

PROTECTING INTANGIBLE CULTURAL RESOURCES: ALTERNATIVES TO INTELLECTUAL PROPERTY LAW

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INTRODUCTION.....	363
I. THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH..	367
A. <i>Review and Risk</i>	370
B. <i>General Requirements of Informed Consent</i>	372
C. <i>Enforcing Human Subjects Protections</i>	373
D. <i>HHS's Advance Notice of Proposed Rulemaking</i> <i>(ANPRM)</i>	374
E. <i>Tribal Regulation of Research Involving Human Subjects</i> ..	377
II. AVAILABILITY OF TORT LAW FOR PROTECTING INTANGIBLE CULTURAL RESOURCES	381
A. <i>Tort Law and Researcher Violations</i>	381
B. <i>Actions in Negligence</i>	382
1. The Element of Duty	383
2. Standard of Care	386
3. Breach of Duty	388
4. Actual Harm	388
CONCLUSION	390

INTRODUCTION

Cultural resources can be defined as “the tangible and intangible effects of an individual or group of people that define their existence, and place them temporally and geographically in relation to their belief systems and their familial and political groups, providing meaning to their lives.”¹ The field of cultural resources includes tangible items, such as land, sacred

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1. Angela R. Riley, “*Straight Stealing*”: *Towards an Indigenous System of Cultural Property Protection*, 80 WASH. L. REV. 69, 77 (2005) (quoting SHERRY HUTT ET AL., *CULTURAL PROPERTY LAW* xi (2004)). This definition parallels many others in the indigenous rights literature. The United Nation’s Human Rights Sub-Commission defines heritage as “all objects, sites and knowledge, including languages, the nature of which has been transmitted from generation to generation, and which is regarded as pertinent to a particular people or its territory of traditional natural use.” U.N. ESCOR Comm’n on Human Rights, *Report of the Seminar on the Draft Principles and Guidelines for the Protection of the Heritage of Indigenous Peoples*, ¶ 12, E/CN.4/Sub.2/2000/26 (June 19, 2000). WIPO defines traditional knowledge as that which is

generated, preserved and transmitted in a traditional and intergenerational context; distinctively associated with a traditional indigenous community of people which preserves and transmits it between generations; and is integral to the cultural identity of an indigenous or traditional community of people which is recognized as

sites, and religious and funerary objects. The field also includes intangible knowledge and customs, such as tribal names, symbols, stories, and ecological, ethnopharmacological, religious, or other traditional knowledge.² The tangible cultural resources of tribes can fall under the protection of statutes such as the Archeological Resources Protection Act of 1979³ and the Native American Graves Protection and Repatriation Act, 1990 (NAGPRA).⁴ The protection of intangible cultural resources, however, is less codified.⁵

The provision of legal protection for intangible cultural resources has focused almost entirely on either linking such protection to human rights or defining intangible culture as intellectual property (IP).⁶ The United Nations Declaration on the Rights of Indigenous Peoples provides for the rights of indigenous groups to maintain and develop their culture and advises member states to establish protections for indigenous culture, both tangible and intangible.⁷ The United Nations Educational, Scientific, and Cultural Organization (UNESCO) has further developed the area through its Human Rights Sub-Commission's Draft Principles and Guidelines for the Protection of the Heritage of Indigenous Peoples, the Convention for the Safeguarding of the Intangible Cultural Heritage (2003), and other documents. Early work on defining intangible cultural resources as IP was conducted jointly by UNESCO and the World Intellectual Property Organization (WIPO), which led to the Model Provisions for National Laws on the Protection of Expressions of Folklore Against Illicit Exploitation and Other Prejudicial Actions (1985). Work by WIPO continues today through its Intergovernmental Committee on Intellectual Property and

holding the knowledge through a form of custodianship, guardianship, collective ownership or cultural responsibility.

WORLD INTELLECTUAL PROP. ORG., REVISED DRAFT PROVISIONS FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE: POLICY OBJECTIVES AND CORE PRINCIPLES, at annex 22 (2006).

2. FELIX COHEN, HANDBOOK OF FEDERAL INDIAN LAW § 20.01 (2012). WIPO, through its Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, has divided intangible cultural resources into three categories: traditional knowledge, genetic resources, and "traditional cultural expressions" or "expressions of folklore." *Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions/Folklore*, WIPO, <http://www.wipo.int/tk/en/> (last visited Mar. 9, 2013).

3. 16 U.S.C. §§ 470aa–470mm (2006).

4. 25 U.S.C. § 3005 (2006) (providing a mechanism for the repatriation of human remains, funerary objects, "sacred objects," and "objects of cultural patrimony" associated with federally-recognized tribes).

5. See COHEN, *supra* note 2, § 20.

6. For a discussion of the field of tangible and intangible cultural property, and efforts to protect it, see Kristen A. Carpenter, Sonia K. Katyal & Angela R. Riley, *In Defense of Property*, 118 YALE L. J. 1022 (2009).

7. Declaration on the Rights of Indigenous Peoples, G.A. Res. 61/ 295, U.N. Doc. A/ Res/61/295, art. 11–13, 31 (Sept. 13, 2007).

Genetic Resources, Traditional Knowledge and Folklore.⁸ This is complemented by a growing body of law, mostly in other countries, using property law to halt cultural appropriation from indigenous communities.⁹

However, as it stands, IP law, in general, may be a poor fit for tribes. In the tribal context, rights to traditional knowledge and other forms of intangible cultural resources may be dispersed among members in ways in which IP would recognize as placing them in the public domain. Thus, IP law would not protect those rights. Copyright protection, for instance, extends only to "original works of authorship."¹⁰ But traditional arts, customs, and expressions, often the target of for-profit appropriation by outsiders, can no longer be traced to an author. In the originating society, informal rules of traditional deference operate to keep intangible cultural resources in the proper hands. Outsiders, however, may not follow these protocols. If such informal rules cannot be upheld by IP law, the originating culture will be left without remedy for misappropriation.¹¹

Additionally, traditional knowledge may also be sacred, or otherwise secret, and require special usage.¹² IP law offers trade secret and patent protection, but it does not offer protection for traditional knowledge such as knowledge of religious rituals or folktales. Trade secret protection requires that the information is "used in one's business" and is "not generally known."¹³ Neither of these is characteristic of traditional knowledge. The element of "used in one's business" demonstrates that the aims of IP law diverge from tribal interests because the primary goal of IP law is the commoditization of knowledge, whereas tribes want protection from that very process, as well as privacy.¹⁴ Tailoring these laws to fit tribal needs and purposes requires expansion of law in ways that Congress currently does not support.¹⁵ If Congress was supportive, however, Native legal scholars note that adoption of the IP framework by tribes could function to fossilize intangible cultural resources and would generally be a neo-colonialist enterprise working against tribal self-determination and sovereignty.¹⁶ These problems show that tribes need alternatives to the protection of intangible cultural resources through human rights and IP frameworks.

8. *Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions/ Folklore*, *supra* note 2.

9. *Id.*

10. 2 WILLIAM F. PATRY, PATRY ON COPYRIGHT § 4.1(2012).

11. See COHEN, *supra* note 2, § 20.01.

12. *Id.*

13. 1 MELVIN F. JAGER, TRADE SECRETS LAW §§ 5:6-5:7 (2012).

14. *Id.* See generally Rosemary Coombe, *The Recognition of Indigenous Peoples' and Community Traditional Knowledge in International Law*, 14 ST. THOMAS L. REV. 275 (2001); James D. Nason, *Traditional Property and Modern Laws: The Need for Native American Community Intellectual Property Rights Legislation*, 12 STAN. L. & POL'Y REV. 255 (2001).

15. See Riley, *supra* note 1, at 85-86.

16. *Id.* at 86-88, 119.

This Comment explores alternatives that exist in the form of regulation of research and tort actions against researchers who violate these regulations. It is premised on the observation that one of the primary means by which culture has been appropriated from American Indian communities has been through social scientific research.¹⁷ Indians¹⁸ are among the most heavily studied groups in fields like medicine, public health, and, recently, genetics.¹⁹ Yet anthropology, more than any other discipline, has made American Indians the subjects of research.

Anthropology began as a social science in the mid-nineteenth century and distinguished itself by specializing in non-Western (called “primitive,” at the time) cultures. The cultural, linguistic, and physical differences between the indigenous population of North America and the colonizers from Europe motivated the testing of theories. Reservations offered a captive population of human subjects. In return for access to data, anthropologists offered help in assimilation. In 1879, the federal government organized the Bureau of American Ethnology to collect research on the archaeology and ethnography of North America. Anthropologists were hired to study indigenous people scientifically so that the government could more effectively administer to these people. Due to academic anthropology’s adherence to the principle of intellectual freedom and the nature of Bureau anthropologists’ as agents of the federal government, ethnographic collections of intangible cultural resources were made available to the public. This was a problem because American Indians considered much of this data sensitive and private.²⁰ Such actions, as well as the motivations behind them, set the stage for contemporary mistrust of scientific research in Indian country.²¹

Today, researchers studying Indian populations face the criticisms that their research serves the needs of the dominant society rather than the Indian community.²² Critics also argue that there is generally a lack of

17. Here, I analogize from Russel Lawrence Barsh, *Who Steals Indigenous Knowledge?*, 95 AM. SOC’Y INT’L L. PROC. 153, 154 (2001) (arguing that biopiracy results more from academics publishing research than pharmaceutical corporations’ patents).

18. In conformity with conventions in federal Indian law, the term Indian or American Indian is used throughout this paper rather than the term Native American. Nearly all federal statutes and federal agencies use the term Indian.

19. See Ron J. Whitener, *Research in Native American Communities in the Genetics Age: Can the Federal Data Sharing Statute of General Applicability and Tribal Control of Research be Reconciled?*, 15 J. TECH. L. & POL’Y 217, 218–19 (2010).

20. The Bureau of American Ethnology, before it merged with the Smithsonian in 1965, published eighty-one *Annual Reports*, two hundred *Bulletins*, and over forty other publications of ethnographic and archaeological materials from North (and South) American research projects. *List of Publications of the Bureau of American Ethnology*, SMITHSONIAN LIBR., <http://www.sil.si.edu/DigitalCollections/BAE/Bulletin200/200conts.htm> (last visited Mar. 9, 2013). Academic publishing has been more robust.

21. Whitener, *supra* note 19, at 242.

22. NAT’L CONG. OF AM. INDIANS, COMMENTS ON ADVANCED NOTICE OF PROPOSED RULEMAKING (ANPRM) FOR “HUMAN SUBJECTS RESEARCH PROTECTIONS: ENHANCING

benefit to the communities studied, that research subjects are often treated without dignity, and that the publication of cultural and religious information impacts the efficacy or significance of the beliefs.²³ Critics further argue that the current regulations governing research on human subjects fail to prevent these and other harms to indigenous peoples.²⁴

In the first part of this Comment, I review this system of federal regulations, in particular, the evaluation of risk to human subjects in approving research, the general requirements of informed consent, and the mechanisms of enforcement. Additionally, I discuss proposed changes to the federal system that will impact tribes' ability to protect intangible cultural resources, and what tribes can and should do to protect their interests by regulating research on their citizens.

Second, this Comment explores the opportunities that tort law offers for the protection of intangible cultural resources. First, I review how tort law is increasingly encompassing harms to research subjects. This will include a discussion as applied in *Havasupai Tribe v. Arizona Board of Regents*, a tort case alleging harm to tribal research subjects.²⁵ I will then describe the elements of a tort case and explain how these elements can be satisfied by drawing on the federal regulations for human subjects protections. The use of tort law can be an alternative to protecting intangible cultural property with IP law. By utilizing the existing framework for research regulation and tort law, tribes can stem the flow of cultural appropriation while allowing tribal political and cultural sovereignty to continue to grow.

I. THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

Before 1974, there were no federal laws or regulations that specifically protected human subjects in research.²⁶ International documents such as the Nuremberg Code established ethical standards, but such documents were not binding on U.S. agencies.²⁷ In 1974, the Department of Health, Education, and Welfare promulgated its first regulations for human subjects research.²⁸ Also at this time, Congress passed the National Research Act, which created the National Commission for the Protection of Human

PROTECTIONS FOR RESEARCH SUBJECTS AND REDUCING BURDEN, DELAY, AND AMBIGUITY FOR INVESTIGATORS" (2011); MODEL TRIBAL RESEARCH CODE 1 (Am. Indian Law Ctr. 1999), available at <http://www.nptao.arizona.edu/research/NPTAOResearchProtocolsWebPage/AI-LawCenterModelCode.pdf>.

23. MODEL TRIBAL RESEARCH CODE 1 (Am. Indian Law Ctr. 1999), available at <http://www.nptao.arizona.edu/research/NPTAOResearchProtocolsWebPage/AI-LawCenterModelCode.pdf>.

24. *Id.*; NAT'L CONG. OF AM. INDIANS, *supra* note 22.

25. 204 P.3d 1063 (Ariz. Ct. App. 2008).

26. Beth S. Rose & Vincent Lodato, *Litigation: The Role of Class Actions in Litigation Involving Human Research Subjects*, 3 Med. Res. L. & Pol'y Rep. (BNA) No. 9, at 1 (May 5, 2004).

27. *Id.* at 2.

28. *Id.*

Subjects of Biomedical and Behavioral Research (National Commission).²⁹ The National Commission's recommendations were published as *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1979) (commonly known, and referred to here, as the "Belmont Report"). Three key guidelines were set for scientific research, all of which were built into the current regulatory scheme: respect for persons, from which is derived the principle of informed consent; beneficence, from which is derived the cost-benefit analysis of research approval; and justice, which promotes fair subject selection criteria.³⁰

In 1981, the Department of Health and Human Services (HHS) developed new regulations for the protection of human subjects based on the Belmont Report. The FDA followed, and soon after numerous federal departments and agencies began developing similar regulations. Today, the HHS regulations, codified at 45 C.F.R. pt. 46, are known as the Common Rule. The Office for Human Research Protections (OHRP), within HHS, implements the regulations.³¹

HHS's Protection of Human Subjects regulations, 45 C.F.R. pt. 46, apply to "all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency" adopting the Common Rule.³² Each federal department or agency that has adopted the Common Rule is governed by its own regulations.³³ The head of that department or agency "retains final judgment as to whether a particular activity conducted or supported by the respective department or agency is covered by the Common Rule," as well as final authority as to whether research conducted complies with regulations.³⁴ Subpart A of Part 46 contains the basic protections for all human subjects; subparts B-D describe additional protections for certain named "vulnerable populations," and subpart E requires registration of institutional review boards (IRBs).³⁵

Every institution conducting HHS-supported research on human subjects must provide an assurance that it will comply with HHS regulations.³⁶ This is provided through a written agreement, called an assurance

29. *Id.* at 1-2; see also Office for Human Research Prots., *Regulations*, U.S. DEPARTMENT HEALTH & HUM. SERVICES, <http://www.hhs.gov/ohrp/humansubjects/index.html> (last visited Mar. 9, 2013).

30. Rose & Lodato, *supra* note 26, at 2.

31. Office for Human Research Prots., *About OHRP*, U.S. DEPARTMENT HEALTH & HUM. SERVICES, <http://www.hhs.gov/ohrp/about/index.html> (last visited Mar. 9, 2013).

32. 45 C.F.R. § 46.101(a) (2011).

33. Office for Human Research Prots., *Federalwide Assurance (FWA) for the Protection of Human Subjects*, U.S. DEPARTMENT HEALTH & HUM. SERVICES, ¶ 3(c), <http://www.hhs.gov/ohrp/assurances/filasurt.html> (last visited Mar. 9, 2013).

34. *Id.*; see also 45 C.F.R. § 46.101(c).

35. 45 C.F.R. pt. 46 (the vulnerable populations identified are: pregnant women, human fetuses, and neonates [subpart B], prisoners [subpart C], and children [subpart D]).

36. *Id.* § 46.103(a).

of compliance, or Federalwide Assurance (FWA).³⁷ An institution's FWA applies to the entire institution, its IRB, and all its investigators, employees, and agents.³⁸ Because it is federal-wide, the FWA can be used for research supported by any federal department or agency that has adopted the Common Rule.³⁹ FWAs are the only form of agreement that can fulfill this requirement.⁴⁰ The FWA also binds the institution to "comply with any additional applicable human subjects regulations and policies of the U.S. federal department or agency which conducts or supports the research and any other applicable federal, state, local, or institutional laws, regulations, and policies."⁴¹ This savings clause is reproduced in the regulations at § 46.101 (e) and (f).⁴²

Assurance of compliance with the Common Rule is achieved by reviewing research on human subjects. This is done through an institution's IRB. IRBs must approve all qualifying research done by an institution, and an institution cannot approve research disapproved by the IRB.⁴³ An IRB also has the authority to suspend or terminate its approval of research violating IRB requirements.⁴⁴ Federal funding cannot be used if research is disapproved or if approval is terminated.⁴⁵

In addition, all IRBs must be registered. Creating an IRB and signing an FWA are simple and can be done online.⁴⁶ According to § 46.107, IRBs must be staffed by members with "varying backgrounds."⁴⁷ This diversity of membership is to be achieved through "consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes."⁴⁸ The purpose of this diversity is "to promote respect for [the IRBs] advice and counsel in safeguarding the rights and welfare of human subjects."⁴⁹

37. Office for Human Research Prots., *Federalwide Assurances (FWAs)*, U.S. DEPARTMENT HEALTH & HUM. SERVICES, <http://www.hhs.gov/ohrp/assurances/assurances/index.html> (last visited Mar. 9, 2013).

38. Office for Human Research Prots., *Compliance Oversight Procedures for Evaluating Institutions*, U.S. DEPARTMENT HEALTH & HUM. SERVICES. (Oct. 14, 2009), <http://www.hhs.gov/ohrp/compliance/evaluation>.

39. *Id.*

40. Office for Human Research Prots., *supra* note 37.

41. Office for Human Research Prots., *supra* note 33.

42. 45 C.F.R. § 46.101(e) ("Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects"); *id.* § 46.101(f) ("This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.").

43. *Id.* § 46.112.

44. *Id.* § 46.113.

45. *See id.* § 46.122.

46. *Electronic Submission System*, OFF. FOR HUM. RES. PROTECTIONS, <http://ohrp.cit.nih.gov/efile/Default.aspx> (last visited May 7, 2012).

47. 45 C.F.R. § 46.107(a).

48. *Id.*

49. *Id.*

The human subjects protections promulgated by HHS establish minimum standards. An IRB may establish more stringent requirements for its membership, the review process, or what research may qualify for expedited review or satisfy informed consent.⁵⁰ The Indian Health Service (IHS) is one agency that has added further protections. For example, IHS's IRB may require either that tribal members review research as IRB members, or that the research statement and purposes that are given to research subjects also be given to their tribes for approval.⁵¹ They also may require investigators to submit manuscripts to tribes and IHS's IRB for approval before publication.⁵²

A. Review and Risk

The regulations under 45 C.F.R. pt. 46 provide for three levels of review of research involving human subjects.⁵³ The lowest level of review is the exempt category. To qualify for an exemption of IRB review, proposed research must fall into one of the following categories: educational research, taste tests, or survey, interview, and observation of public behavior research (in which individual human subjects could not be identified or put at risk).⁵⁴ Whether research falls into this last category is largely a determination of the researcher. If the research poses no risk to subjects, the research need not be reviewed at all.⁵⁵

The intermediate level of review is the expedited review, which is for research "involving no more than minimal risk."⁵⁶ "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."⁵⁷ Again, it is largely the investigator who makes the determination of minimal risk, but an expedited review usually requires review of the research by one IRB member. Certain listed procedures⁵⁸ are automatically considered to pose only mini-

50. See 45 C.F.R. §§ 46.101–124.

51. *Human Research Participant Protection in the Indian Health Service*, INDIAN HEALTH SERVICE, http://www.ihs.gov/Research/index.cfm?module=hrpp_about (last visited March 9, 2013).

52. *Id.*

53. Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44512, 44514 (July 26, 2011) (codified at 45 C.F.R. pts. 46, 160, 164 and 25 C.F.R. pts. 50, 56).

54. 45 C.F.R. § 46.101.

55. Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. at 44514.

56. 45 C.F.R. § 46.110.

57. *Id.* § 46.102(i).

58. Protection of Human Subjects: Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure, at 63 Fed. Reg. 60,364, 60,364–67 (Nov. 9, 1998).

mal risk to subjects, and therefore may be reviewable through expedited review or may even be exempt from review.⁵⁹ Among the procedures listed are:

(A)(6) [c]ollection of data from voice, video, digital, or image recordings made for research purposes [and] (7) [r]esearch on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.⁶⁰

Because social scientific research involving intangible cultural resources is usually limited to these procedures, it will almost always qualify for expedited review or be exempt altogether. Finally, it is important to note that expedited research is still subject to the rules of informed consent.⁶¹

The highest level of review, full IRB review, is applied to studies involving more than minimal risk.⁶² These risks are placed into three categories: physical, psychological, and informational.⁶³ Physical risks are associated with medical research and are the type anticipated by the Common Rule. Psychological risks “include unintentional anxiety and stress including feelings of sadness or even depression, feelings of betrayal, and exacerbation of underlying psychiatric conditions such as post-traumatic stress disorder.”⁶⁴ “Informational risks derive from inappropriate use or disclosure of information, which could be harmful to the study subjects or groups. For instance, disclosure of illegal behavior, substance abuse, or chronic illness might jeopardize current or future employment, or cause emotional or social harm.”⁶⁵

In general, the requirement for approval of reviewed proposals is that risks to human subjects are minimized.⁶⁶ This can be achieved by “using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.”⁶⁷ Full IRB review invokes the

59. 45 C.F.R. § 46.110.

60. Protection of Human Subjects: Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure, 63 Fed. at 60,366–67.

61. Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44,512, 44,514 (July 26, 2011) (codified at 45 C.F.R. pts. 46, 160, 164 and 25 C.F.R. pts. 50, 56).

62. *Id.* at 44,515.

63. *Id.*

64. *Id.*

65. *Id.*

66. 45 C.F.R. § 46.111(a)(1) (2011).

67. *Id.*

three principles of the Belmont Report. First, the regulations require balancing of the risks and benefits of the research: "Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result."⁶⁸ Second, there must be a selection of subjects that is equitable especially taking into account "vulnerable populations, such as . . . economically or educationally disadvantaged persons."⁶⁹ Third, the rules of informed consent apply.⁷⁰ Protection of the privacy of subjects is also required under certain circumstances.⁷¹ Finally, in addition to these requirements, studies should contain additional safeguards when "some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons."⁷²

B. General Requirements of Informed Consent

Investigators cannot involve human subjects in research unless they have obtained those subjects' "legally effective informed consent."⁷³ The circumstances of seeking consent must provide subjects with "sufficient opportunity to consider whether or not to participate" while minimizing the "possibility of coercion or undue influence."⁷⁴ Subjects can neither waive any legal rights in providing informed consent nor release the investigator or the institution "from liability for negligence."⁷⁵

The eight basic elements of informed consent are provided in § 46.116(a). Not all are directly relevant to research on intangible cultural resources, but those that are require that research subjects be provided: (1) a statement of explanation and participation, including procedures; (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"; and (5) a statement describing the extent of confidentiality being provided.⁷⁶

Additionally, informed consent must be documented in a written consent form.⁷⁷ Waiver of documentation is permitted, however, when "research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required

68. *Id.* § 46.111(a)(2).

69. *Id.* § 46.111 (a)(3).

70. *Id.* § 46.111 (a)(4).

71. *Id.* § 46.111 (a)(7).

72. *Id.* § 46.111 (b).

73. *Id.* § 46.116.

74. *Id.*

75. *Id.*

76. *Id.* § 46.116(a).

77. *Id.* § 46.117.

outside of the research context.”⁷⁸ This exception would apply to most, if not all, research on intangible cultural resources because, as noted above, the research methods of social science tend to be those automatically deemed to pose minimal or no risk.⁷⁹

C. Enforcing Human Subjects Protections

The power of an IRB to enforce human subjects protections is limited to disapproval of research and discontinuation of funding. Federal funds cannot be used to support research that fails to meet the requirements of 45 C.F.R. pt. 46, whether through disapproval of the research during review, or suspension or termination of research at continuing review.⁸⁰

IRBs themselves are also subject to scrutiny. OHRP’s Division of Compliance Oversight, pursuant to § 289 of the Public Health Service Act and 45 C.F.R. pt. 46, evaluates complaints of noncompliance by institutions and investigators that conduct human subjects research.⁸¹ Compliance oversight evaluations are made at the discretion of OHRP.⁸² OHRP only has jurisdiction over human subjects research directly supported by HHS or covered under an approved FWA. If the research is conducted by, or solely supported by, a federal department or agency other than HHS, then Compliance Oversight will refer the matter to that department or agency, which will then retain final authority for determining compliance.⁸³

Evaluations by Compliance Oversight may be for-cause or not-for-cause.⁸⁴ For-cause evaluations are those initiated upon receipt of written substantive allegations of noncompliance submitted by research subjects, family members, investigators and their personnel, or institutions; not-for-cause evaluations are initiated by OHRP based on a range of considerations.⁸⁵ Under 45 C.F.R. § 46.103(e), the outcome of an oversight evaluation, either for-cause or not-for-cause, is limited to: (1) a finding of compliance; (2) a finding of compliance but with recommendations for improvements in the institution’s human subject protection policies; and (3) a finding of noncompliance.⁸⁶ Findings of noncompliance can result in

78. *Id.* § 46.117(c)(2).

79. *See id.* § 46.101(b) (listing types of studies exempted from review); Protection of Human Subjects: Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure, 63 Fed. Reg. 60,364, 60,366–67 (Nov. 09, 1998) (compiling a list of procedures considered to pose minimal risk to human subjects).

80. 45 C.F.R. § 46.122.

81. *Compliance Oversight Procedures for Evaluating Institutions*, *supra* note 38.

82. *Id.*

83. *Id.*

84. *Id.*

85. *Id.*

86. *Id.*

a variety of consequences. Such findings can require, for example, re-review of approved research, increased training, the attachment of restrictions or conditions to the institution's FWA, or suspension of the FWA, which mandates a suspension of all supported research.⁸⁷ Upon a finding of noncompliance, OHRP may also recommend to HHS officials that an institution or investigator be suspended or permanently removed from participation in certain projects or even debarred from all government-supported work.⁸⁸

D. *HHS's Advance Notice of Proposed Rulemaking (ANPRM)*

In 2011, HHS issued an advance notice of proposed rulemaking (ANPRM) entitled *Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators*.⁸⁹ The proposed rulemaking was in response to changes in the nature of scientific research involving human subjects and to numerous criticisms about the effectiveness of the current rules and the burden they place on researchers.⁹⁰ Seven broad areas of change were proposed:

1. Refinement of the existing risk-based regulatory framework;
2. Utilization of a single IRB review of record for domestic sites of multi-site studies;
3. Improvement of consent forms and the consent process;
4. Establishment of mandatory data security and information protection standards for all studies that involve identifiable or potentially identifiable data;
5. Establishment of an improved, more systematic approach for the collection and analysis of data on unanticipated problems and adverse events;
6. Extension of federal regulatory protections to all research, regardless of funding source, conducted at institutions in the United States that receive some federal funding from a Common Rule agency for research with human subjects; and
7. Improvement in the harmonization of regulations and related agency guidance.⁹¹

87. *Id.*

88. *Id.*

89. *Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators*, 76 Fed. Reg. 44,512 (July 26, 2011) (codified at 45 C.F.R. pts. 46, 160, 164 (2012) and 25 C.F.R. pts. 50, 56 (2012)).

90. *See id.* at 44,513.

91. *Id.* at 44,514.

The proposals arose from specific criticisms about the appropriateness of IRB review for social and behavioral research. These critics argue that social science research is “overregulated,” pointing to a paucity of research proving that risks even exist in this research, and to a lack of evidence that the rules would provide any protection.⁹² Deregulation, critics argue, may help “identify those social and behavioral research studies that do pose threats to the welfare of subjects and thus do merit significant oversight.”⁹³ Elements of this proposed deregulation include the elimination of continued review for minimal risk studies unless the researcher requests it; revision and regular updating of the list of categories of research that are reviewable under expedited review; and the creation of a presumption that research categories on the list are minimal risk.⁹⁴ More importantly, the ANPRM questions whether research that qualifies for expedited review should have to meet the requirements under § 46.111 at all.⁹⁵

Toward this end, the most significant proposed changes are in the exempt category. First, HHS proposes that this category be renamed the “excused” category.⁹⁶ Second, HHS proposes to expand the excused category to encompass all social and behavioral research utilizing “educational tests, surveys, focus groups, interviews, and similar procedures,” as well as those that

... involve specified types of benign interventions . . . that are known to involve virtually no risk to subjects, and for which prior review does little to increase protections to subjects. These would be methodologies which are very familiar to people in everyday life and in which verbal or similar responses would be the research data being collected.⁹⁷

Under this proposal, nearly all ethnographic research would be excused because the ethnographic method relies almost entirely on verbal responses of subjects to gather data. The only requirements for the new, expanded excused category would be that the informed consent rules are followed, that the research conforms to the new information protection standards, and that research subjects be competent adults—meaning “able to provide legally effective informed consent.”⁹⁸ Researchers would be required to file a statement that the research is exempt before starting research, but after signing, researchers could begin research immediately.⁹⁹ No review of this statement would be required, but random audits may be done to

92. See *id.* at 44,513.

93. *Id.*

94. See *id.* at 44,516–17.

95. *Id.* at 44,517.

96. See *id.* at 44,518.

97. *Id.* at 44,518–19.

98. *Id.* at 44,518.

99. *Id.* at 44,520.

check for compliance.¹⁰⁰ Finally, despite strengthening informed consent rules, HHS seeks to retain the rule allowing for oral consent without written documentation for research procedures such as interviews.¹⁰¹

The National Congress of American Indians (NCAI) was one of the respondents to the ANPRM.¹⁰² In 2003, NCAI established its Policy Research Center.¹⁰³ The goal of this Center's tribal research regulation work is to ensure that research "conducted on [tribal] lands and with [tribal] citizens is ethical, affirms tribal sovereignty, and contributes to community well being." NCAI's comments call for initial and continuing review of research involving American Indians and Alaska Natives, more involvement for tribal IRBs, and oversight of proposed secondary uses of data collected.¹⁰⁴ They are against relaxing the criteria for expedited review and reject the proposal that researchers be allowed to self-declare their research excused.¹⁰⁵ Regarding informed consent, NCAI argues that "[a]s sovereign nations, tribes have jurisdiction over research conducted using information collected on their land and from their citizens; and, as such, their rights must be considered as part of the informed consent, data reporting, and data ownership processes."¹⁰⁶ Finally, they support the idea of extending the Common Rule to all research, regardless of federal funding.¹⁰⁷

These comments reflect the significant weaknesses of the current HHS regulations in protecting tribal human subjects of research. They also anticipate further weakening that would result if the proposed changes are implemented, especially in the areas of intangible cultural resources. Therefore, tribes need to rely less on external support in protecting intangible cultural resources. Instead, they should strengthen their own internal measures for stopping loss.¹⁰⁸ As NCAI points out, the history of research on Indians demonstrates a lack of concern for tribal subjects, sometimes resulting in harm.¹⁰⁹ Tribes have been left out of the research review process, leaving researchers and their institutions to determine what is best for tribal subjects. Moreover, instead of strengthening protections for tribal research subjects, the ANPRM is not primarily concerned with increasing

100. *Id.* at 44,526.

101. *Id.* at 44,519.

102. NAT'L CONG. OF AM. INDIANS, *supra* note 22, at 1.

103. Whitener, *supra* note 19, at 241.

104. NAT'L CONG. OF AM. INDIANS, *supra* note 22, at 1-2.

105. *Id.* at 3-5.

106. *Id.* at 7.

107. *Id.* at 16.

108. As the American Indian Law Center wrote, in describing reasons for developing tribal research protocols, "[t]he fundamental responsibility to govern Indian tribes and to protect their members lies in the tribes themselves." MODEL TRIBAL RESEARCH CODE 4 (Am. Indian Law Ctr. 1999), available at <http://www.nptao.arizona.edu/research/NPTAOResearchProtocolsWebPage/AILawCenterModelCode.pdf>.

109. See NAT'L CONG. OF AM. INDIANS, *supra* note 22, at 1.

protections for human subjects. Since the ANPRM was motivated by complaints from researchers of overregulation, it is instead concerned with reducing oversight. The next section discusses how tribes can protect themselves from harms more likely to occur with deregulation of social science human subjects research.

E. Tribal Regulation of Research Involving Human Subjects

There are many reasons why a tribe would want IRB oversight within its jurisdiction. First, local tribes have a better understanding of local issues and the local culture. They understand which research questions or topics may be more unsettling or improper within their communities, and they also better understand the impact past researchers have had on their people.¹¹⁰ Therefore, during the review process, tribes are much more likely to be aware of, and thus consider, what could potentially harm their communities and what could serve as a benefit.

Second, a tribe's interpretation of harms and benefits could be vastly different from what an outsider would consider to be harmful or beneficial. IRBs apply a risk calculus. Thus, what an outsider considers a justifiable risk in relation to its benefits can vary greatly from what locals, who must bear the risk, would determine.¹¹¹ This is especially pertinent for the expedited and exempt categories; IRBs are allowed, but are not required, to let the investigator make the threshold determination that more than minimal risk is involved.¹¹² For social scientific investigation of intangible cultural resources, an outside researcher is neither obligated to discover what the holders of those resources deem minimal risk to their interests nor obligated to have the subjects evaluate what benefits derive from the research.

But even with a tribal IRB, there are substantial gaps in the protection of human subjects and the cultural resources tribes have. IRBs pertain to research that is generally described as scientific investigation and are for the protection of human subjects only. They have as their only sanction the discontinuation of federal funding. But not all research that can impact tribal cultural resources is "research" involving human subjects and federally funded. Much research will elude the definition provided by HHS, which is "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable

110. See NAT'L CONG. OF AM. INDIANS, *supra* note 22, at 2.

111. See William L. Freeman, *Starting an Institutional Review Board: Suggestions for Tribes and Tribal Colleges*, U. WASH. COMMUNITY-CAMPUS PARTNERSHIPS FOR HEALTH, 1 (May 23, 2007), http://depts.washington.edu/ccph/pdf_files/Start_a_Tribal_IRB.pdf.

112. See Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44,512, 44,514 (July 26, 2011) (codified at 45 C.F.R. pts. 46, 160, 164 (2012) and 25 C.F.R. pts. 50, 56 (2012)).

knowledge.”¹¹³ Researchers in the fields of history, linguistics, and American Indian studies, for instance, typically do not seek IRB approval, even if they use the same research methodologies as anthropologists who are usually required to get IRB approval.¹¹⁴ Research may also be conducted for fictional writing projects, fictional films, documentaries and the like, and that would similarly not be considered “research.”

Projects can also avoid IRB by not having human subjects as their target or source. A human subject is defined by HHS as “a living individual about whom an investigator . . . conducting research obtains (1) [d]ata through intervention or interaction with the individual, or (2) [i]dentifiable private information.”¹¹⁵ The lack of human subjects, according to this definition, in archaeological research is the reason that the discipline does not need IRB approval even though most tribes would argue that archaeology has a significant impact on people. Next, researchers can escape IRB by relying on funding from private foundations and NGOs. Tribes must also consider that there may be researchers who self-designate their research as exempt when it should not be, or who gain IRB approval then violate the terms of that approval.

Tribes need to expand the scope of research regulations and exercise sovereign authority to regulate research on their lands. This may be the most effective way for tribes to stem the loss from cultural appropriation. Tribes are sovereign nations who have the authority to regulate action on their lands, which includes regulating scientific research.¹¹⁶ This may come in the form of IRBs with standards that are more stringent than that which are mandated by HHS or IHS. This can also be done by forming community advisory boards unattached to the IRB system or by adopting laws to regulate research and impose penalties for noncompliance.¹¹⁷ Tribes can

113. 45 C.F.R. § 46.102(d) (2011); see also MODEL TRIBAL RESEARCH CODE 3 (Am. Indian Law Ctr. 1999), available at <http://www.nptao.arizona.edu/research/NPTAOResearchProtocolsWebPage/AILawCenterModelCode.pdf> (examining an IHS definition).

114. The difference is largely due to the professional ethics of the discipline. Compare *Ethics Resources*, AM. ANTHROPOLOGICAL ASS'N, <http://www.aaanet.org/cmtes/ethics/Ethics-Resources.cfm> (last visited Mar. 10, 2013) (the 2009 code is the most recent but the code was originally adopted in 1971), with Linguistic Society of America, *The LSA Ethics Statement*, LSA ETHICS DISCUSSION BLOG, <http://lsaethics.wordpress.com/about/> (last visited Mar. 10, 2013) (noting the LSA's current efforts to develop a professional ethics statement that considers human subjects).

115. 45 C.F.R. § 46.102(f).

116. PUNEET CHAWLA SAHOTA, NCAI POLICY RESEARCH CENTER, RESEARCH REGULATION IN AMERICAN INDIAN/ALASKA NATIVE COMMUNITIES: POLICY AND PRACTICE CONSIDERATIONS 6 (2007), available at http://depts.washington.edu/ccph/pdf_files/Research%20Regulation%20in%20AI%20AN%20Communities%20-%20Policy%20and%20Practice.pdf; NAT'L CONG. OF AM. INDIANS, *supra* note 22, at 2. See generally MODEL TRIBAL RESEARCH CODE (Am. Indian Law Ctr. 1999), available at <http://www.nptao.arizona.edu/research/NPTAOResearchProtocolsWebPage/AILawCenterModelCode.pdf>.

117. SAHOTA, *supra* note 116, at 8–14 (discussing the various approaches to research regulation in American Indian/Alaska Native communities.).

protect their citizens and further assert their sovereignty by exercising self-government instead of waiting for an external agency to change its policies or relying on investigators to self-regulate.¹¹⁸ Several tribes, such as the Navajo Nation, the Hopi Tribe, and Ho-Chunk Nation, already have research codes.¹¹⁹ In addition, the American Indian Law Center has produced a Model Tribal Research Code.¹²⁰ Under a tribal research code, violators could face one or a combination of penalties. Violators could be fined or lose a deposit, or their research can be terminated and confiscated. Violators could also face eviction or banishment from tribal lands under trespass laws.¹²¹

However, this would still not be a perfect solution; the impediment to this system is the limited jurisdiction of tribal courts.¹²² This limitation could be constitutional. Although some tribal constitutions limit the full scope of the tribal government's power, the more significant obstacle is the problem of extraterritorial jurisdiction.¹²³ The vast majority of researchers whose actions a tribe may wish to restrict will be non-Indians. Likewise, most of the actions tribes wish to restrict, such as publication, secondary uses, and data sharing, will occur post-research and will take place outside tribal lands. A tribal court may have civil and not criminal jurisdiction over a non-Indian researcher, but that jurisdiction will not follow a defendant off tribal lands.¹²⁴ Tribal courts would then face a potentially daunting issue of comity, as there exist limits to how far a state court will go in enforcing a tribal court order or judgment.¹²⁵ A state court is less likely to enforce an order if that order is based on principles foreign to it or on

118. MODEL TRIBAL RESEARCH CODE (Am. Indian Law Ctr. 1999), available at <http://www.nptao.arizona.edu/research/NPTAOResearchProtocolsWebPage/AILawCenterModelCode.pdf>.

119. See HO-CHUNK NATION CODE tit. 3, § 3 (2005), available at <http://www.nptao.arizona.edu/research/tribalCodes.cfm>; NAVAJO NATION CODE tit. 13, §§ 3251–3271, available at <http://www.nptao.arizona.edu/research/tribalCodes.cfm>; HOPI CULTURAL PRESERVATION OFFICE PROTOCOL FOR RESEARCH, PUBLICATION AND RECORDINGS: MOTION, VISUAL, SOUND, MULTIMEDIA AND OTHER MECHANICAL DEVICES, available at <http://www.nptao.arizona.edu/research/tribalCodes.cfm>.

120. Native Peoples Technical Assistance Office, *Tribal Codes/Protocols Pertaining to Research*, U. ARIZONA, <http://www.nptao.arizona.edu/research/tribalCodes.cfm> (last visited May 8, 2012); MODEL TRIBAL RESEARCH CODE (Am. Indian Law Ctr. 1999), available at <http://www.nptao.arizona.edu/research/NPTAOResearchProtocolsWebPage/AILawCenterModelCode.pdf>.

121. SAHOTA, *supra* note 116, at 10; MODEL TRIBAL RESEARCH CODE 15–16 (Am. Indian Law Ctr. 1999), available at <http://www.nptao.arizona.edu/research/NPTAOResearchProtocolsWebPage/AILawCenterModelCode.pdf>.

122. Riley, *supra* note 1, at 74.

123. MODEL TRIBAL RESEARCH CODE 10 (Am. Indian Law Ctr. 1999), available at <http://www.nptao.arizona.edu/research/NPTAOResearchProtocolsWebPage/AILawCenterModelCode.pdf>.

124. *Id.*

125. *Id.* at 16.

principles contrary to its own.¹²⁶ For instance, a tribal code regulating research on the reservation could be interpreted by a non-tribal court as either an expression of self-government or as an unconstitutional infringement of free speech.¹²⁷

Another jurisdictional dilemma is that tribes must also deal with individuals who circumvent tribal research regulations by working with community members who live off-reservation, or those subjects who are willing to participate for cash despite their own tribe's rules. One strategy tribal codes could use is to regulate the human subjects of research instead of the investigators; this could deter subjects from cooperating with unscrupulous researchers and providing them with intangible cultural resources. The challenge to this, however, is that statutes curtailing speech would likely face constitutional challenges.¹²⁸ A tribe seeking to regulate research participants must show a compelling governmental interest justifying the restriction of the free speech rights of tribal members.¹²⁹ This would be difficult and ultimately unsatisfactory in cultures that place high value on personal autonomy.¹³⁰

While developing tribal regulation of research will effectively curtail some cultural appropriation, broad protection of intangible cultural resources may require a reliance on state law. State law would provide a forum in state courts for tribes to file their complaints against researchers. Tribes may seek to use contract law, which would be enforceable in state or federal courts. Clearly drafted contracts could clarify the rights and duties of the parties, could require disputes arising under the contract to be heard in tribal courts, could stipulate remedies for non-compliance, and could be used to establish claims against a violating researcher's institution.¹³¹

Another viable avenue for relief may be tort law. Tort law would be attractive to tribes because it is state law, and actions can be filed in state courts, alleviating concerns about jurisdiction. Because tort law is well-

126. *Id.*

127. *Id.* at 9.

128. See Matthew L.M. Fletcher, *Theoretical Restrictions on the Sharing of Indigenous Biological Knowledge: Implications for Freedom of Speech in Tribal Law*, 14 KAN. J.L. & PUB. POL'Y 525, 546-49 (2005).

129. See *id.*

130. See, e.g., CHARLES E. CLELAND, *rites of conquest: The History and Culture of Michigan's Native Americans*, 59 (1992) (discussing the concept of "individual sovereignty" among the Anishinaabek). See generally MATTHEW L.M. FLETCHER, *The Eagle Returns: The Legal History of the Grand Traverse Band of Ottawa and Chipewewa Indians* (2012) (explaining the political power of ogema, traditional leaders, in Anishinaabek culture).

131. There is a small body of case law applying contract law to the investigator-human subject relationship, but it will not be treated in detail here. See E. Haavi Morreim, *Medical Research Litigation and Malpractice Tort Doctrine: Courts on a Learning Curve*, 4 HOUS. J. HEALTH L. & POL'Y 1, 33-35 (2003).

established law, tribes would not need to first convince Congress to change the law. On the other hand, tribes would need to convince courts that tort law is appropriate for their claims. The next section discusses the rise in tort actions alleging researcher harm to human subjects. These actions show a trend toward increasing legal liability of researchers and their institutions. This trend indicates the possibility of recognition of tort-based harms and remedies for intangible cultural resource appropriation.

II. AVAILABILITY OF TORT LAW FOR PROTECTING INTANGIBLE CULTURAL RESOURCES

A. Tort Law and Researcher Violations

Plaintiff's attorneys are increasingly filing class action suits and mass torts suits (also called multidistrict litigation) on behalf of research subjects against investigators, their institutions, IRBs, and the sponsors of research.¹³² Litigation, as frequently argued by plaintiffs' attorneys, can be an effective tool to bring about change in a broken system. The deficiencies of the federal system for protecting human subjects of research have been expressed multiple times; since the late 1990s, there have been calls to overhaul the system, including those that led to the current Proposed Rulemaking.¹³³ Unfortunately, as noted above, the current rulemaking will not address tribal concerns.

Rose and Lodato note that suits prior to the 1990s involved "egregious conduct" by investigators, such as lack of failing to notify patients that they were participants in medical research.¹³⁴ Now, lesser allegations are being used to initiate suits. Deficiencies in informed consent (not including within it everything that a research subject might want to know), deficiencies in IRB review (not properly balancing risks and benefits), and violations of federal regulations are all emerging claims in medical research torts.¹³⁵ Intentional infliction of emotional distress has also been used in a number of medical cases, as have been negligence, fraud and misrepresentation, and even "claims of the constitutional right to be treated with dignity."¹³⁶ Though the research discussed in this Comment is not medical, tort claims such as the ones brought in the medical cases are instructive because of the similarity of the possible claims. The Havasupai Reservation case is a good example.

In 1989, the Havasupai Tribe asked anthropologist John Martin, who had worked with the Tribe since the 1960s, to investigate the high rates of

132. Rose & Lodato, *supra* note 26. See generally Morreim, *supra* note 131 (reviewing case law regarding clinical research).

133. David B. Resnik, *Liability for Institutional Review Boards: From Regulation to Litigation*, 25 J. LEGAL MED. 131 (2004).

134. Rose & Lodato, *supra* note 26, at 4.

135. *Id.*

136. *Id.* at 1.

diabetes among its members.¹³⁷ Martin enlisted the aid of geneticist Theresese Markow, and a research project was properly drawn under the IRB protocols of Arizona State University, Martin and Markow's institution. From the start, Markow was interested in expanding the study to include the topic of schizophrenia. The Tribe, however, agreed only to the diabetes research. Using broad and ambiguous consent forms, researchers collected blood samples from over a hundred participants over the course of several years. The search for a genetic explanation for the high rate of diabetes among the Havasupai was fruitless and ended. However, unbeknownst to the Tribe, additional studies were conducted on the samples, including research on the genetic causes of schizophrenia, rates of inbreeding, and population migration.¹³⁸

Two lawsuits (later joined), *Tilousi v. Arizona State University*¹³⁹ and *Havasupai Tribe v. Arizona Board of Regents*,¹⁴⁰ emerged from these facts. Although the cases ended in settlement, they are instructive for the development of tort actions against researchers. The claims listed were: contract enforcement; breach of fiduciary duty; negligent and intentional infliction of emotional distress; fraud and misrepresentation; deficiencies in informed consent and IRB review; negligence; conversion; unreasonable disclosure of private facts; intrusion on seclusion and solitude; and violations of federal regulations.¹⁴¹ The court dismissed most of the counts. The claims of negligence and negligent and intentional infliction of emotional distress, however, survived.¹⁴²

This case is instructive because it indicates the difficulties tribes face in getting a court to recognize their harms as cognizable claims. It also illustrates the deference courts grant to researcher's understandings of what constitutes a risk or harm and what constitutes a benefit. The following sections discuss these issues in reference to the elements of an action in negligence.

B. Actions in Negligence

Tribes can make out a claim for actions in negligence that can help protect cultural resources. Negligence is generally understood as action that falls below an acceptable standard of due care.¹⁴³ The basic elements of negligence are (1) duty; (2) standard of care; (3) breach of duty; (4) a

137. Whitener, *supra* note 19, at 236.

138. Katherine Drabiak-Syed, *Lessons from the Havasupai Tribe v. Arizona State University Board of Regents: Recognizing Group, Cultural, and Dignitary Harms as Legitimate Risks Warranting Integration into Research Practice*, 6 J. HEALTH & BIOMEDICAL L. 175, 175 (2010).

139. No. 04-CV-1290-PCT-FJM, 2005 WL 6199562, at *2 (D. Ariz. Mar. 3, 2005).

140. 204 P.3d 1063, 1066–67 (Ariz. Ct. App. 2008).

141. *Tilousi*, 2005 WL 6199562, at *2–6; *Havasupai Tribe*, 204 P.3d at 1072–77.

142. See Whitener, *supra* note 19, at 237; Drabiak-Syed, *supra* note 138, at 189–94 (analyzing how the court treated each count).

143. RESTATEMENT (SECOND) OF TORTS § 282 (1965).

causal relation between the defendant's conduct and the harm; and (5) actual harm or damages.¹⁴⁴ The elements of breach and cause are highly dependent upon the facts of a particular case. As a result the questions to be addressed here are whether investigators owe human subjects a duty, what standard of care applies, and what are the harms arising from research that can be cognizable by a court. Additionally, a tribe instigating a tort action against a researcher, an IRB, or an institution must consider the issue of consent. Consent is a defense to negligence and because informed consent is a required component of IRB approval, that defense will always be available.¹⁴⁵

1. The Element of Duty

Establishing that researchers owe a duty to the human subjects of their research is a critical issue in developing tort case law that tribes could use as ground for claims against specific researchers and their IRBs. As *Tilousi* illustrated, courts may be quick to dismiss claims that such a duty even exists.

However, in *Grimes v. Kennedy Krieger Institute*, the court held that a researcher owed a duty to their human subjects.¹⁴⁶ In the 1990s, the Krieger Institute, an affiliate of John Hopkins University, conducted a study of lead paint abatement procedures.¹⁴⁷ As part of the study, researchers facilitated leasing of apartments with known risks of lead dust to families with small children, so that the absorption could be measured and compared.¹⁴⁸ The plaintiffs (the families in the study) alleged, among other things, that the researchers did not obtain appropriate informed consent. The court issued a scathing opinion, finding that "no degree of parental consent and no degree of furnished information to the parents could make the experiment at issue here, ethically or legally permissible."¹⁴⁹ Tort law generally recognizes that duties can arise from the relationship of the parties when there would ordinarily be no duty owed between plaintiff and defendant that would establish the duty.¹⁵⁰ At issue was whether researchers in a scientific, health-related study can be said to have entered into a special relationship with research subjects that can create duties, the breach of which

144. RESTATEMENT (SECOND) OF TORTS § 281 (1965). Duty and standard of care are often conflated, but it is desirable to keep them separated for the purposes of this Note. The causal relationship is often divided into cause-in-fact and proximate cause, but the distinction need not be made here.

145. See RESTATEMENT (SECOND) OF TORTS § 892A (1979) ("One who effectively consents to conduct of another intended to invade his interests cannot recover in an action of tort for the conduct or for harm resulting from it."). See generally Morreim, *supra* note 131.

146. 782 A.2d 807, 851 (Md. 2001).

147. *Id.* at 811–12.

148. *Id.* at 812.

149. *Id.* at 857–58.

150. 65 C.J.S. *Negligence* § 57 (2010) (citing *Brown v. United States*, 583 F.3d 916 (6th Cir. 2009)).

may give rise to negligence claims.¹⁵¹ The court answered in the affirmative, holding that “normally, such special relationships are created between researchers and the human subjects used by the researchers.”¹⁵²

It is broadly recognized that a person owes a duty to “all others to guard against injuries which naturally flow as a reasonably probable and foreseeable consequence of an act.”¹⁵³ In scientific investigation, it would seem likely that those who would best be able to foresee the consequences of the investigation are the investigators themselves. This was recognized in *Grimes*. The *Grimes* court found that “investigators are in a better position to anticipate, discover, and understand the potential risks to the health of their subjects. Practical inequalities exist between researchers, who have superior knowledge, and participants who are often poorly placed to protect themselves from risk.”¹⁵⁴

Part 46 also anticipates that investigators will know the risks to which they are subjecting research participants. First, Part 46 requires that informed consent include “[a] description of any reasonably foreseeable risks or discomforts to the subject.”¹⁵⁵ Second, the requirement for approval of reviewed proposals is that risks to human subjects are minimized.¹⁵⁶ This can be achieved by “using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.”¹⁵⁷ Next, the balancing required under full review presumes the awareness of risks to balance against anticipated benefits.¹⁵⁸ When vulnerable populations are involved, this requires “additional safeguards” to “protect the rights and welfare” of the subjects.¹⁵⁹ In fact, HHS regulations and the Common Rule exist for the protection of human subjects in research, specifically their rights and welfare. This is based on the general understanding that research may entail risk to subjects. An IRB’s FWA assures that the institution will comply with the policy. Assurances must contain “[a] statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution”¹⁶⁰

Finally, the fact that a duty is owed can be established by the numerous provisions in Part 46 that demand investigator and IRB compliance with law—which must necessarily include state tort duties—and otherwise

151. *Grimes*, 782 A.2d at 834.

152. *Id.* at 858.

153. 65 C.J.S. *Negligence* § 57 (2010) (citing *Forsythe v. Clark USA, Inc.*, 864 N.E.2d 227 (Ill. 2007)).

154. *Grimes*, 782 A.2d at 851 (internal quotation marks omitted).

155. 45 C.F.R. § 46.116(a)(2) (2011).

156. *Id.* § 46.111(a)(1).

157. *Id.*

158. *See id.* § 46.111(a)(2).

159. *Id.* § 46.111(b).

160. *Id.* § 46.103(b)(1).

preserve liabilities. One of the terms of the Federalwide Assurance that all IRBs must sign is that they also comply with all “applicable federal, state, local, or institutional laws, regulations, and policies.”¹⁶¹ The regulations then reiterate that “[c]ompliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects” and “[t]his policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.”¹⁶² If the research involves pregnant women, human fetuses, or neonates, the regulations specify that the “local laws” referred to in § 46.101(f) “include the laws of federally recognized American Indian and Alaska Native Tribal Governments.”¹⁶³ Additionally, HHS informed consent requirements “are not intended to preempt any applicable federal, state, or local laws, which require additional information to be disclosed in order for informed consent to be legally effective.”¹⁶⁴ Consent forms (or oral agreements, when applicable) cannot waive or appear to waive “any of the subject’s legal rights,” nor can they release or appear to release “the investigator, the sponsor, the institution or its agents from liability for negligence.”¹⁶⁵ Thus, the regulations contemplate that researchers owe a duty to the human subjects of their research.

Another type of relationship giving rise to a duty is the fiduciary relationship; however, this may not be a winning argument to establish a duty. Plaintiffs in *Tilousi* alleged that a fiduciary relationship had been created and that it was subsequently breached.¹⁶⁶ Breach of fiduciary duty, which results in harm, gives rise to its own cause of action.¹⁶⁷ The fiduciary relationship exists “when one of them is under a duty to act for or to give advice for the benefit of another upon matters within the scope of the relation.”¹⁶⁸ This “liability is not dependent solely upon an agreement or contractual relation between the fiduciary and the beneficiary but results from the relation.”¹⁶⁹ Where particular substantive law does not control the relationship, as it does not between researcher and human subject, it

161. *Federalwide Assurance (FWA) for the Protection of Human Subjects*, *supra* note 33, ¶ 3(c).

162. 45 C.F.R. § 46.101.

163. *Id.* § 46.201(c).

164. *Id.* § 46.116(e).

165. *Id.* § 46.116.

166. *Tilousi v. Ariz. State Univ. Bd. of Regents*, No. 04-CV-1290-PCT-FJM, 2005 WL 6199562, at *2 (D. Ariz. Mar. 3 2005).

167. RESTATEMENT (SECOND) OF TORTS § 874 (1965) (“One standing in a fiduciary relation with another is subject to liability to the other for harm resulting from a breach of duty imposed by the relation.”).

168. *Id.* § 874 cmt. a.

169. *Id.* § 874 cmt. b. *Tilousi* raised the issue as well, but I will not address the contracts issues in this Comment. I will, however, note that in *Grimes*, the court found a contract claim between the parties stemming from informed consent. See *Morreim*, *supra* note 131, at 33–34. Also, in *Wright v. Fred Hutchinson Cancer Research Center*, the court considered, and rejected, a

may be implied in law or based on specific facts and circumstances of a relationship between parties.¹⁷⁰ Under the Florida law applied in *Greenberg*, and upon which the court in *Tilousi* drew, the fiduciary relationship is implied when it is shown on specific pleaded facts that one party placed their trust in the other and that the other accepted that trust.¹⁷¹ In *Tilousi*, the court rejected altogether the claim that plaintiffs had a fiduciary relationship on the grounds that they had failed to even allege that the researchers had accepted their trust and confidence.¹⁷² The court relied on *Greenberg*, which found that “[t]here is no automatic fiduciary relationship that attaches when a researcher accepts medical donations and the acceptance of trust, the second constitutive element of finding a fiduciary duty, cannot be assumed once a donation is given.”¹⁷³

2. Standard of Care

If a duty is established, the plaintiff must then argue for a particular standard of care to be adopted, by which to evaluate the defendant’s actions for breach. Negligence normally relies on the reasonable person standard.¹⁷⁴ This standard may be supplied by “the requirements of a legislative enactment or an administrative regulation” if its purpose is found

(a) to protect a class of persons which includes the one whose interest is invaded, and (b) to protect the particular interest which is invaded, and (c) to protect that interest against the kind of harm which has resulted, and (d) to protect that interest against the particular hazard from which the harm results.¹⁷⁵

Where a legislative enactment or administrative regulation provides that a violation entails civil liability, a court “must apply it.”¹⁷⁶ But where the enactment or regulation provides only for criminal liability or contains no provision for any liability, a court is not compelled to accept it as the standard of care.¹⁷⁷ The court may adopt it, however, and when it does, it does so in furtherance of the enactment’s or regulation’s general purpose. Because HHS regulations exist for the purpose of protecting the rights and welfare of human subjects in research, it should be in the furtherance of

claim that research subjects were third party beneficiaries of the FWA. See Resnik, *supra* note 133, at 147.

170. See *Greenberg v. Miami Children’s Hosp. Research Inst., Inc.*, 264 F. Supp. 2d. 1064, 1071 (S.D. Fla. 2003).

171. *Id.*

172. *Tilousi v. Ariz. State Univ. Bd. of Regents*, No. 04-CV-1290-PCT-FJM, 2005 WL 6199562, at *2 (D. Ariz. Mar. 3 2005) (citing to *Greenberg*, 264 F. Supp. 2d. at 1064).

173. *Greenberg*, 264 F. Supp. 2d. at 1072.

174. RESTATEMENT (SECOND) OF TORTS § 282 (1965).

175. RESTATEMENT (SECOND) OF TORTS § 286 (1965).

176. *Id.* § 286 cmt. c.

177. *Id.* § 286 cmt. d.

that purpose to adopt them as the standard in a negligence suit brought by a subject harmed in research. Then, it would depend on the facts of a particular case to determine whether the particular harm suffered was one the research protocols were designed or should have been designed to protect against.

In *Tilousi*, it was clear that the court was not compelled to adopt Part 46 as the standard of care. The plaintiffs alleged, under a claim of breach of fiduciary duty, that the defendants were in violation of federal regulations, specifically 45 C.F.R. § 46.116.¹⁷⁸ The court dismissed the claim, however, holding that “this federal regulation regarding institutional review boards does not provide a private right of action nor does it evidence an intent to do so.”¹⁷⁹

Part 46 has been generally interpreted to not establish a private right of action.¹⁸⁰ The Supreme Court found that “private rights of action to enforce federal law must be created by Congress.”¹⁸¹ A court, in determining whether a private right of action exists, must also examine the statute to see whether a private remedy has been created. Without one, “a cause of action does not exist and courts may not create one, no matter how desirable that might be as a policy matter, or how compatible with the statute.”¹⁸² However, even if the court in *Tilousi* would have declined to adopt IRB regulations as the standard of care, other courts have held that researchers have duties imposed by federal regulations and that those regulations establish the standard of care.¹⁸³ In *Kus v. Sherman Hospital*¹⁸⁴ and *Gregg v. Kane*,¹⁸⁵ for example, courts found that the duties that medical researchers violated were grounded in FDA regulations for conducting clinical trials.¹⁸⁶

178. *Tilousi v. Ariz. State Univ. Bd. of Regents*, No. 04-CV-1290-PCT-FJM, 2005 WL 6199562, at *2 (D. Ariz. Mar. 3 2005).

179. *Id.*

180. *Wright v. Fred Hutchinson Cancer Research Ctr.*, 269 F. Supp. 2d 1286 (W.D. Wash. 2006).

181. *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001).

182. *Id.* at 287; *see also Transamerica Mortgage Advisors, Inc. v. Lewis*, 444 U.S. 11 (1979).

183. Resnik, *supra* note 133, at 143.

184. 644 N.E.2d 1214, 1221 (Ill. App. 1995).

185. WL 570909 at 4 (E.D. Pa. 1997)

186. Resnik, *supra* note 131, at 142. The FDA, and other agencies and departments that oversee materials directly affecting the health of individuals, may have much stricter standards than those overseeing social scientific research (which many argue has no capacity whatsoever to harm subjects). Therefore, *Kus* and *Gregg* may not actually be promising precedents in a case involving the appropriation of intangible cultural resources. However, professional codes of ethics are also good choices for courts to adopt as establishing a standard of care, and the social sciences, unlike the humanities generally, have codified ethics to consult.

3. Breach of Duty

Next, in establishing a claim in negligence, a plaintiff must establish that the defendant breached the duty owed. A person's failure to exercise due care constitutes breach of duty.¹⁸⁷ Showing breach, and more so, showing causality, would depend greatly on the specific facts of an actual case. However, some general comments can be made. In the process of developing a claim of investigator negligence, a plaintiff should file a complaint with OHRP's Division of Compliance oversight. OHRP may undertake an investigation of a researcher and/or the institution approving his or her research at its discretion.¹⁸⁸ OHRP maintains a database of compliance oversight determinations that lists examples of noncompliance.¹⁸⁹ These precedents can be used to establish that a particular researcher has failed to comply with HHS policy. The effect of a violation depends on whether a court adopts HHS regulations as the standard of care. Under the *Restatement (Second) of Torts*, "The unexcused violation of a legislative enactment or an administrative regulation which is adopted by the court as defining the standard of conduct of a reasonable man, is negligence in itself."¹⁹⁰ Therefore, adoption of a regulation as the standard of care supports a claim of negligence per se, which obviates the need to show causality. In *Tilousi*, the court rejected the claim of negligence per se but preserved the claims of negligence and gross negligence, finding that plaintiffs had stated a "legally sufficient claim that defendants breached a duty owed to plaintiffs to exercise reasonable care in conducting research with human research subjects and that the alleged breach caused damage to plaintiffs."¹⁹¹

4. Actual Harm

The final element of the tort of negligence is the showing of actual harm. Again, it can be shown that the HHS regulations intend to protect against specific harms to human subjects. When research only involves methods such as a survey or an interview—methods characteristic of social science—the research usually is exempt. However, the research will not qualify as exempt if "any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation."¹⁹² Thus the rules contemplate distinct harms

187. 65 C.J.S. *Negligence* § 57 (2010).

188. *Compliance Oversight Procedures for Evaluating Institutions*, *supra* note 38.

189. Office for Human Research Prots., *Recent Compliance Oversight Determinations*, U.S. DEPARTMENT HEALTH & HUM. SERVICES, <http://www.hhs.gov/ohrp/compliance/findings/index.html#A4> (last visited May 7, 2012).

190. RESTATEMENT (SECOND) OF TORTS § 288B(1) (1965).

191. *Tilousi v. Ariz. State Univ. Bd. of Regents*, No. 04-CV-1290-PCT-FJM, 2005 WL 6199562, at *5 (D. Ariz. Mar. 3, 2005).

192. 45 C.F.R. § 46.101(b)(2) (2011).

that could arise from research using these methods, such as criminal and civil liability, damage to financial standing, employability, and reputation—but only for individuals. Furthermore, the three categories of risk that are anticipated by the regulations and guide the assessment of level of review identify specific types of harm that may be the consequence of research. As discussed above, physical risks are associated with medical research and are unlikely to result from social science research, but psychological and informational risks are much more foreseeable in the social science context. Some of these specific harms include: anxiety, stress, depression, feelings of betrayal, and inappropriate disclosure of information that can cause emotional or social harm, to individuals or groups.¹⁹³

These harms, while general, are quite difficult to show. In fact, the greatest challenge in using tort law to address wrongs to tribal citizens by outside researchers will be in showing harm. This is because what constitutes a cognizable harm and its conceptions of what is acceptable treatment of one human being by another is rooted in Euro-American common law. These conceptions will naturally vary somewhat from culture to culture, but the courts that would hear the tort claims of tribes operate in a culturally foreign environment that may prescribe different rights and duties to persons and thus may recognize harm in different way. The harms alleged in *Tilousi*, for instance, were culturally specific. As Drabiak-Syed explains, the court there failed to appreciate the tribal beliefs about biological materials, especially blood.¹⁹⁴ Instead, the court agreed with scientists who argued that such beliefs are mere superstitions and that the plaintiffs' claims were "hysterical" and an impediment to scientific progress.¹⁹⁵ Such polarizations—where what is common decency to one is offensive to another—implicate the issue of the cultural locatedness of the reasonable person and will drastically skew a court's evaluation of the balancing between risks and benefits that any researcher has made.

The most significant obstacle in achieving common law recognition of a tribe's culturally-based harms lies in the fact that in most areas of Euro-American law, the focus is on the individual. But individuals are not the only ones who can suffer harm from research.¹⁹⁶ In fact, individuals are not even the only persons who are targeted as the subjects of research. Ethnography, for instance, is the study of the group, not the individual even if the individual is one through whom information about the group is

193. Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44512, 44515–16 (July 26, 2011) (codified at 45 C.F.R. pts. 46, 160, 164 (2012) and 25 C.F.R. pts. 50, 56 (2012)).

194. Drabiak-Syed, *supra* note 138, at 196–97.

195. *Id.* Note the similarities between this argument and how archaeologists framed the debates about repatriation before NAGPRA's passage.

196. *Id.* at 216–21; see also Debra Harry, *Indigenous Peoples and Gene Disputes*, 84 CHI.-KENT L. REV. 147, 154 (2009); 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).

extracted. However, human subjects protection focuses on the individual, not the group. Sahota notes that the Belmont Report focuses on the individual and does not consider the rights of groups or their needs for protection in the context of human subjects research.¹⁹⁷ The tribe, not just the research subjects, needs to know that research is being conducted. Also, the tribe and not just subjects needs to give consent for that research.¹⁹⁸ Furthermore, any benefits that could result from research may be beneficial to the tribe and not just the individual subjects. Any risk involved in participation may be a risk borne by the tribe and not just the individual.¹⁹⁹ Despite these risks, convincing a court that the tribe, and not just individuals, has a cause of action is difficult. In *Tilousi*, the primary argument of one of the defendants in their motion to dismiss was that the tribe could not have suffered any harms because only individuals, not the tribe, provided biological materials.²⁰⁰ The court in its analysis treated the plaintiffs as a collection of individuals, which included those from which blood was drawn, and did not consider the tribe as a plaintiff.

CONCLUSION

IP law is problematic as a way to protect intangible cultural resources. Developing tribal-based research regulation and asserting tribal interests in state courts under existing tort law is a better way to protect intangible cultural resources in a way that respects tribal interests. Tribes should develop IRBs, and possibly tribal codes, to exercise regulatory jurisdiction over outside researchers on their lands. Tribes should also seek remedies under state tort law for expropriations of their heritage. Certainly, difficulties exist in extending tort law to harms Indians and tribes have suffered from researcher appropriation of intangible cultural resources. However, because these harms are anticipated by human subjects protections regulations, it is possible to satisfy all the elements for an action in negligence when researchers violate those regulations.

197. SAHOTA, *supra* note 116, at 3.

198. *Id.* at 3–4.

199. *Id.* NCAI, in its comments to the HHS's ANPRM, also recommended that the regulations be changed to recognize group harms to tribes and Indian communities. NAT'L CONG. OF AM. INDIANS, *supra* note 22, at 9.

200. Whitener, *supra* note 19, at 237–38.