

summarizes "[t]he taking of blood, hair, and tissue samples is an affront to the religious beliefs, cultural values, and sensitivities of many indigenous peoples."[194] The centrality of biological materials to both the individual and tribe directly, therefore, directly conflicts with how current law and ethical principles view the meaning of blood.[195] Researchers and institutions reviewing research protocol may still not recognize the significance of blood and biological materials if they view this attachment as "trivial" or "superstitious."[196] In fact, current law and practice often still reflect the incongruous dichotomy that once blood is separated from the body, the law may classify blood as a waste product; whereas, and in the hands of research, the blood contributes to a gold mine of raw materials.[197] Maintaining current legal policy vis-a-vis ownership of biologic materials will likely continue to result in spiritual harm to Native American individuals and tribes.[198]

E. Expanding the Scope of Harm

To prevent this disconnect, researchers, institutions, and courts should factor in

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[194] *See* Harry, *supra* note 101, at 190.

[195] *See* McGregor, *supra* note 82, at 363 (commenting on the differing views of Native Americans and investigators and the resulting inability of investigators to comprehend the cultural harm Native Americans would experience as a result of genetic research).

[196] *See* McGregor, *supra* note 82, at 363 (stating that "[t]o investigators who do not attach spiritual significance to their biological materials, for example, they either would not recognize the significance that the group attaches to them or view their value to biological materials as trivial or superstitious, and therefore not worth acknowledging").

[197] *See* Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 491-95 (Cal. 1990) (classifying excised biological materials as waste); *see also* Jennifer Couzin-Frankel, *Science Gold Mine, Ethical Minefield*, 324 SCI. 166 (2009), *available at* http://sciencemag.org/cgi/reprint/324/5924/166.pdf (referring to the value of newborn blood). At birth, a blood sample from the baby will be taken, which allows physicians to test for "rare metabolic diseases" that must be treated immediately. *Id.* Additionally, baby blood spots are valuable because if stored after birth, they can assist physicians in studying the origins of genetic mutations, birth defects, leukemia, and toxin exposure in-utero. *Id.* at 166-67.

[198] *See* Harry, *supra* note 101. There has been a long ongoing history of researchers perpetuating human subject violations when conducting research with Native American tribes. *Id. See generally* 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 Research be Reconciled?,* FLA J. TECH. L. & POL'Y (forthcoming Fall 2010). Standing to sue, however, requires some type of "judicially cognizable" injury. *See* Allen v. Wright, 468 U.S. 737 (1984) (setting forth and discussing the injury, causation, and redressability requirements for standing). Given the vast differences between the Native American sacred view of biological materials and the more trivial view of modern America, it may continue to be difficult for our court system, with non-Native American tribe members acting as judges, to find that an entire population has suffered an ascertainable injury due to genetic research efforts. *See* McGregor, *supra* note 82.

the potential types of cultural and spiritual harm that arise from the misuse of blood and biological materials. As indicated above, disrupting an individual's biological materials has implications for both the individual and the rest of the tribe. Consequently, researchers, institutions, and courts should re-envision the concept of harm to include group harm, cultural harm, and dignitary harm for research involving Native American populations. Traditionally, the ability to control medical and personal information was solely an individual decision.[199] But, because genetic information also reveals information about the larger group, members should also have a right to be fully informed regarding the breadth of the research that is to be conducted using the materials they have donated.[200]

1. Risks to the Tribe and Group Harm

Genetic research using the biological materials from an individual within a Native American group implicates the rest of the tribe. Since the individual shares the genes with the rest of the tribe, information that the research exposes about the individual also reveals the characteristics of the group.[201] This unique connection of an individual to the group is distinct for Native American tribes based on their insularity and small population size.[202]

Risk of harm to the members of the group mirrors harms that an individual may face based on the release of personal information. These harms include psychological harms, such as shame or humiliation, which can lead to members of the group potentially adopting a deterministic attitude that they possess "defective" or faulty genes.[203] The existence of a genetic correlation with a particular disease may also give

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[199] *See* Laura Underkuffler, *Human Genetics Studies: The Case For Group Rights*, 35 J.L. MED. & ETHICS 383, 387 (2007), *available at* http://onlinelibrary.wiley.com/doi/10.1111/j.1748-720X.2007.00162.x/pdf.

[200] *See id.* at 387 (discussing how it is impossible for genetic information to pertain to solely one individual, and therefore, collection of genetic material raises the issue of whether the members of the gene pool to which it pertains deserve some sort of control over the information as well as the individual). Genetic testing can reveal a tendency to develop certain diseases in the subject of the test and also their family members. *See* Henry T. Greely, *Genes, Patents, and Indigenous Peoples: Biomedical Research and Indigenous Peoples' Rights*, 20 CULTURAL SURVIVAL QUARTERLY 54, 57 (1996), *available at* http://culturalsurvival.org/publications/cultural-survival-quarterly/canada/genes-patents-and-indigenous-peoples-biomedical-rese.

[201] *See* McGregor, *supra* note 82, at 362.

[202] *See generally* Tsosie, *supra* note 156, at 402 (discussing why tribes are distinct from other identifiable population groups).

[203] *See* McGregor, *supra* note 82, at 362-63 (discussing the kinds of risks to third parties and identifiable groups that may arise from the disclosure of genetic research findings).

rise to stereotypes about the individuals and the tribe itself.[204] Focusing on genetic causations of disease without acknowledging non-genetic factors can result in stigmatization of the tribe as being inherently flawed.[205] Harry notes how recent scientific journal headlines have proclaimed a certain tribe possesses the "warrior gene" or "alcoholism gene," which is indicative of research that prioritizes genetic factors over other determinants of health.[206] For instance, Harry points to how a history of colonization and oppression, together with a loss of land and culture, poverty, and exposure to environmental contamination are factors that are ignored by proclamations, which improperly attribute behavior solely to genetics.[207] Bill Freeman, a physician and former director of IHS, also noted that this stigma is one reason that tribes are hesitant to participate in mental health research. Referring to the Havasupai, Freeman noted, "[s]chizophrenia is a stigmatizing condition . . . no one wants to be known as the 'crazy tribe.' Doing that research without specific permission from the subjects is a real harm."[208] In addition to mental health studies, researchers may target tribes based on their genetic homozygosity and publish studies declaring inbreeding among the tribe, as researchers did in the Havasupai case.[209] Beyond the clear stigma from such a pronouncement, this allegation poses additional individual and group harm. For instance, according to Carletta Tilousi, the Havasupai believe that inbreeding causes a close relative to die, which means the mere hypothesis of such research can lead to un-consented to mental and emotional anguish among the tribe.[210]

2. Cultural Harm

In addition to group harms, participation and research results can produce cultural harm to the tribe. Release of research results can cause community disruption if

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[204] *See* McGregor, *supra* note 82, at 363. For example, genetic research revealed lymphotropic viruses spread by the use of intravenous drug used by the Nuu-chah-nulth of Vancouver Island, Canada resulted in risk of stigmatization to the group as a whole. *Id.*

[205] *See* Harry, *supra* note 101, at 154 (questioning the ethics involved in linking a gene to a race); *see also* McGregor, *supra* note 82, at 363 (referencing stereotypes experienced by Ashkenazi Jews and Native Americans).

[206] *See* Harry, *supra* note 101, at 153. A genetic epidemiologist claimed that the Maori people in Aoteoroa/New Zealand have a "striking representation" of monoamine oxidase, which has been called the "warrior gene." *Id.* This notion of the "warrior gene" means that the Maori people are going to be more aggressive and violent and more likely to engage in risk-taking behavior. *Id.*

[207] *See* Harry, *supra* note 101, at 154 (noting that many non-genetic factors might also explain group behavior).

[208] *See* Rubin, *supra* note 37.

[209] *See* Hart, *supra* note 5, at 118, 125-26.

[210] *See* Amy Harmon, *Indian Tribe Wins Fight to Limit Research of Its DNA*, N.Y. TIMES, Apr. 21, 2010, at A1.

study results conflict with the group's closely held beliefs about their identity, origin, historical narrative, and spiritual traditions.[211] Cultural harm is defined by Native American tribes as "actions or practices that . . . would challenge or disparage their spiritual traditions, historical narratives, or traditional beliefs."[212] Disruption can take the form of loss of solidarity or barriers to social traditions and operations.[213] Members of the tribe may initially assist in the research process based on the belief that they are helping the tribe, but if they subsequently discover the reason for or impact of the research, then they could feel a sense of complicity in acting against the interests of the group and face being outcast as a result. Members of the Havasupai tribe that helped recruit donors expressed that their participation was subject to personal cultural shame because they thought they misled or failed the tribe.[214] This creates harm to the individual, who participated in the research process, because it undermines this individual's sense of individual altruism, as well as the individual's cultural and spiritual connection to the community.

There are several instances in the research studies, some of which used the Havasupai's blood samples, where the research conclusions critically undermined the tribe's spiritual traditions or belief of origin.[215] For instance, Markow based her initial grant application and IRB submission for research involving the Havasupai on the assumption that the tribe's revered shaman who lived during the 1880s was merely a man with schizophrenia.[216] Such a categorization ignores the history and importance to Havasupai and other Native American tribes of the shaman as the intermediary between the physical and spiritual worlds.[217]

Similarly, publications on migration theories undermine many of the tribe's beliefs of origin. The Bering Strait migration theory, for example, posits that all Native American people originally lived in Asia, traveled through Siberia and the Bering Strait

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[211] *See* McGregor, *supra* note 82, at 363 (discussing risks of research results to third parties).

[212] *See* McGregor, *supra* note 82, at 363. The existence of multiple and varying threats to the identity of a group and to their own self-understanding can be a serious cultural harm. *Id.*

[213] *See* Lainie Friedman Ross et al., *Human Subjects Protections in Community-Engaged Research: A Research Ethics Framework*, 5 J. OF EMPIRICAL RESEARCH ON HUMAN RESEARCH ETHICS 5, 11 (2010).

[214] *See* Harmon, *supra* note 210 (noting how one Havasupai woman felt she had disappointed her tribe by recruiting blood donors).

[215] *See* Hart, *supra* note 5, at 87-88 (discussing how Markow failed to realize that research relating to the Bering Strait theory of migration would be upsetting to the Havasupai).

[216] *See* Hart, *supra* note 5, app. A at 168.

[217] *See generally* Harry, *supra* note 101 (discussing the need to protect rights and interests of indigenous peoples when conducting human genetic research).

land bridge into what is now Alaska, and dispersed throughout the United States.[218] For many tribes, including the Havasupai, this assertion directly contradicts their belief of creation. The Havasupai believe that a global flood retreated to create the Grand Canyon; they and the human race emerged from floor of the Grand Canyon, and the Creator assigned the Havasupai to be the Grand Canyon's guardian.[219] Research results that conflict with a tribe's original narrative can undermine how a group identifies itself and further threaten community cohesion.[220]

Despite the obvious cultural harms such publications trigger, researchers are mandated to focus only on the harms to the individuals.[221] Notably, when Markow described the research on the Bering Strait theory, she explained it "[never] occur[red] to her that the research may be upsetting to the [tribe]."[222] Even a *New York Times* editorial dismissed the sensitive issue of cultural identity by stating the Havasupai "deplored" the migration research because it ran contrary to "their traditional *myths*."[223] These statements suggest not only a profound disconnect, but a complete failure to acknowledge the legitimacy of an entire distinct cultural system.[224] Furthermore, failing to recognize the significance of blood and biological materials is in and of itself a cultural harm to tribes because it is central to both individual and tribal identity.[225]

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[218] *See* Harry, *supra* note 101, at 161-62 (discussing use of molecular anthropology studies to develop theories of human migration). Researchers compared indigenous DNA to ancient DNA taken from the same geographical area and developed a migration theory. *Id.*

[219] *See* Harmon, *supra* note 210 (detailing tribe's traditional stories of its origin as rising up from the Grand Canyon to protect it); Rubin, *supra* note 37 (explaining tribal history of a great flood that produced the Grand Canyon and their tribe).

[220] *See* McGregor, *supra* note 82, at 363 (explaining potential harms of genetic determinism). Results of a study may risk creating a feeling of self-stigmatization, which is a common problem that occurs around the time that the research results are published. *Id.*

[221] *See* McGregor, *supra* note 82, at 363 (acknowledging researchers do not address various risks beyond mandated concern for individual physical harm).

[222] *See* Hart, *supra* note 5, at 87-88. Markow went on to say that she was not even sure at what point to seek further consent from the tribe once a study significantly deviated from its originally communicated goals. *Id.* at 88.

[223] Editorial, *Tribal Genes and a Fair Settlement*, N.Y. TIMES, Apr. 26, 2010, at A22 (emphasis added).

[224] *See* McGregor, *supra* note 82, at 365. McGregor discusses why research that conflicts with North American tribes' religious beliefs is a real risk that must be disclosed during the informed consent process. *Id.* McGregor distinguishes this from research censorship, such as when the religious community attempted to censor Galileo because his research showed that the Earth was not the center of the universe and would thus upset that widely held world view. *Id.* The two examples are inapposite, as the former deals with distinct individuals and communities whose consent is required; whereas, the latter included no humans and thus required no consent. *Id.*

[225] *See* McGregor, *supra* note 82, at 363.

Procuring blood without proper consent and subsequently using it for unauthorized research obstructs an individual's ancestral connection, as well as the connection to the Creator.[226] As described above, this harm is compounded when the tribe is prohibited from practicing specific spiritual traditions, such as ensuring a person's biological materials are intact at the time of burial.[227]

3. Dignitary Harm

This divide between what researchers, institutions, and the courts view as reasonable beliefs and harms also causes dignitary harm to individuals within the tribe and the tribe itself.[228] If actions by researchers and institutions harm the practices, identity, or cohesion of the tribe, then the principle of dignitary harm is similarly implicated.[229] Such harm arises when researchers insult an individual's domain of control; in this instance, the individual's right over one's own biological materials.[230] Jurisprudence relating to donating biological materials holds that once the biological material is removed from the body, the individual is precluded from exerting control over that material.[231] However, that holding conflicts with some tribes' beliefs that the

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[226] *See* McGregor, *supra* note 82, at 363. McGregor suggests that intra-group harm can cause the breakdown of their relationships within the group, harm to self-identity, and spiritual harms that define who they are and where they come from. *Id. See also* Tsosie, *supra* note 156, at 403.

[227] *See also* Tsosie, *supra* note 156, at 403. Tsosie discusses two different ways to view cultural harm. *Id.* One way to view cultural harm is when the harm arises from situations in which Native peoples' access to their own cultural systems is somehow blocked or precluded. *Id.* Tsosie further explains that this harm continues to occur today in cases "where the federal government allows land use development that jeopardizes Native access to sacred sites on government land or precludes groups from repatriating Native American human remains that are culturally tied to contemporary groups within their own traditions and belief systems." *Id.*

[228] *See* McGregor, *supra* note 82, at 363. McGregor discusses the two types of harm caused from research, tangible, and dignitary harm. *Id.* According to McGregor, dignitary harms to a group include undermining the value of the group in the eyes of others, treating the group disrespectfully or in a humiliating manner, and treating the group as less than or subordinate to others. *Id.* Cultural harm is categorized as dignitary harm. *Id.* Cultural harm arises when a group's rights to their own culture are violated. *Id.*

[229] *See* McGregor, *supra* note 82, at 363. McGregor goes on to further state that other harms to Native Americans include practices that challenge their spiritual tradition, historical narratives, or traditional beliefs. *Id.*

[230] *See* McGregor, *supra* note 82, at 362. McGregor provides an example of dignitary harm. *Id.* "Dignitary harms might occur by giving a person's biological specimen away or putting it in a repository, which might be later used without her approval . . . ." *Id.*

[231] *See e.g.*, Moore v. Regents of the Univ. of Cal., 793 P.2d 479 (Cal. 1990). Moore underwent treatment at the UCLA Medical Center after he discovered he suffered from hairy-cell leukemia. *Id.* at 481. As part of Moore's treatment, the doctors at the UCLA Medical Center withdrew

extensive amounts of Moore's blood, bone marrow, and other bodily substances. *Id.* When the doctors removed Moore's blood, they were aware that it was of significant value to commercial and scientific efforts. *Id.* Moore continued to receive treatment from UCLA Medical Center over the course of approximately seven years, based upon the representations by his doctors that such treatment was necessary for his health and well-being. *Id.* During Moore's treatments, the doctors continuously withdrew additional blood samples, and they conducted research on Moore's cells. *Id.* The doctors eventually developed a cell line from Moore's blood cells and applied for a patent, all without Moore's knowledge. *Moore*, 793 P.2d at 481-82. The doctors negotiated an agreement with the Genetics Institute and acquired 75,000 shares of common stock, as well as $330,000.00, over the course of three years. *Id.* at 482. Moore sued UCLA Medical Center and several doctors for thirteen causes of action, including conversion. *Id.* Moore argued that he continued to own his cells after the doctors removed them from his body; therefore, he never consented for his cells to be used for lucrative medical research. *Id.* at 487. The court reasoned that in order to recover for conversion, Moore had to retain an ownership interest in his excised cells. *Id.* The court stated that Moore could not recover on the theory of conversion because there was no reported judicial decision to support his claim; California statutory law limits any continuing interest of a patient in excised cells, so the patented-cell line could not be Moore's property. *Id.* The court held that the use of the medical research results was inconsistent with Moore's wishes, but it was not conversion because Moore had no property interest after the donation was made. *Moore*, 793 P.2d at 487. *See also* Greenberg v. Miami Children's Hosp. Research Inst., 264 F. Supp. 2d 1064 (S.D. Fla. 2003). Greenberg, a parent of a child who suffered from Canavan disease, approached Dr. Matalon, a research physician, to help discover the gene that caused Canavan disease. *Id.* at 1066. Canavan disease is a rare genetic disease that occurs most frequently in Ashkenazi Jewish families. *Id.* Greenberg located other Canavan families and convinced them to provide Dr. Matalon with tissue and financial support for research. *Id.* Using the families' blood and tissue, Dr. Matalon isolated the gene that caused Canavan disease. *Id.* at 1067. After Dr. Matalon discovered the gene that caused Canavan disease, he applied for a patent application in order to restrict any research activity related to Canavan disease. *Id.* Plaintiffs filed suit against Dr. Matalon alleging that they had a property interest in their body tissue and genetic information. *Greenberg*, 264 F. Supp. 2d at 1074. The court declined to find that the families had a property interest in either their body tissue or genetic information because the families gave donations for research without the expectation of the body tissue or genetic information being returned. *Id.* The court also reasoned that the families gave up their property interest when they freely gave donations to a third party. *Id.* at 1075. The court held that if it found in favor of the families it would "cripple medical research as it would bestow a continuing right for donors to possess the results of any research conducted . . ." *Id.* at 1076. *See also* Wash. Univ. v. Catalona, 490 F.3d 667 (8th Cir. 2007). Washington University ("WU"), a private research university, employed Dr. Catalona, a urologic surgeon, to perform surgery on prostate cancer patients. *Id.* at 670. Dr. Catalona was also employed by WU to perform prostate cancer research by using patients' blood and tissue that were removed during surgery. *Id.* While employed at WU, Dr. Catalona helped establish a bio-repository (a storage facility for biological samples). *Id.* A few years later, Dr. Catalona left WU and accepted a faculty position at Northwestern University ("NWU"). *Id.* at 672. However, Dr. Catalona still wanted to conduct research on prostate cancer. *Id.* As a result, Dr. Catalona sent a letter to all of his patients and other individuals who previously provided biological samples informing them of his departure from WU and requesting a transfer of the biological materials. *Catalona*, 490 F.3d at

excised biological material is still part of the individual and holds the essence of the individual.[232] By overlooking this belief when determining what constitutes a legal harm, a dignitary harm to the individual is produced because it undermines the individual's right to control what is still viewed as part of one's self.[233] McGregor observes that using biological materials outside the scope of consent in this manner not only demonstrates a lack of respect for the individual, but it also signals that the individual's framework to conceptualize the meaning of biological materials is subordinate to the researcher's.[234]

To classify these concepts, Friedman Ross and colleagues created a harm analysis grid to categorize risks to well-being and agency, on both the individual and group level, as well as to mitigate future harms in these research contexts.[235] The grid describes the potential risks to agency from the individual perspective, the individual by relation to the group, and the community.[236] Causing group and cultural harm undermines the principles of autonomy and authority on both the personal level and group level.[237] Friedman Ross and colleagues note that ASU's failure to obtain proper consent from the Havasupai illustrated how researchers harmed the moral agency of the

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672. Approximately six thousand patients wrote to Dr. Catalona granting him permission to transfer their biological materials. *Id.* WU filed a declaratory judgment action against Dr. Catalona alleging that WU owned the bio-repository and the biological materials stored in it. *Id.* Dr. Catalona counterclaimed, seeking a declaration that the contributing individuals could direct the transfer of their biological materials to him. *Id.* The court considered whether individuals who make an informed decision to voluntarily contribute biological materials for the purpose of medical research retain an ownership interest allowing individuals to direct or authorize the transfer of such materials to third parties. *Id.* at 673. The court answered in the negative and held that neither Dr. Catalona nor the contributing individuals had any ownership or proprietary interest in the biological materials; rather, WU owned the disputed biological materials. *Id.*

[232] *See* Tsosie, *supra* note 156, at 405. Native groups seek to protect the integrity of bodily substances against potential abuses that may affect the individual or the individual's family. *Id.* This concept holds true even after the bodily substances are removed from the body. *Id.*

[233] *See generally* McGregor, *supra* note 82, at 363.

[234] *See* McGregor, *supra* note 82, at 365. McGregor further notes, "the advancement of scientific knowledge is not such an important value that it trumps the interests of subjects understanding the risks of the research they are being asked to join—groups and cultural risks included," and that "the foundation of informed consent is respect for persons, which we can now extend to respect for groups, and that means respect for *their* values." *Id.* (emphasis added).

[235] *See* Friedman Ross et al., *supra* note 213, at 8-9 (describing taxonomy of risks).

[236] *See* Friedman Ross et al., *supra* note 213, at 9 (noting that structured and non-structured groups are susceptible to what is termed "individual by group" risks but that only structured groups are susceptible to community risks).

[237] *See* Friedman Ross et al., *supra* note 213, at 9-10 (characterizing risk to agency as an undermining of personal or group authority).

individual and the tribe because they failed to respect the individuals' decision-making and the tribe's right to refuse participation in particular research projects.[238] Undermining the moral agency of the individual and the group inherently connects to the group's moral and sociopolitical authority.[239] In this instance, the course of research further undermined the tribe's authority to practice self-governance when the ASU refused to return the blood.[240] Refusing to return the blood produced multiple harms from the Havasupai's perspective: it disrupted individual sense of identity, disconnected individuals from their ancestral web, and prohibited recently deceased tribal members, who had donated blood, to travel to the afterlife.[241] When the tribe sought redress through the legal system, the district court in *Tilousi v. Arizona State University Board of Regents* compounded the harm to the tribe when it found as a matter of law that ASU's actions did not amount to actionable harm for many of the plaintiffs' claims.[242]

Several scholars have connected how perpetuating dignitary harm in the research context parallels colonialism.[243] However, as the Havasupai case indicates, many tribes are not only uninterested in research to inform them of their ancestry or migration, but such research is offensive and constitutes a threat to the cohesion and very continuation of the tribe.[244]

Tellingly, the academic community fully recognized Markow's work as "progress" in the research field.[245] Benyshek described Markow as a "true star" when she worked at ASU, who prolifically obtained grants, wrote numerous articles, and earned the prestigious title of Regents Professor.[246] These designations of progress in

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[238] *See* Friedman Ross et al., *supra* note 213, at 11 (noting that moral agency was undermined because the group had not given consent to additional uses of its blood samples).

[239] *See* Friedman Ross et al., *supra* note 213, at 9. Friedman Ross explains how the devaluation of cultural concerns expressed by community leadership calls into question the leader's moral authority and responsiveness to group members needs. *Id.* This in turn may have negative repercussions for community members' relations with leadership and for their relations with other members of the group. *Id.*

[240] *See* Rubin, *supra* note 37.

[241] *See* Rubin, *supra* note 37, at 8 (discussing the religious need among the Havasupai to have a ceremony with ASU officials present to bury the blood taken).

[242] *See* Tilousi v. Ariz. State Univ. Bd. of Regents, No. 04-CV-1290, 2005 WL 6199562 (Ariz. Dist. Ct. Mar. 3, 2005); *see also supra* notes 73-89 and accompanying text (discussing inadequacy of ruling).

[243] *See generally* Harry, *supra* note 101 (discussing the impact of colonialism and environmental abuses on diseases).

[244] *See* Tano, *supra* note 4, at 303.

[245] *See* Bommersbach, *supra* note 47, at 134-35.

[246] *See* Bommersbach, *supra* note 47, at 134-35; *see also* Hart, *supra* note 5, at 25.

the scientific arena overlook the damage of this neo-paternalism to the research subjects themselves. Annas summarized, "[w]e're taking from them their DNA, which we now consider life gold. It's even worse than standard colonialism and exploitation because we are taking the one thing they value. And after we take that, we have no real interest in whether they live or die."[247] Displacement from land or control over biological materials comes with the price of alienation from one's self, one's tribe, and one's culture.

V. Conclusion

The combination of a high incidence of health conditions among Native American tribes, along with tribes' genetic insularity, means that researchers will continue to seek their participation to contribute biological material to study genetic underpinnings of disease. The Hart Report's investigation into ASU's research conduct related to the collection and use of the Havasupai's blood samples revealed egregious shortcomings in the consenting process and how ASU's subsequent actions deviated from representations made to the subjects. In particular, the investigation showed ASU researchers initiated research prior to obtaining approval from the IRB for any project, conducted research outside the scope of consent, ignored promises of privacy, and failed to consider that these actions could produce devastating effects on members of the tribe and the tribe as a whole. Despite these discoveries, the judicial system problematically mirrored an inherent flaw in the connection by summarily dismissing allegations of legal harm because the legal system does not recognize the profound significance of blood to the tribe and why ASU's additional research caused the tribe extreme harm. Furthermore, after the parties consolidated the two lawsuits and finally reached a settlement, the damages portion of the agreement between the Havasupai and ASU also suggests that despite the information revealed in the Hart Report and argued in litigation, ASU still may not comprehend the severity and gravity of actual harm the ASU research team inflicted upon the tribe and its members.

The Havasupai case provides an unfortunate checklist of shortcomings in federal law governing human subjects research and research compliance in practice. To minimize the possibility of repeating harmful research practices against another tribe, researchers and institutions should acknowledge gaps in the current federal law and compliance mechanisms. This means recognizing the Common Rule's coverage based on identifiability is insufficient to shield subjects who donate biological materials from un-consented to risks. Subjects may experience significant psychosocial risks even

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[247] *See* Harry, *supra* note 101, at 182.

without consideration of re-identification; further, many IRBs fall short of ensuring that their institution's protocols include vitally relevant information to subjects, which would also allow the subjects to be fully informed prior to consenting to the research.

Finally, to address these shortcomings, researchers and institutions should re-envision research standards from the subjects' perspective. Because Native American tribes are sovereign political entities, we must respect and honor these groups' potentially distinct analyses of what constitutes a harm or benefit of research. Comprehending these assessments requires researchers and institutions to understand that according to several tribal belief systems, blood and biological materials are integral to a sense of identity, they are spiritually significant, and they form the basis of cultural cohesion. Researchers and institutions should expand the scope of what is considered legitimate and cognizable harm arising from the misuse of an individual's biological material. Within this consideration, researchers and institutions should recalculate potential harm to include each of the following. First, researchers and institutions should acknowledge that individual subjects share genes with the rest of the tribe, so research involving some of the tribe implicates the rest of the tribe and can expose the entire tribe to stigma, stereotypes, and discrimination. Second, researchers and institutions should consider the potential for cultural harm from conducting and publishing research that would threaten a tribe's identity, historical narrative, or spiritual traditions, and consequently, undermine the internal cohesion among tribal members. Lastly, researchers and institutions should note that overlooking these risks of harm undermines the agency, autonomy, and authority of both individual subjects and the tribe itself.