

Implementing Free, Prior and Informed Consent:

Investigating Processes for Community Review Boards and
Community-Based Participatory Consent in Native American and
Alaska Native Communities

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Executive Summary

This investigation examined how the principle of Free, Prior and Informed Consent might be operationalized to protect indigenous communities from unwanted or unsafe development on indigenous lands. Free, Prior, Informed Consent (FPIC) is a human right for indigenous peoples and forest-dependent communities as outlined by the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP). Specific language on FPIC in UNDRIP describes how development on indigenous land should be presented to, explained to, and discussed by the community before the project can proceed. Although governing bodies and organizations – national, provincial, state, regional – worldwide recognize the basic principles of FPIC, there is an absence of legally binding policy that implements and enforces the principle of FPIC. Additionally, there is a lack of consistency in descriptions of what these principles are or what they dictate. In short, the international debate is how FPIC should be implemented on site and who should be responsible for implementing and enforcing these rights.

The objective of this paper is to examine whether and how Community-Based Participatory Review Boards might serve as a vehicle through which FPIC is operationalized at the local level. Carolyn Raffensperger of the Science and Environmental Health Network (SEHN) set this objective and acted as a guide throughout the research process. The research sought to analyze various models for ensuring consent that are currently in practice. Models included the Institutional Review Board system for human subjects research in the United States, as well as Community Advisory Boards and Community-Based Participatory Research practices in Alaska Native communities. Processes for this investigation included semi-structured interviews with experts on Native American tribal research and consent, an analysis of existing IRB policy, and a review of literature on FPIC, Institutional Review Boards, and Community-Based Participatory Research.

This investigation found that although Community Advisory Boards are powerful bodies for protecting indigenous community interests, current models for these boards are often unsustainable for communities with already burdened members. This paper recommends that government departments such as the U.S. Environmental Protection Agency provide communities with sufficient information to then consent to or reject development on their territory, and that a new model of a Community Review Board might be employed to assess the risk and benefit of development on indigenous land.

My Background

Indigenous voices in South America: Argentina

In the spring of 2013, I studied abroad in Buenos Aires, Argentina with a program focusing on Social Movements and Human Rights. The program structure allowed my group to not only study in the capital city of Buenos Aires, but also around the country to look at social conflict and change within a variety of communities. During trips out of the city, our group visited a few indigenous communities: we visited the Mapuche communities of Chiuquilihuin and Ranquehue in Patagonia fighting for land titles, the Wichí of Mosconi in the province of Salta to the north fighting against soy plantations and oil pipelines, and the Kolla communities of the Salinas Grandes in the province of Jujuy fighting against lithium mines. In each community, we were fortunate enough to be able to sit down with members of each community, share a meal, and learn about their cultural history and their place as part of the larger indigenous group to which they belonged. We also discussed the variety of aforementioned conflicts, and how each community was struggling to combat the variety of individual investors, corporations, and even government bodies infringing on their human, land, and environmental rights.

I was interested in learning more about the conflict of the lithium mines of the Salinas Grandes from a paper in a prior Oxy course where I examined various research investigations on lithium mining practices in the Lithium Triangle in South America. The Lithium Triangle – the *Puna* (high plains) of Northwestern Argentina, Southern Bolivia, and Northern Chile – contains about 75-85% of the world's lithium resources. These resources have a market that has grown exponentially since 2009 with the technology

boom and the lithium-ion battery used in cars, buses, and planes. This new market boom generated a wave of corporate interest in the Lithium Triangle, making huge swaths of land whose economy was once based in tourism and salt mining into incredibly (monetarily) valuable resource. My paper focused on studies in the Salar de Uyuni in Bolivia, one of the most lithium-rich *salar*s in one of the poorest countries in the world. The investigation looked at the environmental side effects of the lithium mining process that includes open evaporation pools on site to concentrate the lithium held in underground brines.

The effect of economic development on indigenous peoples

My time at the Salinas Grandes of Jujuy allowed me to see with my own eyes the effects of the lithium boom through the experiences of few indigenous communities living on the salt flats. I visited the Salinas Grandes Cooperative, a community-owned business of indigenous salt miners whose work on the salt flats was threatened by the construction of an Orocobre lithium mine nearby. In my two weeks I spent in Northern Argentina during my time abroad, I was able to speak with Alicia Chalabe and Agustina Roca, some of the head organizers of the Red Puna; an organization of 33 indigenous communities living on the *puna* of Jujuy who organized against the lithium mines beginning in 2011. I worked with Victor Cuezco, an activist who had been involved in the anti-mining movement for most of his life. I visited Tres Pozos and Pozo Colorado, two Kolla communities living on the salt flats with populations that worked in salt mines. These communities taught me that lithium mining and salt mining can not both exist simultaneously. Lithium mining requires huge amounts of water that – in the case of the

Salinas Grandes – would be taken from springs and wells in the nearby mountains. These water resources not only provide the only water resource in an arid region to these communities, but also help with regeneration of clean salt crystal for mining, which is the sole source of income for most of the communities. Since both mining processes cannot successfully exist on the same land, establishing lithium mines inhibits these indigenous communities from supporting themselves on their own territory.

Prior consent for indigenous peoples: law or principle?

A theme that remained constant throughout all my conversations in the Salinas Grandes was *consejo previo*, which can be translated as prior council or prior advice. Loosely outlined in national Argentinean law under the Ministry for Social Development, covenant 169 law 24.071, the term *consejo previo* means that indigenous individuals and communities have the right to be informed before any action is taken on their land. Specific language, however, as to what prior council is, what the council should be, or who should do the counseling is up for interpretation. During my studies in Northern Argentina, I learned that there are information sessions, or *talleres*, held by the prospective lithium mining company that all indigenous community members are invited to attend. Though I was never able to attend one of these information sessions and experience firsthand how information was relayed, it appeared that “scientists” and “experts” were feeding these communities misleading information about the effects of a lithium mine on their land. Additionally, the community had no resources – legal or scientific, community-based or third party – to protect themselves or provide any other conclusions than what the *talleres* fed them.

I later learned that *consejo previo* is not exclusive to Argentina, but is part of the internationally recognized principle of Free, Prior and Informed Consent (FPIC) for Indigenous Communities. FPIC can be interpreted as a community's right to self-determination, or the power to consent to or reject any development that may concern the community's livelihood or land. It means that before any development occurs on indigenous land, the project must be clearly explained to the community and be accepted (or vetoed) by the community. However, similarly to *consejo previo* in Argentina, although FPIC is supported by the United Nations, there are no standardized processes, enforcement, or verification; it is therefore more theoretical than legally binding.

The Precautionary Principle, SEHN, and Native Peoples in the United States

Although continuing this investigation with Kolla communities of the Salinas Grandes was impractical once I returned to the United States, I decided that I wanted to continue my work with issues of indigenous consent and the principle of FPIC. Through Professor Bhavna Shamasunder, I was introduced to Carolyn Raffensperger of the Science and Environmental Health Network (SEHN), an organization that is concerned with protecting the longevity of environmental and human health. Dedicated to preventing the misuse of science and technology in development, SEHN has been one of the leading proponents in the United States of the Precautionary Principle. In summary, the Precautionary Principle advises that if an action or policy may lead to risk or harm of humans or the environment, it is the burden of the developers or active parties to prove

that no harm to the environment or human life will result.¹ I was asked by Raffensperger to investigate processes that might protect indigenous communities by holding corporations accountable for their actions through community informed consent. During my first conversation with Raffensperger, she mentioned the strides Alaska Native communities have made using community advisory boards (CAB) which function similarly to the federal Institutional Review Board while using exclusively community members or community elected representatives. By using examples of Community Based Participatory Research (CBPR) through CABs in Native communities – specifically Alaska Native communities – my goal is to examine what processes of community consent were successful in ensuring the human rights of all members of the community were respected. Utilizing literature and case studies, interviews and a review of policy, the following paper will explore the question of how we operationalize consent for Native communities in the United States and indigenous populations worldwide.

¹ “About SEHN,” *Science & Environmental Health Network*, accessed March 21, 2014, <http://www.sehn.org/about.html>.

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Glossary

- ✦ **Free, Prior, and Informed Consent** is the right for indigenous communities to make collective decisions for all development or action taken on their land. “**Free**” implies that indigenous communities should be allowed to make decisions in their own time, in adherence to their own cultural processes, in languages of their choosing, and subject to their own customary laws. This requires that they should not be subject to outside pressure, bribery, or placed unwillingly under the jurisdiction of other organizing bodies. “**Prior**” indicates when this consent should be given. Before any exploration, development, extraction, or other action is taken on community territory, the community should be educated on all possible outcomes and effects of the project. “**Informed**” refers to the information that the community has in order to make an educated decision. This means that institutions, corporations, or governments must provide communities with all facts regarding possible outcomes (i.e. changes to their water resources, air pollution), to review construction/destruction plans, to results in other indigenous communities with similar projects or development, etc. **Consent** is whether the community accepts or rejects the project. Consent should also be explicit and can be refused or withdrawn at any time.

- ✦ **Community-Based Participatory Research (CBPR)** is research that equitably includes members of the community in all aspects of the research process. Members may include community-based researchers, leaders and representatives, academics, or other interested community individuals or groups. Participants from the community are able to integrate community-based knowledge and needs into the research process, so as to assure results that respect and improve the quality of life for the contributing community subjects.

- ✦ **Beneficence** is the act of maximizing benefits and minimizing risks for research subjects. This means that human subjects and their communities should reap the most benefits from the research findings with minimal harm from participation.

- ✦ **Institutional Review Boards (IRB)** are, under United States federal law, mandatory for all research involving human subjects. All research institutions including universities must have at least one IRB. IRBs must include at least five members who can be reasonably considered experts on the subject, men and women, at least one scientist and one non-scientist. In the instance of vulnerable or protected subject populations, IRBs will include at least one community member from this population.

- ✦ **Community Advisory Boards (CAB)** are advisory councils composed entirely of members of the community where the research will take place. They function as a liaison between the subjects and the investigative party, and work with researchers to suggest revisions to various documents or provide supplemental recommendations to the community.

- ✦ **American Indian / Alaska Natives (AI/AN)** are all individuals, communities – both urban and rural – and nations of folk native to the United States and/or the state of Alaska.

- ✦ **Native/Indian** are terms usually substituted with “indigenous” in many academic or international sources of literature, but are terms commonly used amongst members of Tribal Nations in the United States to identify themselves. This paper will use the term ‘Native American’ to apply to all indigenous or American Indian/Alaska Native tribes, communities, and individuals in the United States.

Chapter I: Introduction

People and Progress

The United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) provides a set of articles that outline the human rights guaranteed to all indigenous persons and communities. Under this declaration, a few sections make brief mention of indigenous people's right to Free, Prior and Informed Consent (FPIC). Through examination of the various sections where the term is mentioned, it is reasonable to assume that FPIC can be generally understood as indigenous people's right to approve or reject proposed development or projects that may affect their communities, territories, or natural resources. The basis for FPIC emerged as a necessary outgrowth of a long history of violence and disenfranchisement of indigenous communities worldwide. FPIC combines international human rights, environmental policy, and development law to advise growth in a way that is respectful and beneficial to all stakeholders.

Although the UNDRIP recommends that "states shall consult and cooperate in good faith with the indigenous peoples concerned"⁴, it does not explain the process for doing so. Although most countries internationally have endorsed the UNDRIP, and programs like the United Nations Collaborative Programme on Reducing Emissions from Deforestation and Forest Degradation in Developing Countries (UN-REDD) utilize principles of FPIC, there is still ambiguity on whether indigenous peoples have the right

⁴ "United Nations Declaration on the Rights of Indigenous Peoples" (United Nations, March 2008).

to outright reject development or action on their land. With the example of the UN-REDD Programme, the guidelines for the program affirm, “that indigenous peoples have the right to effective participation in the decisions, policies and initiatives that affect them and that FPIC is a legal norm that imposes duties and obligations on the States.”⁵ What ‘effective participation’ is and description of who enforces the ‘duties’ of States is vague throughout the UN-REDD Programme Guidelines on FPIC, which claims to provide policy the operationalization of FPIC in the field.⁶

In the United States there are no existing programs or laws that explicitly utilize the principle of FPIC to inform processes of consent to development for indigenous communities. However, the United States does provide detailed processes for other forms of consent. The U.S. Office for Human Research Protections (OHRP) in partnership with Human Health Services (HHS) mandate that all institutions that conduct research on human subjects construct an Institutional Review Board (IRB). All researchers working through institutions must first submit a proposal of their investigation to be reviewed by the five members of the IRB, whose job is to evaluate the proposed research for possible risk to subjects. The IRB also requires researchers to provide informed consent forms delineating research intent, possible risks for subjects, and the subject’s right to abstain from the research. Once research is approved, each individual subject is then required to sign the form, consenting to all processes and conditions on

⁵ “Launch of FPIC Guidelines,” United Nations, *UN-REDD Programme*, (2009), http://www.un-redd.org/Launch_of_FPIC_Guidelines/tabid/105976/Default.aspx.

⁶ Jennifer Laughlin, “Guidelines on Free, Prior and Informed Consent” (UN-REDD Programme, January 2013).

the form. The IRB process is intended to protect the human rights of individuals who choose to participate in research.

Although the IRB provides significant protections for individual subjects, there is often no community voice in the process of consent. For indigenous communities, where cultural values often center around tradition and unity of community members, individual consent is often insufficient in securing that the rights of the community are protected. Additionally, each indigenous community is united under one name – a name that implies shared heritage, shared present existence, and a shared investment in the future of their community.

This is where the value of Community-Based Participatory Research (CBPR) is seen. CBPR is, in simplified terms, the inclusion of community members in all aspects of the research process, so as to allow the community control over the research process. This ensures that communities have the right to *consent with conditions*, or community participation in research through complete involvement of the community in the research design, editing, recommendations, and publishing of findings.

This paper will address the issue of community consent through a review of literature concerning issues of FPIC, ethical principles for research on human subjects and IRB protocol, and CBPR in Alaska Native communities. Primary research will include interviews with researchers and administrators working with issues of Native consent for research, as well as an analysis of the existing policy for human subjects research in the United States.

Research Question

While FPIC, as declared by the United Nations, provides a set of principles to be applied within a global framework for indigenous rights, specific delineation and explanation of these rights must then be operationalized by each nation. In the United States the Institutional Review Board process provides a model through which researchers can obtain the consent of individuals, but does not apply to consent by a larger community or culture, which is crucial for Native American communities. Using examples of CBPR in Alaska Native communities, this paper examines whether and how community-based participatory review boards might serve as a vehicle through which FPIC is operationalized at the local level.

Chapter II: Review of Literature

The following review includes existing literature on FPIC, human subjects research protections and IRB protocol in the United States, and CBPR in Native communities. Of the literature on FPIC, case studies include indigenous communities from countries such as the Philippines, Peru, West Sumatra, Indonesia, Malaysia, Kenya and Suriname in addition to Native American Indian communities including the Nations of Navajo, Havasupai, Mohawk, and Alaska Native communities of Inupiat. The literature review of FPIC focused on how indigenous land was identified, what community organizations should have the voice of “consent”, who is responsible for implementing and enforcing FPIC policy (corporate, international, national, and/or local organizations), what research auto-regulation looks like for indigenous communities, how research

regulation can be enforced through policy, and what position indigenous communities should have in ensuring their own human rights. Of the existing literature on human subjects research, this paper reviewed international and domestic standards and protocol for the respectful treatment and protection of human subjects.

Section 1 - Free, Prior, and Informed Consent

Free, Prior, and Informed Consent (FPIC) is the principle that indigenous folk have the right to decide what will or won't happen to their community, on their land, and to their natural resources. Although many countries, corporations, conventions, and industry review boards have drafted and discussed the theory behind FPIC, few examples currently exist that demonstrate a fully realized operation or procedure for implementation of these principles. Of these few procedural examples, almost no current processes for FPIC have been successfully effectuated. FPIC practice is still lacking justice for indigenous folk, the respect of their human indigenous rights, and their right to give or withhold consent. The following sections will discuss the components and implementation of FPIC internationally.

Declaration on the Rights of Indigenous Peoples

Although the United Nations provides a wealth of literature from a variety of council and programs pertaining to the rights of indigenous peoples, there is still ambiguity on what special protections or rights are guaranteed to indigenous communities and persons. Kanyinke Sena, a native Ogiek of Kenya who sits on the United Nations Division for Social Policy and Development under the United Nations

Department of Economic and Social Affairs, points out in his report on *Empowering Indigenous Peoples*:

The **United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP)** provides the basic framework for empowering Indigenous Peoples. A **non-binding declaration of moral import**, UNDRIP provides essential standards for the recognition and protection of indigenous peoples rights internationally by providing both policy makers and indigenous peoples the framework to mitigate the disadvantages experienced by many of the world's 370 million indigenous peoples.

UNDRIP does not confer new rights. It affirms the social, political, economic, cultural and political rights recognized by other international instruments which most countries have ratified. Indigenous Peoples rights are not therefore special rights but an articulation of universal human rights as they apply to indigenous peoples. However, many countries still remain reluctant to take proactive steps to actualize the rights enshrined in UNDRIP. By refusing to recognize, protect and promote these rights, many states are not only missing the opportunity to address issues of poverty that affect the most impoverished sections of their populations, but are also perpetuating the continued impoverishment of their citizenry.⁸ [emphasis added]

It is important to note that, as Sena confirms, the UN Declaration of the Rights of Indigenous peoples does not prescribe new rights to indigenous peoples on top of the rights already outlined in the UN Declaration of Human Rights – it restates them in the specific context of indigenous peoples.

Indigenous Peoples

What constitutes an Indigenous Community?

One of the most simple and yet frustrating issues with implementing policy that enforces FPIC is whether or not a community can be deemed 'indigenous' in the eyes of

⁸ Kanyinke Sena, *Empowering Indigenous Peoples, Policies and Strategies to Promote the Empowerment of People in Achieving Poverty Eradication, Social Integration and Productive and Decent Work for All* (New York: Division for Social Policy and Development, United Nations Department of Economic and Social Affairs, September 11, 2013).

international, national, local, organizational or corporate bodies. The United Nations' working definition of Indigenous Community is as follows:

"Indigenous communities, peoples and nations are those which, having a historical **continuity with pre-invasion and pre-colonial societies that developed on their territories, consider themselves distinct from other sectors of the societies now prevailing on those territories, or parts of them**. They form at present non-dominant sectors of society and are determined to preserve, develop and transmit to future generations their ancestral territories, and their ethnic identity, as the basis of their continued existence as peoples, in accordance with their own cultural patterns, social institutions and legal system.

"This historical continuity may consist of the continuation, for an extended period reaching into the present of one or more of the following factors:

- a) **Occupation** of ancestral lands, or at least of part of them;
- b) Common ancestry with the original occupants of these lands;
- c) Culture in general, or in specific manifestations (such as religion, living under a tribal system, membership of an indigenous community, dress, means of livelihood, lifestyle, etc.);
- d) Language (whether used as the only language, as mother-tongue, as the habitual means of communication at home or in the family, or as the main, preferred, habitual, general or normal language);
- e) Residence on certain parts of the country, or in certain regions of the world;
- f) Other relevant factors.

"On an individual basis, an indigenous person is one **who belongs to these indigenous populations through self-identification as indigenous** (group consciousness) and **is recognized and accepted by these populations as one of its members** (acceptance by the group).

"This preserves for these communities the sovereign right and power to decide who belongs to them, without external interference".⁹ [emphasis added]

Self-identification as indigenous does not necessarily guarantee classification as indigenous under the law – many indigenous communities are not federally recognized as distinct groups, or in the case of the United States, sovereign nations. As can be seen clearly in the history of the colonization of the Americas, many indigenous communities were historically moved from their native lands to be used as slaves to work in mines, fields, or simply to free up their land. This displacement or forced migration moved indigenous communities across regions and even continents as enslaved peoples and,

⁹ United Nations, "The Concept of Indigenous Peoples" (Department of Economic and Social Affairs - Division for Social Policy and Development, Secretariat of the Permanent Forum on Indigenous Issues, January 2004).

eventually, left these communities to search for new land. This leaves communities worldwide that do not reside on their “ancestral land” but on land that originally belonged to another community, land that is barren by the standards of the communities traditional agricultural or gathering practices. Some even reside on land that they consider “temporary residency”, or land that is now owned by a corporation or company. Additionally, in the United States, urban AI/AN enrolled members (as opposed to rural) are often subject to different legal protections, depending on their status within the tribe and urban community.

One example of many unrecognized communities is the indigenous American Indian Duwamish Tribe, whose ancestral land includes the greater area of Seattle, WA. According to the Tribe’s website, the absence of federal recognition and, consequently, access to human services has prompted many of the 600 Duwamish members to enroll with neighboring tribes.¹⁰ Around thirty years ago, the Duwamish Tribal Services non-profit was founded to provide social, educational, health, and cultural programs for members. The Duwamish Tribal Services helps Duwamish Tribe members enroll with neighboring Suquamish and even Tulalip tribes in order to access the few privileges granted to American Indian sovereign nations. Even in the United States, which grants more protection to Native folk than many countries, there are legal barriers that prevent indigenous people from accessing basic rights – to health care, education, social programs – guaranteed to all other citizens.

¹⁰ “Duwamish Tribe,” accessed January 5, 2014, <http://www.duwamishtribe.org/>.

Defining Land & Territory

One of the first issues that arise out of the concept of FPIC is how indigenous territory is defined – both by the community and other political authorities. Depending on the type of community – hunter-gatherer, agrarian, with familial or collective ownership – traditional lands may or may not be defined by geopolitical boundaries. In Peru, while indigenous rights to village or familial lands are protected, larger swaths of territory are often not recognized as belonging to specific communities.¹¹ The influence of external political powers can also significantly change the landscape for indigenous communities. For example, the small Indonesian island of Flores was colonized in the 16th century by the Portuguese, by the Dutch in the 17th, and finally accepted into the Republic of Indonesia in the 20th. Changes in control complicated the land rights for indigenous communities of Flores: it changed the way they saw “their lands” over the years, and the ways they remained linked to their land.¹² Lewolema communities of Flores argued that the Portuguese gave them these lands during colonization, and, therefore, belonged to them by local customary authority. Some communities in Lewolema even asserted that they acquired their rights in land through conquest.¹³

An important note when looking at FPIC is what authority in the community has the right to make decisions regarding land use and ownership. In the Minangkabu communities of West Sumatra lands are a matrilineal inheritance and are held under a

¹¹ Marcus Colchester and Maurizio Farhan Ferrari, “Making FPIC - Free Prior and Informed Consent - Work: Challenges and Prospects for Indigenous Peoples” (Forest Peoples Programme, Moreton-in-Marsh, June 2007).

¹² Ibid.

¹³ Ibid.

number of traditional tenures.¹⁴ Additionally, matrilineal clans may hold land collectively: any process of FPIC within these clans must ask for collective consent across multiple communities. These examples show how the variety of structures within indigenous communities must be considered in due process. The variance in aforementioned territorial ownership structures also demonstrate how one model for FPIC may not be sufficient to address the needs of all indigenous groups.

Community & Tribal Sovereignty

According to the UN Declaration on Indigenous Peoples, “Indigenous communities, peoples and nations are those which...consider themselves distinct from other sectors of the societies now prevailing on those territories, or parts of them...and are determined to preserve [their communities] in accordance with their own cultural patterns, social institutions and legal system.”¹⁵ Although UNDRIP acknowledges that indigenous communities often live separately from other societies – separate in the sense of location as well as culture and language – the status of the community or tribe as legally separate or free from national jurisdiction is up to the government of each country. While Native American communities are considered sovereign nations within the United States, other communities internationally do not enjoy the same level of legal and governmental power. The following subsection will explore the legal status of Native Americans and sovereignty.

¹⁴ Ibid.

¹⁵ United Nations, “The Concept of Indigenous Peoples.”

Native American Sovereign Nations

According to the website of the US Department of the Interior for Indian Affairs, Article 1, Section 8 of the Constitution grants the Executive and Judicial branches of government “authority to engage in relations with tribes,”¹⁶ thereby legally incorporating tribes into the United States. However, the same page mentions an articulation from 1830’s Supreme Court Chief Justice John Marshall: the principle “that tribes possess a nationhood status and retain inherent powers of self-government.”¹⁷ American Indian or Alaska Native tribes that are considered “federally recognized” have a government-to-government relationship with the United States, and are eligible for federal funding and human and health services. Of the 566 federally recognized tribes in the United States, 229 of these tribal nations are located in Alaska; the remaining tribes are located in 34 other states.¹⁸ As noted earlier with the Duwamish Tribe, not all indigenous American communities are respected and federally recognized as distinct bodies. Like Duwamish members, Native American individuals must choose to enroll or join a federally recognized tribe to receive benefits guaranteed to AI/AN citizens. This also means that ancestral Duwamish land does not legally belong to the tribe members, nor is protected and respected as such.

In regards to sovereignty: “Tribal sovereignty ensures that any decisions about the tribes with regard to their property and citizens are made with their participation

¹⁶ “Frequently Asked Questions,” *US Department of the Interior - Indian Affairs*, n.d.

¹⁷ *Ibid.*

¹⁸ “Tribal Governance,” *National Congress of American Indians*, accessed April 9, 2014, <http://www.ncai.org/policy-issues/tribal-governance>.

and consent.”¹⁹ Although language in this statement appears to affirm that Native Americans are already promised a form of FPIC – that the tribe has the power to decide what will happen on their land – this does not guarantee an ethical process. Although Native nations do have jurisdiction for all action on their land, this does not assure that the consent processes – if any – will be conducted with *respect* for the tribe, will *benefit* the tribe more than harm them, and will guarantee that the tribe will reap the benefits of the research and bear the burdens of development *fairly*. These three principles, key to a successful FPIC protocol, will be described in detail in the second section of this chapter as part of the Belmont Report.

Understanding the structure of Community Governments

The ‘consent’ portion of FPIC begs the question of whose voice within the community has the power to accept or veto proposed development. Leadership structure in indigenous communities across the world is as varied as the spoken language, dress, and food. In Indonesia, *musyarawah* – communal meetings and discussions within communities – are intended to build consensus-based decisions called *mufakat*. Both vary depending on the village and customary norms.²⁰ Even within very small geographical areas, where language and general culture is the same, each village may have its own specific rules. Some communities maintain self-governance, such as the Minangkabau of West Sumatra, where communities normally have a king supported by hierarchy of authorities. In this community, the council may speak for the

¹⁹ “Frequently Asked Questions.”

²⁰ Colchester and Ferrari, “Making FPIC - Free Prior and Informed Consent - Work: Challenges and Prospects for Indigenous Peoples.”

king, depending on the importance and nature of the issues.²¹ In Suriname, the Gaama (paramount leader) does not have authority to make land-use decisions. This power is in the hands of 12 matrilineal clans, which make land decisions collectively.²²

Since FPIC seeks community consent, operationalization of its principles must freely inform the community in accordance with existing governing structure. The wide variation in types of community organizations, even within a country or small region, begs the question of how to create a standardized process of FPIC when leadership and community structure is not standardized. Colchester and Ferrari argue that government agencies and corporations are rarely aware of these systems, and therefore neglect to consult communities appropriately. This ties into the issue of cultural considerations for researchers, which will be further investigated in the third section of this literature review.

Institutional Support: FPIC Enforcement by National Governments

In some countries, national law and policy mandate certain forms of FPIC, such as the laws for ‘prior consent’ in Argentina. Some countries have territorial law for native peoples, or specific swaths of land reserved for its ancestral inhabitants. The following subsections will analyze the responsibility for enforcement for national and financial authorities.

Government Responsibility

²¹ Ibid.

²² Ibid.

There is a wide variation of how national laws protecting indigenous territorial rights and FPIC are written, presented to the communities, and enforced. Colchester and Ferrari note that there are serious deficiencies in implementation and verification. Indigenous land rights – which do not include FPIC – in Peninsular Malaysia have been noted and affirmed by government systems, but they are weakly written and protected in national law.²³ In Peninsular Malaysia, the Centre for Orang Asli Concerns confirms that the Malaysian government accepted an 82 billion yen loan from the Japanese Bank for International Cooperation for development of a dam on Orang Asli land. The bank’s ‘Guidelines for Confirmation of Environmental and Social Considerations’ contains the rhetoric that “Efforts must be made to obtain the consent of indigenous people after they have been fully informed...”²⁴ Peruvian law requires FPIC for indigenous community property holders. However, the law only applies to people who already hold a government-issued title to their land.²⁵

Corporate Responsibility

According to the Filipino Legal Rights and Natural Resources Center (LRC), companies reduce FPIC policy to a nominal procedure with “tokenistic” compliance.²⁶ In this example, “tokenistic” implies that FPIC requirements are applied case-by-case; FPIC policy is seen as an option rather than law. Even when corporations profess to respect indigenous rights and international law, they may not adhere to their own standards in

²³ Ibid.

²⁴ Ibid.

²⁵ Ibid.

²⁶ Ibid.

their actual dealings with communities.²⁷ Alcoa and BHP-Billiton – extraction companies operating out of Suriname – note that there is a lack of international consensus on the application of FPIC law.²⁸

The Royal Bank of Canada's (RBC) supplier management policy includes requirements in the procurement process to review environmental and social issues that could impact business or communities. In other words, the RBC views funding projects that may have an adverse social and environmental impact as bad business practices. On the RBC site's Responsible Procurement page, the bank requires suppliers to give information on everything from environmental action plans, to NGO relationships, to, "Impacts on indigenous communities and the degree to which the principles of *free, prior and informed consultation* are applied."²⁹ Notably, Canada is not one of the few countries worldwide that have incorporated FPIC into their domestic legal framework.³⁰ Although RBC policy does not explicitly align with policies of FPIC – RBC mentions a form of consultation rather than outright consent – it sets an example for a powerful force for policy enforcement. In principal, if banks refuse to fund projects that do not follow the processes of FPIC, fewer projects that disrespect indigenous communities would exist. However, although RBC may provide prospective suppliers with further explanation to what "free, prior and informed consultation" should include, there is no publically available information that describes a process for this consultation.

²⁷ Ibid.

²⁸ Ibid.

²⁹ "About RBC: Responsible Procurement," *Royal Bank of Canada*, accessed April 9, 2014, <http://www.rbc.com/community-sustainability/environment/responsible-procurement.html>.

³⁰ "RBC Sticks Its Neck out on Consultation," *Windspeaker*, 2011.

With the operationalization of FPIC, it is not only important to mandate processes for consent, but to also create a protocol for the conversations between the indigenous communities and authorities.

Prior On-site Consultation

A key element of FPIC is the process of communication between the community and the researcher, company, or institution. The need for FPIC protocol comes from the absence or loss of community voice in construction and development planning that may affect the community. For example, in “Making FPIC Work”, Colchester and Ferrari provide the case of the Chewong indigenous group of Malaysia. The Chewong belong to the Centre for Orang Asli Concerns, a community organization that seeks to facilitate indigenous initiatives and defend the rights of indigenous communities.³³ The Centre for Orang Asli Concerns of Malaysia reported on FPIC with construction of a new dam on Chewong community land. According to the local Department for Aboriginal Affairs, the Chewong were adequately consulted and accepted the proposal of resettlement.³⁴ Upon a visit to the Chewong community, it was clear to the Centre that the community was not willing to move and added that no officials had ever visited the community. Although this case may seem like an anomaly, where FPIC clearly did not exist, it shows that local or even provincial legal declarations of FPIC do not necessarily translate to

³³ “About COAC,” *Center for Orang Asli Concerns of Malaysia*, accessed April 9, 2014, <http://www.coac.org.my/beta/>.

³⁴ Colchester and Ferrari, “Making FPIC - Free Prior and Informed Consent - Work: Challenges and Prospects for Indigenous Peoples.”

application of FPIC principles. The issue of implementation of operations leads into the following subsection of this review.

Operationalization & Implementation: FPIC on the ground

Processes in Practice

In “Making FPIC Work”, Colchester and Ferrari assess various examples of FPIC implementation worldwide. For example, in the Philippines there is strong legal language supporting FPIC policy. However, according to the Filipino Legal Rights and Natural Resources Center (LRC) there have been a number of instances where community objections to operations on their lands appear to have been bypassed.³⁵ In a 2007 presentation, the LRC argued that defects in the process of implementation of FPIC led to this negligence. Defects included too much latitude of interpretation by government authorities and simplified guidelines that allowed for superficial consultations with communities. Additionally, FPIC policy only applied to previously listed territory, thereby excluding communities who had not already legally claimed their land.³⁶ This case is important inasmuch as it highlights some of the issues with FPIC implementation even after

Another Filipino FPIC policy research group, TebTebba Foundation, noted that current FPIC procedure is hurried and mechanical, provides limited information to communities, and prescribes the establishment of indigenous authorities (which may

³⁵ Ibid.

³⁶ Ibid.

contradict traditional or communal indigenous cultural governance).³⁷ Other findings from TebTebba researchers include how companies and local officials purposefully misled communities and falsified documents in order to secure FPIC certificates. The foundation notes that in their field studies, often if a project was rejected by a community, they were sometimes subject to repeat demands to give the project further consideration.³⁸ This case begs the question of what when FPIC is implemented, who should enforce due process and verify that community decisions were respected.

Enforcement & Verification of FPIC

If FPIC is to be correctly implemented on site – where the community is involved in the process of deciding whether or not a project moves forward – there is the question of who is responsible for enforcing correct processes and verifying whether said processes were executed in the community’s best interests. Validation of FPIC can also be understood as whether or not the community is satisfied with the process and outcome, but is more often seen as the final stamp of approval in the bureaucratic legal process. Both enforcement and validation require some kind of body to hold responsible for “checking” FPIC processes. There are debates throughout the indigenous and FPIC communities as to whom should be responsible for enforcing FPIC, including the national government, third parties, or simply the communities themselves. As Colchester and Ferrari explain in their paper, “verifiers are unduly lenient about what

³⁷ Ibid.

³⁸ Ibid.

constitutes adequate compliance, thereby weakening any leverage that communities may gain from companies' obligations"³⁹ Although many communities may

"Free" Consent: Bribery, Coercion, and Force

The principle of Free, Prior and Informed Consent implies a partnership or fair relationship between indigenous communities and corporate or governmental interests. However, many indigenous communities live in rural areas with little economic development and, to developers, lots of economic potential. In contrast, most indigenous peoples have little monetary bargaining power, while developers may include multi-billion dollar corporations like Coca Cola and Golden Agri-Resources palm oil. In the case of the TebTebba Foundation in the Phillipines, researchers found that FPIC policy abuse included force and bribery to secure consent from community leaders.⁴⁰ In her paper "Indigenous Peoples' Right to Free, Prior, Informed Consent: Reflections on Concepts and Practice", Joji Cariño reflects on her time working with indigenous community organizations in the Philippines: "Everywhere, companies promise jobs and roads and clinics and the moon to decision-makers in extremely poor communities. However, their promises have few controls and no bonds against failure to deliver."⁴¹

Moving Forward

³⁹ Ibid.

⁴⁰ Ibid.

⁴¹ Joji Cariño, "Indigenous Peoples' Right to Free, Prior, Informed Consent: Reflections on Concepts and Practice" (Arizona Journal of International & Comparative Law, 2005).

In “Making FPIC Work”, Colchester and Ferrari suggest that indigenous peoples can proactively prepare and take time to make decisions with due care.⁴² The same study also concludes that whether or not FPIC is explicitly recognized in national laws should not dissuade indigenous communities from insisting on respect from this right.⁴³ However, earlier in the same document they include a case study from Indonesia where national indigenous organizations, “noted that companies and local government officials often get away with expedited FPIC processes because communities are unsure of their rights or the required FPIC process”.⁴⁴ One of the most prevalent issues related to FPIC policy is the fact that most indigenous communities are unaware that FPIC exists, do not have access to specific language outlining their rights, or are unclear of the due process under FPIC law. These same discrepancies in knowledge are apparent in IRB dealings with Native American communities: the IRB does not

As part of her conclusions, Cariño projects that ultimately FPIC will require “a political process that prioritizes cultural and national diversity as core values in our lives and survival.”⁴⁵ Shortly after this statement, she notes that the indigenous voice continues to be manipulated and ignored in the face of foreign owned mining firms;⁴⁶ industry interests trump indigenous interests. This dichotomy suggests that FPIC might not necessarily be the solution for countries with struggling economies.

⁴² Colchester and Ferrari, “Making FPIC - Free Prior and Informed Consent - Work: Challenges and Prospects for Indigenous Peoples.”

⁴³ Ibid.

⁴⁴ Ibid., 16.

⁴⁵ Cariño, “Indigenous Peoples’ Right to Free, Prior, Informed Consent: Reflections on Concepts and Practice.”

⁴⁶ Ibid.

Findings and Considerations for FPIC

To conclude this section of the review, though FPIC carries great ethical importance as a principle, there have been few successful implementations of any sort of policy guaranteeing indigenous communities due process. Although the United Nations provides a framework for FPIC theory, there are insufficient recommendations for implementing and enforcing this theory. The rights of indigenous inhabitants continue to be pushed aside by corporate and economic interest that drives exploration and development. Insufficient protections leave indigenous communities vulnerable to these powerful institutions.

Although there is no due process for consent guaranteed with FPIC, the United States hosts a different system for guaranteeing a different form of consent: consent for research on human subjects. The following section will study the benefits and risks of research on human subjects, and will examine the Institutional Review Board system as a federal wide structure for guaranteeing respect for persons, benefit for persons, and justice.

Section 2 - Research on Human Subjects: Codes of Conduct and the Institutional Review Board

While the previous section of this literature review analyzes why the implementation of Free, Prior and Informed Consent has been ineffective for ensuring indigenous right to consent, the following section will examine existing law and policy that grants the right to consent. Although principles for FPIC in current practice are a relatively new development for the United Nations, principles and law for research on

human subjects have been written and reevaluated numerous times by a variety of countries throughout the 20th century. Significant growth in the legal and ethical protections granted to human subjects can be seen in federal documents, from the 1931 German Guidelines on Human Experimentation and subsequent Nuremberg Code, to the 1979 Belmont Report. In the United States, we see processes protecting the human right to consent with the Institutional Review Board (IRB), whose job is to review a research proposal before it reaches the subjects.

The following review of literature will provide a brief history of research on human subjects, analyze the IRB model, and begin to analyze how the IRB is used to evaluate research conducted in Native American communities.

2.1 – A Contemporary History of Research on Human Subjects

One of the earliest modern documents outlining best practices for research on human subjects was a Circular published by the German Reich Minister of the Interior in 1931, which offers guidelines for therapeutic and scientific research on human subjects. A set of 13 guidelines for biomedical researchers, the Guidelines on Human Experimentation delineate conditions for respecting subjects, including special considerations for subjects under 18 years of age, respecting the dignity of subjects, and that “experimentation shall be prohibited in all cases where consent has not been given”.⁴⁷ Just sixteen years later, similar guidelines are delineated in the Nuremberg

⁴⁷ Warren T. Reich, ed., “German Guidelines on Human Experimentation,” *Encyclopedia of Bioethics* (Circular of the Reich Minister of the Interior, February 28, 1931).

Code, a code in response to the grotesque human experiments by Nazi doctors on inmates in concentration camps during WWII.

The Nuremberg Code was written after the Trials of Nazi War Criminals, and continues to be a reference for human subjects principles, although the code itself still carries no legal weight.⁴⁸ The code clearly builds upon the Guidelines on Human Experimentation to provide more specific language outlining what should or should not be permissible in research using human subjects. For example, the code details voluntary consent of human subjects in the first point. Through examination of this first point, is critical to note that there is exact language in the Nuremberg Code that delineates FPIC:

The voluntary **consent** of the human subject is absolutely essential. This means that the person involved should have *legal capacity* to give consent; should be so situated as to be able to exercise **free** power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have **sufficient knowledge** and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision This latter element requires that **before the acceptance** of an affirmative decision by the experimental subject there should be made known to him the *nature, duration, and purpose of the experiment;*...⁴⁹ [emphasis added]

This first point states that *consent* is the *free* choice of the individual, who should have sufficient *knowledge* of the research subject to make a decision, and that this knowledge should happen *before* the consent is given. Using similar words, this first point sums up FPIC. The point also mentions the importance of “legal capacity”, which

⁴⁸ “Nuremberg Code - United States Holocaust Memorial Museum Note,” *United States Holocaust Memorial Museum*, accessed April 2, 2014, <http://www.ushmm.org/information/exhibitions/online-features/special-focus/doctors-trial/nuremberg-code>.

⁴⁹ “Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10” (Washington D.C.: U.S. Government Printing Office, 1949).

may refer to minors and vulnerable populations, and that subjects should be informed the “nature, duration, and purpose of the experiment”⁵⁰. Both qualifications are mentioned specifically in Informed Consent for the IRB system, and will be further described in the second part of this section as well as in Analysis of primary research later in this paper. Although the Nuremberg Code provides an admirable set of principles for instilling good practices for researchers, it – like much of the policy for FPIC – carries no legal weight and does not provide examples or advice for implementing good practices; the document in its entirety is no more than a page of writing. However, the Nuremberg Code is by no means the most recent or complete set of principles for research on human subjects.

Responsibility for risk in the Declaration of Helsinki

The 18th General Assembly of the World Medical Association (WMA) adopted the Declaration of Helsinki in 1964 as a set of ethical Principles for medical research involving human subjects, including research on identifiable human material and data.⁵¹ This declaration builds upon the Nuremberg Code in that it provides specific descriptions of where responsibilities for upholding the principles of research. For example, the third Principle claims that it is the, “duty of the physician to promote and safeguard the health of patients”⁵², and Principle 16 even explains that the protection of the research subject always rests with the physician and never with the subjects,

⁵⁰ Ibid.

⁵¹ World Medical Association, “Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects” (World Medical Association, June 1964).

⁵² Ibid.

although they have already given consent. The 30th and final Principle holds authors, editors, and publishers responsible for ethical obligations; it points out the need for accuracy of factual data and that “Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.”⁵³ The third section of this literature review will cite the research malpractice cases of the Havasupai Tribe and the Barrow Alcohol Study, both of which violate this Principle. Both of these cases also relate closely to Principle 18, which mandates that research studies must be “...preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation.”⁵⁴ Principle 18 is crucial to both FPIC and Community Based Participatory Research, since it includes community needs as intrinsically intertwined with individual consent; it acknowledges that burdens and risks that individuals take on may also burden and harm the community. From this Principle, it can be reasonably understood that researchers need to assess community risks as well as individual risks when writing and revising their proposals.

Although these Principles provide many important recommendations, they are a set of ethical principles and only legally binding only as much as national governments choose to write them into law. Again – like much of the United Nations literature on FPIC, and the Nuremberg Code and Guidelines for Human Experimentation – it is up to

⁵³ Ibid.

⁵⁴ Ibid.

governing bodies or authoritative institutions to decide whether (and which) principles should be adopted into law and practice.

Domestic Principles for Consent: Ethics for research in The Belmont Report

On July 12, 1974, the National Research Act was signed into law by the United States government, thereby creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission was charged with creating a set of ethical principles for researchers and research conduct, and also to develop guidelines that would direct research processes to employ these principles in action. It is important to note that the Belmont Report “does not make specific recommendations for administrative action”, but instead the Commission suggested that the Report be adopted in its entirety “as a statement of the Department’s policy.”⁵⁵ Therefore, the following ethical guidelines are not legally binding, but again, principles for code of conduct. The Belmont Report is composed of three main guidelines: respect for persons, beneficence, and justice.

Respect for persons

The first ethical guideline, respect for persons, is in short that all persons are autonomous agents, and should be treated and respected as such, and that those with diminished autonomy are entitled to protection. Ethical implications include that as autonomous persons, they should be free to make unbiased, informed judgments; that

⁵⁵ National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report*, National Research Act (U.S. Department of Health & Human Services, April 18, 1979).

is to say, that lack of respect would be to withhold information necessary to make a considered good judgment.⁵⁶ Later under the same guideline, the Report states that persons should enter the research voluntarily with adequate information, and should not be unduly coerced to engage in research activities for which they would not otherwise volunteer.⁵⁷ This first guideline ties back to ‘informed’ consent; that consent should be based on judgments made from accurate and adequate information.

Beneficence

The second guideline, beneficence, is the act of maximizing benefits and minimizing risks for research subjects. Beneficence includes the important obligation of researchers to protect subjects from harm and to secure their wellbeing.⁵⁸ Human subjects and their communities should reap the most benefits from the research findings with minimal harm from participation. The obligation of beneficence also implies that “one should not injure one person regardless of the benefits that might come to others”.⁵⁹ This last point connects to Carolyn Raffensberger’s questioning of utilitarianism; what is best for most is not necessarily what is best for all. Beneficence for persons is an essential piece of development and environmental ethics that is often overlooked. To place the guideline in context, no lithium mine or palm oil plantation should ever be constructed – no matter how many jobs or how much economic growth it will provide – if the well-being of the land or its inhabitants is threatened. This paper

⁵⁶ Ibid.

⁵⁷ Ibid.

⁵⁸ Ibid.

⁵⁹ Ibid.

will refer to the ethical connotations and implications of beneficence throughout a variety of the following chapters.

Justice

The final ethical guideline in the Belmont Report is justice. This guideline asks the researcher to consider who will reap the benefits of the research, and who will bear its burdens. If there are burdens, how will these burdens be distributed and if there are benefits, how will these benefits be distributed. The Report then breaks up justice into five sections with regards to how people should receive benefits and burdens: first, to each person an equal share of both; second, to each person according to need; third, to each person according to individual effort; fourth, to each person according to societal contribution; fifth, to each person according to merit.⁶⁰ In summary, these points rationalize the idea that burdens should be carried equally, or should be carried by those who can most ably carry them. Additionally, benefits should go to those most in need, but should also be distributed equally. This guideline also provides historical context for justice: in the 19th and 20th century, poor ward patients were used as subjects, while benefits of research served private patients who could afford healthcare.⁶¹ This guideline also mentions the Tuskegee syphilis study, which used the bodies of poor, black men as petri dishes to examine the untreated course of the disease. This study will be further explained in the following section on the Institutional Review board.

⁶⁰ Ibid.

⁶¹ Ibid.

Both examples of research malpractice highlight how ethnic minorities and economically disenfranchised persons are often used and abused in research studies because of their compromised, vulnerable position and manipulability. The historical examples also demonstrate how these populations are often excluded from the benefits of their own research participation. The second half of the Belmont Report is dedicated to applications of the three ethical guidelines, which suggest modes for addressing the ethical guidelines in practice.

Applying ethical principles of the Belmont Report: Informed Consent, Assessment of Risk and Benefit, and Selection of Subjects

Informed consent is a process employing three elements: information, comprehension, and voluntariness. Not dissimilar to the principle of FPIC, the objective of informed consent is to give subjects the adequate opportunity to decide what shall or shall not happen to them.⁶² To continue delineating informed consent, Belmont Report also explains how “...a simple listing of items does not answer the question of what the standard should be for judging how much and what sort of information should be provided.”⁶³ This employs the idea that informed consent is more than just a form with a brief explanation of the investigation; consent is a process and a conversation, not a signature or a simple verbal ‘yes’. The element of comprehension is necessary to ensure that information is conveyed in an understandable fashion; researchers must adapt the presentation the information to fit subjects capacities.

⁶² Ibid.

⁶³ Ibid.

For example, when development of a coalmine is proposed on territory belonging to a rural indigenous community it is highly unlikely that members would understand construction processes, terminology, science or environmental effects that a researcher might present to them. Researchers typically have an academic background and deep understanding of their own research that is clearly not accessible to their subjects. This is especially problematic if subjects belong to impoverished, rural communities where education and access to any kind of information and support is difficult to find. As the Report notes, when researchers are in informational positions of authority or commanding influence, unjustifiable pressures usually occur.⁶⁴ Undue coercion might not be apparent to both researcher and subject, but it is intrinsically woven into all research where this disparity in understanding exists.

In addition to proper relaying of information, an integral piece of FPIC is that informing and consent is a process of *community* involvement. The second application of the Belmont Report asserts that, “Risks and benefits of research may affect the individual subjects, the families of the individual subjects, and society at large (or special groups of subjects in society).”⁶⁵ In other words, interests not directly related to the subject as an autonomous individual might experience harm or receive benefit separate from that of the subject. This application in particular will be explored in the third section of this chapter on CBPR for Native communities, and is a crucial piece of the principles of FPIC policy.

⁶⁴ Ibid.

⁶⁵ Ibid.

The third application, selection of subjects, relates to prejudice and unjust research investigations, which often target disenfranchised communities. Poor people of color, and especially those from cultural and religious backgrounds different from that of the research institution, were historically targeted as easy populations to research. This application will unravel throughout the second half of this section with the Tuskegee Syphilis study, as well as in the third section of this chapter, which examines research in Native American communities.

It is significant that the three guidelines and three applications were written by a Commission of the United States Government Human & Health Services (HHS) to be used in principle for all research investigations utilizing human subjects nationwide. Therefore, the Belmont Report as a government document can reasonably be interpreted to serve as evidence that the United States government and its policy support these specific ethical protections for human subjects. The following section of this chapter will examine the Institutional Review Board, a section of the Code of Federal Regulations of HHS policy for the protection of human research subjects.

2.2 – Consent for Research: Institutional Review Board

The Institutional Review Board (IRB) is a federally mandated evaluation process for all research involving human subjects. The IRB aims to protect human subjects regulating the research process to minimize potential risks, maximize potential benefits, ensure compliance with federal regulations, promote good research, and provide accurate documentation of processes outlined in the Code of Federal Regulations Title

45, Part 46 Protection of Human Subjects (45 CFR 46).⁶⁶ As outlined under the National Research Act of 1974, IRBs are required for all United States institutions receiving federal support for research and evaluation studies.⁶⁷ An IRB consists of at least five members with varying backgrounds in respect to race, gender, culture, and profession. IRB members should have expertise in the field of research that they review, and at least one member of the IRB must not be directly affiliated with the institution.⁶⁸ All research that is conducted by members of an institution – universities, hospitals, nonprofit organizations, etc. – must first go through the institution’s federally assured IRB.

The National Research Act was a response to the “Tuskegee Study of Untreated Syphilis in the Negro Male,” one of the most flagrant cases of research malpractice and human subject abuse in United States history. As the title suggests, the study observed the disease in rural, low-income black males – who were completely unaware of the nature of the study – between 1932 and 1972.⁶⁹ Although penicillin was discovered in 1947, the study continued without offering treatment to the subjects; many men died, and countless family members or partners were infected.⁷⁰ In 1974, both the IRB system

⁶⁶ Phillip L. Smith, “American Indians and the Institutional Review Boards: A Tribal Governance Perspective” (Indian Health Service, n.d.), accessed April 6, 2014.

⁶⁷ Ibid.

⁶⁸ “Code of Federal Regulations: Title 45 Public Welfare - Department of Health and Human Services: Part 46 Protection of Human Subjects” (Department of Health and Human Services, January 15, 2009).

⁶⁹ “About the USPHS Syphilis Study,” University, *Tuskegee University*, accessed April 7, 2014, http://www.tuskegee.edu/about_us/centers_of_excellence/bioethics_center/about_the_usphs_syphilis_study.aspx.

⁷⁰ Ibid.

and the Belmont Report were created so that no investigation would ever repeat the immoral study of the Tuskegee research team, and to ensure the protection of future human subject volunteers.

Before moving forward with any investigation involving human subjects, all researchers must first submit a research proposal to their institution's IRB. The proposal often includes descriptions of the purpose of the investigation, the subject group and processes for recruitment, the type of research – such as medical, verbal (interviews), physical, etc. – and possible risks to subjects. Researchers also submit an Informed Consent Form, which is brief description of the research, risks and benefits intended for the subjects. Human subjects volunteers sign this form before the study begins as an agreement – not a promise – to participate in the study. Once the researcher submits the proposal, there is an initial review by an administrator in the IRB office that determines if there is minimal risk to the subjects or if the proposal needs to go through a full review. A full review would include consideration and deliberation by the official IRB. Only once the researcher receives approval for the investigation – with or without edits or conditions with respect to the proposal – can they begin the research process.

As discussed in the previous half of this section, the ethical guidelines of the Belmont Report afford considerable protections to human subjects. However, these guidelines and their applications were clearly not innately written into IRB policy 45 CFR 46. Language in IRB policy for research ethics is minimal rather than comprehensive, and does not create a standard for research evaluation, but rather requires each institution

to write its own IRB protocol.⁷¹ The following study by a government agency calls attention to possible flaws and loopholes in the IRB system.

Flaws in the IRB system

The United States Government Accountability Office (GAO) conducted an undercover study to evaluate the quality and efficiency of the Institutional Review Board System. GAO investigated three aspects of the IRB system: firstly, the process for establishing and registering an IRB; secondly, the interaction between HHS and researchers seeking federal funding; and thirdly, the process that medical research companies follow to receive approval for their research.⁷² Testimony by GAO Managing Director Gregory D. Kutz presented GAO's findings that the IRB system is vulnerable to unethical manipulation.⁷³ Although the investigation targeted tests on risks associated with experimental medical products and procedures, GAO investigators also tried the system with fictitious companies and counterfeit documents. After the study was completed, the GOA briefed HHS officials on the results. In response to the findings of the bogus IRB research investigation, officials "stated that Human Health Services receives 300 IRB registrations and 300 assurance applications every month, and that OHRP currently has three employees who review all registrations and applications."⁷⁴ The findings of this study are important so much as they highlight the inefficiencies of a national system like the IRB, which supports thousands of institutions across the United

⁷¹ "45 CFR 46."

⁷² Gregory D. Kutz, "Undercover Tests Show the Institutional Review Board Is Vulnerable to Manipulation" (United States Government Accountability Office, March 26, 2009).

⁷³ Ibid.

⁷⁴ Ibid.

States. Though this paper aims to employ systems for consent already in use in the United States – like parts of the IRB – in the creation of FPIC policy structure, it is clear that the IRB system and the OHRP are burdened and imperfect institutions.

It is important to note the significant discrepancy between the extent of details and protections outlined in the Belmont Report and the lack of specificity in 45 CFR 46 and other documents outlining IRBs. Nowhere in 45 CFR 46 makes mention of research affecting more than the autonomous individual, whereas the Belmont Report advises that research can affect individuals or, “society at large (or special groups of subjects in society).”⁷⁶ Although the United States Department of Human Health Services categorizes both documents under “Institutional Issues” on their website⁷⁷, the law and policy of 45 CFR 46 does not explicitly follow the ethical principles and applications of the Belmont Report.

Although these ethical guidelines are not written into law, they may be written into the protocol outlined by institutions. For example, the University of Alaska Fairbanks explicitly states in their Background for Protection of Human Research Participants: “The fundamental ethical principles of respect for persons, beneficence, and justice as described in the Belmont Report are the cornerstone for the UAF Human Research Protections Program.”⁷⁸ However, this is one institution that explicitly utilizes the Report of many that do not. Although explicit mention of the three ethical

⁷⁶ National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report*.

⁷⁷ “Policy & Guidance Index,” *United States Department of Health & Human Services*, accessed April 6, 2014, <http://www.hhs.gov/ohrp/policy/index/index.html>.

⁷⁸ “Protection of Human Research Participants” (University of Alaska Fairbanks, n.d.).

guidelines does not necessarily exact ethical conduct from researchers or institutions, it suggests to researchers – especially student researchers – that these are ethical expectations for IRB approval.

The following cases of Research Malpractice in Native American Communities are clear examples of researcher and publisher neglect for research ethics, which resulted in the humiliation and enragement of Tribal community members. This final section of the Review of Literature will also examine processes for community-based consent, using examples from Alaska Native community research investigations.

Section 3 – Community-Based Participatory Research in Native American and Alaska Native Communities

3.1 – Research Malpractice and Native American Communities

Havasupai Tribe vs. Arizona State University

One of the most recent examples of harmful research investigation of a Native American community was the case of the Havasupai Tribe vs. Arizona State University (ASU) in February of 2004. The Tribe charged the researchers of ASU with misusing blood samples taken from volunteer tribe members, claiming that members were told their blood would be used to study on the genetics of diabetes.⁷⁹ These samples were then shared with other research communities, where they were used for studies on schizophrenia, inbreeding, and possible migrations of the Tribe’s ancestors from Asia to the United States. The findings were then published in a number of papers discussing

⁷⁹ Puneet Chawla Sahota, “Research Regulation in AI/AN Communities - Policy and Practice” (NCAI Policy Research Center, n.d.).

these studies, which Havasupai Tribe members say was humiliating. The case of the Havasupai Tribe was a catalyst for a wave of AI/AN communities taking proactive measures to protect themselves from similar forms of deception. Another key takeaway from this case is the community's right to control the rights to the community's own data and portrayal, and regulate all actions taken on AI/AN land, with AI/AN individuals and in AI/AN communities.

The Barrow Alcohol Study

On January 22, 1980, a research study with Alaska Native Iñupiat subjects was published in *The New York Times*: "Alcohol Plagues Eskimos."⁸⁰ The study was conducted in Barrow, Alaska, the northernmost city in the state. The city's population is slightly more than half Alaska Native Iñupiat. Although alcoholism is present throughout all demographics in the town, the study focused on the drinking habits of a group of 88 Iñupiat of the 2,000 Iñupiat currently living in Barrow. Despite widespread community discontent with the conclusions of the study, and uproar once the findings were presented to the community, the study was released to the press. Intersect, the subcontractor, and the Barrow Department of Public Safety, "hoped that public awareness would shock the Iñupiat into action to control the problem."⁸¹ However, the aftermath resulted in, "grievances among many individuals and institutions associated with the community."⁸²

⁸⁰ Edward F. Foulks, "Misalliances in the Barrow Alcohol Study" (Centers for American Indian and Alaska Native Health, Colorado School of Public Health, n.d.).

⁸¹ Ibid.

⁸² Ibid.

In 1979, Edward Foulks was a member of the research team that conducted the Barrow Alcohol Study. In his paper “Misalliances in the Barrow Alcohol Study”, Foulks provides retrospective analysis of his team’s ethics and procedure to serve as a consideration for future investigations. In his analysis of the study, Foulks describes how one of the first factors that led to an ethically unsound investigation was the selection of subjects. In a city of 4,000 inhabitants, half Native and half other, only 88 Native subjects participated in the study. However, the study was aimed to examine the detention program for alcohol treatment, so therefore, any findings from the study would benefit programs accessible to all Barrow citizens. This inequity in the selection of subjects relates to the ethical principle of Justice in the Belmont Report: burdens and benefits should be distributed equally, and they should be distributed to those who can best carry the burdens or most need the benefits. Although Iñupiat are already detained for alcohol abuse in numbers much higher than non-Native persons⁸³, they carried the burden – during research and subsequent national embarrassment – while the entire city was posed to benefit from the research.

One of the final instances where the Barrow Study went wrong was the swell community-wide discontent with the study’s conclusions before the final presentation. This discontent apparently went unnoticed by the research team, who proceeded to publish the study.⁸⁴ In short, the subjects and their community were not informed of the entirety of the conclusions before they were released to the public. This is a clear breach of Respect for Persons: like in the case of the Havasupai tribe, a community should have

⁸³ Ibid.

⁸⁴ Ibid.

control of their own personal data, even after it enters the possession of researchers. Additionally, before the study was released, a non-Native faculty member of the Iñupiat University of the Arctic in Barrow issued a public attack on the study, calling it “ethnocentric and parochial, demeaning and denigrating to the Iñupiat people.”⁸⁵ It is clear that the research team was aware of this community anger with the study, but dismissed community concerns and released the study to the public. There was no move to *inform* the community of the study’s conclusions *prior* to releasing them; these principles of FPIC are essential to respecting a community’s voice, and were neglected in the study.

As his final recommendation, Foulks states that successful studies are, “predicated upon establishing cooperative and informed relations, wherein the benefits of the research clearly outweigh the risks to the subjects, their families, and their communities.”⁸⁶ Foulks also mentions the importance of examining the moral values of the community with care before the research proposal is created, so as to ensure that the study best addresses the needs of the community.

The following case of Culturally Anchored Participatory Action Research on Sobriety with Alaska Natives can be viewed as a direct response to the “misalliances” of the Barrow Alcohol Study, and introduces the empowering process of Community-Based Participatory Research (CBPR) in Alaska Native communities.

⁸⁵ Ibid.

⁸⁶ Ibid.

3.2 – Community-Based Research In American Indian and Alaska Native Communities

Unheard Alaska: Culturally Anchored Participatory Action Research on Sobriety With Alaska Natives

This research investigation aimed to address a need of culturally anchored participatory action research with Alaska Native Yup'ik communities to address the critical need for a guide to alcohol abuse prevention and treatment. The narrative that most Native people have a drinking problem, “ignores the unheard narratives of sobriety and healing among Alaska Natives that celebrate strength and resiliency...”⁸⁷ This project aimed to create Native ownership of the research process and outcomes to empower the community. The study maintains commitment to the theory of equal partnership; that knowledge and the research process empowers the community, who takes charge of the methods, interpretations and conclusions.⁸⁸ Throughout the entire study, it was clear that researchers were self-reflecting on their own positions of knowledge and power. “From our experience, researchers must closely attend to their own values and beliefs when they are shaped by a Western scientific paradigm.”⁸⁹

After primary interactions with the Yup'ik Native communities, it was clear to everyone involved that the research should focus on sobriety rather than alcohol abuse.⁹⁰ Although many studies, like the Barrow Alcohol Study, enter communities looking to solve the ‘problem’ of alcoholism, they rarely highlight any positive forces of

⁸⁷ Gerald V. Mohatt et al., “Unheard Alaska: Culturally Anchored Participatory Action Research on Sobriety With Alaska Natives,” *American Journal of Community Psychology* 33 (June 2004): 263–73.

⁸⁸ Ibid.

⁸⁹ Ibid.

⁹⁰ Ibid.

health or resiliency that reside within the community. As coresearchers, the team decided that the flexibility of research was important to the development of a project that was run by equal partners.

The review of the research notes that the pivotal point in the research process was a discussion of Alaska Native wellness and sobriety as embodied in the Yup'ik concept of *Ellam-iinga*, or the eye of awareness. By combining this cultural power of healing and balance, the research team was able to integrate native culture and spirituality with research recommendations.

Some of the setbacks the team experienced were in terms of time and therefore funder cooperation. The methodology first designed by the institutional researchers was soon replaced with a community-sourced process – a process more qualitative than quantitative. In Western scientific values, qualitative research is often viewed skeptically, or as having little value to the greater society. However, the team was able to discuss their proposal with funders, maintaining the importance of their equal partnership, and completed the study as designed by the communities. The team does attest to the fact that “sustained persistence and determination” was what kept the research funded. It is apparent that in other cases, possibly with a smaller team or less-prominent or understanding funders, this research would not have the backing to continue as planned.

Critical takeaways from the Unheard Alaska study is that first, research consultants need to know how to participate as equals and collaborators with the

community and research team.⁹¹ Secondly, funders need to support these kinds of relationships and the resources they require. Thirdly, a focus on health and healing was seen as valuable to the community, as opposed to the shame associated with alcohol abuse. Finally, the culture and spirituality of a community that does not belong to a Westernized society can often be the most important factor in leading research studies. For example, while researchers and institutions may value quantitative research, Native communities from all over can relate to and benefit from research that is delivered in a traditional oral narrative. If the goal of the research is to solve problems within these communities, and not for the researcher to benefit from published material, then it is integral to the success of the research to be presented in a format that can be useful to its recipients.

Cultural Considerations for Researchers

As seen in the “Unheard Alaska” study, there is value when “...culture informs the design and process of research, instrumentation, interpretation of results, and dissemination. Failure to understand the cultural context can result in misunderstanding the causes and consequences of human behavior.”⁹² Culturally anchoring research is essential to the article on “Culturally Competent Research With American Indians and Alaska Natives (AI/AN)”, written by the First Symposium of the Work Group on American Indian Research and Program Evaluation Methodology (AIRPEM). The article describes

⁹¹ Ibid.

⁹² Joyce Y. Caldwell, “Culturally Competent Research with American Indians and Alaska Natives: Findings and Recommendations of the First Symposium of the Work Group on American Indian Research and Program Evaluation Methodology,” *American Indian & Alaska Native Mental Health Research: The Journal of the National Center* 12 (2005).

the collective experience of a multidisciplinary collection of researchers, practitioners, and evaluators, which focuses on the “critical importance of culture in understanding and conducting research with the diverse populations of American Indians and Alaska Natives...”⁹³ The article posits that ‘full partnership’ – similar or identical to the idea of equal partnership – of Native communities enables the communities to address the issues that affect their own lives, while bringing significant benefits to other communities as well.

As the Declaration of Helsinki provides a collection of guiding principles for research on human subjects, the AIRPEM symposium provides 20 guiding principles of “collaborative, participatory, and verbally competent research with AI/ANs.”⁹⁴ Of these principles there are a few that stand out as positive research practices and also practical advice for a successful implementation of FPIC.

The fourth principle suggests that, “AI/AN community partners should be involved in the oversight of research from inception to completion of the project.”⁹⁵ To interpret this principle using terms of FPIC, information and consent should be not only prior but *continual* – research is a process, not a form, so consent and partnership should be a fluid and continuing relationship. Principle six notes that the factors of tribal, cultural, and linguistic diversity need to be taken into account in the development of research designs.⁹⁶ Previous examples of FPIC on the ground in countries such as Malaysia, Suriname, and the Philippines show that often, outsiders misunderstand

⁹³ Ibid.

⁹⁴ Ibid.

⁹⁵ Ibid.

⁹⁶ Ibid.

cultural institutions, and as a result these cultural institutions are neglected or disrespected. The thirteenth principle mentions the importance of community review of all research findings. The principle asserts that, “this review must include the freedom to be critical and, if needed, to include dissenting opinions in any publication of research findings.”⁹⁷ In the current system of the IRB, subjects can consent to research with conditions. Consent with conditions is one of the most critical components to the success of FPIC – that consent can be a conversation, rather than just a yes or no. However, consent needs to also be respected for the rights it grants: the right to accept or outright veto proposals.

Review of Literature - Conclusions

Though FPIC may sound like part of a precautionary principle, the basic logic behind it can be seen as flawed. In an ideal case scenario, FPIC would not be necessary because *clearly* native communities do not want to give up their land or have it stripped of its natural resources and balanced ecosystem. There is no just process for corporations to acquire land: if the indigenous community has nothing to gain from the development, logically they will withhold consent, and veto the development. As Cariño argues: “The Philippine experience demonstrates a failure to implement the ‘spirit’ of FPIC, as distinct from engineering consent.”¹⁰³ Nevertheless, the power and influence of corporations, developers, and growers necessitates a protective system that legally binds companies to a kind of moral obligation. Indigenous communities need legal

⁹⁷ Ibid.

¹⁰³ Cariño, “Indigenous Peoples’ Right to Free, Prior, Informed Consent: Reflections on Concepts and Practice.”

protections in order to seek justice if their communities or lands are polluted and stripped of their natural resources. The following sections and final Recommendations will address the issue of these protections.

Cariño's "engineering consent" easily applies to the IRB process in the United States. The IRB process was designed by the government for requirements for federal funding, and 45 CFR 46 provides guidelines that institutions must obey, and in turn create their own systematic processes for consent. This top-down system produces Informed Consent Forms, which protect the institution from liability; only in some cases does it actually produce consent.

Where the IRB fails to provide cultural respect when seeking consent from communities, the CBPR in AI/AN communities demonstrates the socio-cultural value of the community voice and equal partnership in research investigations. Respecting indigenous property and knowledge of having inherent value that can benefit not only Native peoples but the larger society is essential to healthy FPIC.

Chapter III: Methodology

This paper includes an extensive review of existing literature on case studies of processes, implementation, and enforcement of FPIC policy. Additionally, this paper includes an analysis of community-based participatory research in Native communities, and IRB processes.

Primary research included an analysis of UN documents delineating the rights to FPIC for indigenous peoples, as well as a review of OHRP documents and policy for

research on human subjects. Also included in primary research were interviews with Puneet Chawla Sahota, former NCAI researcher and MD/PhD medical anthropologist currently pursuing residency training in psychiatry; William Freeman, former Director of the IHS IRB and current Director of Tribal Community Health Programs at Northwest Indian College; Julie Raymond-Yakoubian, anthropologist and current researcher with Kawerak Inc.; and Gretchen Hundertmark, Research Integrity Administrator for the Institutional Review Board at the University of Alaska Fairbanks. Policies were selected from the United States federal OHRP and HHS regulations for the Protection of Human Subjects.

The purpose of these interviews was to build a working knowledge of CBPR and the use of IRBs in indigenous communities and Alaska Native communities, and how work within these communities can further inform operationalization of indigenous individual and community consent. These interviews provided personal comments and inferences from some of the most connected and informed individuals who have worked with these communities as well as individuals whose work addresses broader issues of consent and human rights for indigenous communities. Interviews were conducted between January 17th and March 4th of 2014. The interview included sections pertaining to CBPR, the IRB protocol within native communities, and community consent for research. The interview with Dr. William Freeman prompted an IRB review due to the policy of his institution, the Northwest Indian College. This investigation's experience with the Northwest Indian College IRB is described in Appendix A.

Chapter IV: Analysis of Primary Research

Puneet Chawla Sahota

The first interview for this investigation was with Puneet Chawla Sahota. Sahota's work with Native American communities began with her time in Arizona, aiding labs with the National Institutes of Health that were conducting research investigations within Native communities over 10 years ago. Sahota also worked for a few years with the National Congress of American Indians (NCAI) Policy Research Center, where she published several papers and recommendations for Research Regulation in American Indian and Alaska Native (AI/AN) communities. During her time working for the National Institutes of health, Sahota interviewed Native Americans about clinical depression symptoms. Sahota mentioned that when she would conduct interviews, tribe members would ask her lots of questions: "why are you writing all this stuff down? What will you do with all this information? Why is it that researchers come and go from our community?"¹⁰⁴ This prompted her interest in research as a cultural institution. When working on her dissertation for her MD/PhD, she worked with a different tribe in the American Southwest to examine their experience with genetic research. Sahota describes how during her conferences with the tribal council, they accepted her research with conditions: that her research would give back to the tribe. This entailed using her research to help the council develop what she described in the interview as a "research regulation committee or a research regulation board."¹⁰⁵

¹⁰⁴ Puneet Chawla Sahota, Interview, Phone interview, January 17, 2014.

¹⁰⁵ Ibid.

This idea of a research regulation board is not dissimilar to existing models of Community Advisory Boards, which function as liaisons between researchers and communities. It is interesting to note that Sahota found her focus of research as an institution through her work with communities. Through interactions, conversations, and interviews with community members she learned what really mattered to the community. It is apparent that both aforementioned tribes were not concerned so much with the genetics or mental health research as they were with *how* this research was conducted. Especially with the first Arizona tribe, who queried why researchers would “come and go,” there was an apparent lack of communication between the tribe members and the lab researchers. To refer back to the principle of FPIC, these tribe members were not informed about what the research would bring their tribe. According to the Belmont Report, this lack of information connotes a lack of respect for persons: despite their time in the community, the lab researchers never truly communicated the process to the community.

With regards to consent, Sahota mentioned the idea of sovereign nations being “fundamentally from other urban communities in the US” in that they are domestic dependent nations with “unique in legal and political status.”¹⁰⁶ Sahota argues that therefore, when a researcher or developer seeks consent, they need to address the nation as a whole, or the entire community. She continued to explain how consent is

¹⁰⁶ Ibid.

important also for reasons like the Havasupai case; when a tribe's name is attached to the research, the entire group can experience the harm or benefit of publications.¹⁰⁷

When prompted with a question about the viability of a research group or board within the community, and some of the difficulties for communities who want to create their own Community-Based Review, Sahota said that she thinks some of the biggest challenges are the resources. She explains that the term "equal partnership" in CBPR can sometimes be interpreted tribal inclusion in every part of the process, which is a huge commitment level for a "small community that is already under-resourced."¹⁰⁸ Often tribe member time is already spread thin, with familial, work and chores, and other cultural tasks, and many tribes do not have the finances to support a type of review board in the same way a university can. However, Sahota added in a post-interview email that there are tribes already conducting review for research, such as the Navajo Nation. In her opinion, AI/AN communities can and should conduct community review – this review just might be different from how an IRB reviews research. She asserts that possible models for review could include one professional (such as a doctor) working with the tribe, a review by the Tribal Council, or even a small group of community members.¹⁰⁹

Dr. William "Bill" Freeman

The second interview was with William Freeman, who established the IRB at Indian Health Services. His current work is with the Northwest Indian College, where he

¹⁰⁷ Ibid.

¹⁰⁸ Ibid.

¹⁰⁹ Puneet Chawla Sahota, "Additional Commentary," April 25, 2014.

serves as the Director of Tribal Community Health Programs. This interview was broken into two separate interviews, conducted on two separate days. The first interview was a review of policy and practices for IRBs and research in Native communities. The second interview was a full interview, which included personal opinions and descriptions of Freeman's current and past work with IRBs. The need for two interviews was due to a month-long IRB application process and review through the NWIC IRB.

In the Policy interview, Dr. Freeman quickly clarified his definition of consent: "community consent is giving permission to the researcher to interact with the community members, and ask if they will individually consent."¹¹⁰ He adds that community consent does not replace individual consent. Freeman continues to add that technically if tribes are federally recognized, and therefore, sovereign nations, they have the right to reject any activity on their land. In practice, he added, "no one has gone to court, as far as I know, to deal with it with a resolution"¹¹¹, other than the example of the Havasupai case. If the sovereignty of tribes grants them power over their own land and peoples, and the companies and researchers who come onto their land, then it is apparent that sovereignty does not adequately protect the tribe's wellbeing. As the interview with Sahota can confirm, research malpractice – the lack of community consent, distant researcher relations, unclear research protocol, insufficient information given to volunteers – continues to be present in research investigations involving human subjects, then tribal nations are not exercising their sovereignty. Perhaps this may give inference to the fact that when authorities – academic, financial, political – set foot on

¹¹⁰ William Freeman, Policy Interview, Phone, February 14, 2014.

¹¹¹ Ibid.

Native land, Tribal Nations do not have the resources to push back or question their presence.

In this interview, Dr. Freeman spoke on the importance of the Tribal Council in the process for consent. In his experience on IRBs, Freeman describes that the board would learn of the harm to the community only after the Tribal Council reviewed the proposal. He explains that, “the IRB learned from the tribal council something that we had not realized”, and therefore, “even with an IRB that pays attention to community harms, it is important for the Tribal Council...to have that research reviewed by the tribe and approved before it is done.”¹¹² The importance of the Tribal Council will be addresses in Finding 1.1.

In the second, and full, interview with Dr. Freeman, he mentions that it should be the responsibility of the researcher to use the findings of the study to, “help those in the community to develop a receptive framework so those results can be acted on...”¹¹³ Directly after this quote, Freeman suggests that it “may take 5 years to do that...but that’s part of the responsibility.” The issue of time is crucial to the success of a research study. Researchers need to spend considerable amounts of time with community members, like the researchers in the “Unheard Alaska” study, conversing and building relationships with the tribal community. This time builds mutual understanding, and aids the researchers in focusing their work in a positive direction to produce results that can best serve and benefit the community and participants who bear the burden of research.

¹¹² Ibid.

¹¹³ William Freeman, Full Interview, Phone interview, March 4, 2014.

Julie Raymond-Yakoubian

The third interviewee was Julie Raymond-Yakoubian, a researcher with Kawerak Inc. Kawerak Inc. is a tribal consortium based in Nome, Alaska that serves twenty Native communities in the Bering Strait in Northwest Alaska, just south of the Arctic Circle. The region is home to three culturally distinct groups of Eskimo people: the Inupiaq of Seward Peninsula and the King and Diomed Islands; the Central Yupik, who reside in villages south of Unalakleet; and the Siberian Yupik of St. Lawrence Island.¹¹⁴ Kawerak's role in these communities is like that of one large advocacy community center, which organizes programs and services for the region. Through their connection with the federal government, Kawerak employees and researchers aid these communities in management of economic development, natural resource protection, educational programs, and cultural heritage activities.

Raymond-Yakoubian works directly within tribal communities through Kawerak's Social Science Program to build research projects that serve their interests. Many of the investigations gather Native knowledge – such as traditional knowledge about migration patterns of seal and walrus – from participating Kawerak communities. This knowledge is used to create reports, advocacy documents, archival sources of Native knowledge, and other products valuable to a variety of communities, institutional researchers and academics in the region. As a professionally trained anthropologist and researcher, Raymond-Yakoubian takes community sourced research topics and seeks grant funding.

¹¹⁴ "We Are Kawerak," accessed March 20, 2014, <http://www.kawerak.org/weare.html>.

Funding for her research comes from federal pots of funding for Alaska Native research, private funders such as the Oak Foundation, and agencies such as the Fish and Wildlife Service and the National Science Foundation.

While describing her work within the communities, Raymond-Yakoubian says that her work is much different from a lot of the research done with other institutions and community organizations. She first community sources ideas for research, consults with the Board of Directors at Kawerak, and then writes the proposal for funding. Once the funding is secured, she holds community meetings for the tribes to ask who would like to participate. According to Raymond-Yakoubian, Kawerak's research projects do not go through an IRB process unless it is required by the funders; she asserts that the Board of Directors feels that they – in addition to Tribal Councils – are best suited to determine the appropriateness of a research project and its methods, and does not seek outside review or approval of an IRB unless required to.¹¹⁵

This case adds an interesting piece to this investigation in that the interviewee does not engage with federal systems unless required to, substituting community organizing and meetings instead. In theory and – in the case of Kawerak – practice, the IRB will never replace CBPR that is managed, conducted, and owned by the community. The individual research participants, Tribal Councils, and the Board of Directors review the research produced by Kawerak's Social Science Program at various stages throughout the research project to ensure that it is a positive force throughout the entire region.

¹¹⁵ Julie Raymond-Yakoubian, Interview, Phone, February 18, 2014.

In her interactions with other IRBs and researchers, Raymond-Yakoubian remembers an example of a researcher who was investigating a controversial topic. In her words, she recalls the consent form for participation listing that with regards to the results of the investigation, “something to the effect of ‘we just do the research; we have no control over how other people use our results’ and that was the end of it.”¹¹⁶ She notes that this particular kind of controversial research has the potential to cause problems in participating communities – problems that were mentioned nowhere on the consent form. This example raises two issues. The first is the issue of informed consent; it is the job of the researcher to describe in detail all possible risks to the subjects. This is federally mandated law for research on human subjects, as described in 45 CFR 46.¹¹⁷ The second issue is the role of the community academic. As a researcher with IRB experience, it is interesting to observe Raymond-Yakoubian’s inside-outside position in Kawerak’s communities. In post-interview comments, Raymond-Yakoubian clarified that conversations with individual participants and Tribal Councils concerning IRBs is limited; the IRB system is usually explained only when a research project is subject to IRB review. Her position as knowledgeable community researcher brings up the question of her role in deflecting possibly harmful investigations. As a researcher with this knowledge and academic power, this paper suggests that she might protect all Kawerak communities from harm by teaching them about the IRB system and what they should expect from IRB reviewed research.

¹¹⁶ Ibid.

¹¹⁷ “45 CFR 46.”

Gretchen Hundertmark

The fourth interview for this investigation was with Gretchen Hundertmark, IRB Proposal Administrator at the University of Alaska Fairbanks. Hundertmark's work includes a preliminary review of protocols before they are evaluated by the university's IRB. In her conversations with researchers, Hundertmark says she often gives researchers who want to use Native subjects general advice for forming relationships and respecting the community.¹¹⁸

Early on in the interview Hundertmark mentioned that there are certain populations of vulnerable subjects who are granted extra protections for research as dictated by federal regulation. Hundertmark attested to the fact that at UAF, Alaska Native tribes and communities are subject to special consideration during the review process.¹¹⁹ Therefore, research proposals utilizing Alaska Native participants are subject to additional review and analysis. Hundertmark explained that if a researcher's proposal or the "scope of their research" was unclear, she would instruct the researcher on how to edit their protocol to create an investigation with a Native village to ensure that they are "being respectful, and doing it in a proper way."¹²⁰ When prompted with a follow up question about what resources the UAF provides for outside researchers, who are unfamiliar with Alaska Native communities, Hundertmark mentioned that she suggests the paper "Walk Softly and Listen Carefully." This paper – written by variety of Native

¹¹⁸ Gretchen Hundertmark, Interview, February 26, 2014.

¹¹⁹ Ibid.

¹²⁰ Ibid.

and non-Native academics, researchers and communities – advises non-Native researchers on how to create research relations with tribal communities.

Another important takeaway from this interview was Hundertmark’s explanation that when she looks over an applicant’s proposal, she makes sure they know that “consent isn’t a piece of paper, it’s a process.”¹²¹ This explanation of what consent should mean is important for all researchers, and especially researchers from outside the Alaska Area.

Chapter V: Findings

The intent of this project was to examine the processes of consent for research in Alaska Native communities, and to investigate whether and how community-based participatory interaction with IRBs might serve as a vehicle through which FPIC is operationalized at the local level.

The following findings are separated into two categories: findings drawn from interviews with a variety of experts, researchers, and academics, findings from an analysis of IRB policy and protocol. Interviewees included Puneet Chawla Sahota, former NCAI researcher and MD/PhD medical anthropologist currently working on an additional degree in psychiatry; William Freeman, former Director of the IHS IRB and current Director of Tribal Community Health Programs at Northwest Indian College; Julie Raymond-Yakoubian, anthropologist and current researcher with Kawerak Inc.; and Gretchen Hundertmark, Research Integrity Administrator Institutional Review Board

¹²¹ Ibid.

administrator at the University of Alaska Fairbanks. Policies were selected from the United States federal Office for Human Research Protections and Human Health Services regulations for the Protection of Human Subjects.

The interview questionnaire was comprised of three basic sections: questions about CBPR and its upsides and downsides, questions about IRBs and Native communities, and a couple questions pertaining to the issue of obtaining consent for research in terms of the IRB model. The interview also included an introductory section, where subjects were asked to explain their past and current work as well as a description of the intent of this project with issues of FPIC and consent for development on Native land. Although during the interview the investigator mentioned FPIC as an important part of this project, no questions associated with FPIC were included in the interview. Although all interviewees are active organizers and academics within the world of Native rights and consent, very few have done any work with the principle of FPIC, and more than one interviewee was not even familiar with the term.

Findings: Interviews

1: Tribal Council

1.1 Most researchers fail to consult with the Tribal Council before meeting with individual tribe members. Depending on the tribe, the Tribal Council is the deciding voice in whether the community will engage with or reject research proposals

During their interviews, both Sahota and Freeman mentioned the importance of Native American communities not just as communities but also as domestic sovereign nations. Sahota spoke on how outside bodies cannot speak for tribes, and that

sovereignty is the property of the tribe.¹²² Mentioned later in these findings, it is clear there is a serious lack of cultural consideration when researchers from outside the region enter a native community; Raymond-Yakoubian describes that through her work with Kawerak, she often witnesses researchers neglect to converse or build relationships with tribal leadership and Council. In her work with the UAF IRB, Hundertmark will refer outside researchers to confer with the Tribal Council or other leadership within the community on what IRB or legal process the tribe expects from the researcher; to her, this communication is an important responsibility of the researcher.

1.2 – There is a lack of communication during and after the investigation to ensure that communities understand research

While describing her background working with Native American communities, Sahota mentioned her post-graduate experience working with a research lab focusing on clinical depression in native communities in Arizona. Sahota describes how when she would conduct interviews, tribe members would ask her lots of questions: “why are you writing all this stuff down? What will you do with all this information? Why is it that researchers come and go from our community?”¹²³ This experience triggered her interest in research as a cultural institution, and prompted the focus of her dissertation, where she examined how native communities understand research. Sahota’s experience shows not only that communities may not receive enough information prior to research to make educated decisions on whether or not to participate in research, but also that

¹²² Chawla Sahota, Interview.

¹²³ Ibid.

the findings or benefits of the research do not necessarily make their way back to the community. If researchers are “coming and going” from communities, and communities are not completely clear on why and what will be done with their personal and biological data, there is a clear failure in the communication between institutions, researchers, and Native American communities.

This finding is also supported by the case of the Havasupai tribe as mentioned in section 2 of the literature review. Inadequate communication between the Havasupai tribe and the research team prior to research, during research, and post-research showed negligence and disrespect on the part of the team and ultimately harmed participants.

2: IRB

2.1 - Institutional IRBs often have little or no contact with the communities themselves during any portion of the review process

The interview with IRB Proposal Coordinator of the University of Alaska Fairbanks, Gretchen Hundertmark, made it clear that throughout the review process, the UAF IRB does not directly contact or communicate with Alaska Native Tribal Councils or communities. Notably, Hundertmark added in later correspondence that UAF has formed strong relationships with specific communities.¹²⁴ Earlier in the interview, Hundertmark explained that most of the research proposals she reviews are not from outside researchers, but from students. She included that many student researchers choose to conduct research with native communities, and that all UAF students must go

¹²⁴ Hundertmark, Interview.

through the UAF IRB, a process consistent with all colleges and universities. Therefore, although the UAF regularly approves research with subjects in Native Alaskan communities, there is no direct communication between these communities and the institution's IRB.

2.2 - Tribe members are often not aware of the protections available for them through IRB processes

Kawerak Inc. researcher Raymond-Yakoubian explained that some of the members of tribes included in her organization are not familiar with what an IRB is – she said that if an informed consent form was to list the “IRB office” as a contact for any questions participants might have, tribe members might not know what that is.¹²⁵ Notably, this does not apply to participants of Kawerak projects that require IRB review, to whom the IRB review process is explained. This finding relates to the previous finding, 2.1, which notes the lack of communication between institutions and communities. In Raymond-Yakoubian's experience, IRBs often only require researchers to provide a letter or note from the community – not necessarily from Tribal leadership or the Tribal Council – to show that the researcher has formed a relationship with the community and has their approval to conduct research. Although, as Hundertmark attested to in her interview, language on informed consent forms is often at an eighth-grade reading level, the average layperson might not know what an IRB does or even what the acronym stands for. Although it is possible to assume that frequently studied populations such as native communities may have more persons with experience with IRBs and IRB

¹²⁵ Raymond-Yakoubian, Interview.

documents, this should not prompt the assumption that they fully understand what an Institutional Review Board is or what protections they are legally due as participants.

2.3 - Although IRBs formed within tribal nations are often successful, most tribes do not have the resources to create and maintain an IRB

When prompted with a question on an IRB within Alaska Native communities being used for CBPR, Sahota confirmed that often communities do not have the resources to support and maintain an IRB¹²⁶. Although this interview did not contain specific explanation of why a community-based IRB is unsustainable, Sahota's past research with the National Congress of American Indians (NCAI) Policy Research Center lends inferences into this confirmation. In her paper *Research Regulation in AI/AN Communities: Policy and Practice*, under "Creating an AI/AN Community IRB", Sahota describes the benefits of a Tribal IRB, which include accurate representation of community interests and legitimization of the community in the eyes of researchers.¹²⁷ However, Sahota acknowledges that the main disadvantage with the Tribal IRB is that it requires considerable money and time to create and maintain, both of which are often scarce resources in Native communities. Notably, as mentioned in an email following the interview, Sahota concludes that though there are obstacles for tribes to administer their own review, tribes should and can review research in ways that do not require a full IRB model.

¹²⁶ Chawla Sahota, Interview.

¹²⁷ Sahota, "Research Regulation in AI/AN Communities - Policy and Practice."

3: Researchers

3.1 - Researchers are often uneducated in cultural processes and therefore disrespect the community

This finding addresses a crucial piece of research malpractice. It is apparent that there is often a disconnect between what the researcher thinks is the protocol for working with a community, and what the community requires from the researcher. As the UAF IRB proposal coordinator, Hundertmark often recommends that researchers – especially those from outside the Alaska area – refer to the paper “Walk Soft, Listen Carefully”, written by Native Tribal members to educate outsiders entering Native communities.¹²⁸ Hundertmark described the paper as one written with reoccurring themes throughout the paper, consistent with the cultural style and oral tradition of many Native communities. However, prescribing cultural reading or recommending certain processes does not necessarily create cultural understanding between the researcher and the community. As mentioned in the report “Unheard Alaska” from the section 3 of the literature review, time and effort with open communication between the community and researcher are required to build the relationship necessary for respectful and participatory research.

A critical part of this finding refers to finding 1.1 referring to Tribal Councils or Tribal boards, which should be the voice of the tribe for consenting to research.

4: Other Findings

4.1 - Alaska Native tribe members can suffer from research fatigue

¹²⁸ Hundertmark, Interview.

During my interview with tribal consortium researcher, Raymond-Yakoubian, I learned that the number of researchers – often from outside the Alaska region – who focus on areas such as the Bering Strait has grown significantly in the past few years. This peak in interest, she says, may be due to environmental issues such as climate change, fishery development, and increases in vessel traffic through the Bering Strait. Raymond-Yakoubian argued that the people in the communities her organization works with are “sick of interviews and surveys”¹²⁹. To give an example, Raymond-Yakoubian described how once during her work with Kawerak she visited one of the communities in the organization to complete a series of Council approved interviews only to find that many community members had undergone lengthy interviews the day before. One tribal member she spoke with did not want to take any more time away from daily work and chores after taking three hours the previous day to sit down with a researcher from a different organization. This finding ties back into the theme of cultural understanding and the Belmont principle of beneficence; although this research may or may not help these communities, there is a disconnect between tribes and institutions in understanding what is the best protocol for conducting obtaining this research.

Findings: Policy

5: Risk

5.1 – There is a lack of explicit legally-binding language pertaining to minimalizing post-research risks

¹²⁹ Raymond-Yakoubian, Interview.

§46.111(a)(1-7) of regulation 45 CFR 46 delineates the criteria approval of research with the specific focus on the minimization of risks, maximization of benefits, and equitable selection of subjects. However, there is a lack of explanation for the post-research use of information obtained during research. This means that not only are subjects not explicitly entitled to benefit from research, but also there is no explicit language that outlines the regulations of data usage post-research.

6: AI/AN Communities

6.1 – Under 45 CFR 46, indigenous or Native American peoples are not considered a protected population or vulnerable group

In OHRP regulation 45 CFR 46 on the Protection of Human Subjects, protected populations include children, prisoners, pregnant women, handicapped or mentally disabled persons, and economically or educationally disadvantaged persons. The rule provides additional regulations for protected populations; for example, in the case of prisoners one member of the IRB must be a prisoner, ex-prisoner, or prisoner representative with appropriate background and experience to serve in that capacity.¹³¹

This federal regulation does not explicitly include indigenous groups or Native Americans, though some tribes may unfortunately fall under the category of economically disadvantaged persons. In her interview, Hundertmark mentioned that in addition to these federally mandated protected populations, UAF also considers indigenous or Alaska Native persons a “special” population. It is apparent that while institutions choose to add extra protections for Native folk – which may include an

¹³¹ “45 CFR 46.”

AI/AN tribe member on the IRB – there is no federal regulation that requires all institutions that may work with AI/AN communities to add this protection.

6.2 – There is an absence of any explicit language which mentions communities or groups as a consenting body

Thorough review of regulation 45 CFR 46 reveals that nowhere in the document is there explicit mention of communities or community leadership as bodies that need to consent to research. This means that there is no regulation for the process of entering a sovereign nation and asking lay-members to participate in research. Additionally, no protections are provided to assure that post-research risks are minimized not only for individuals but also for communities.

7: Institutions

7.1 – Institutions (universities, colleges) are required to create their own individual statement of protocol for research

Under §46.103 of 45 CFR 46 – the Code of Federal Regulations under the Department of Human Health Services for the Protections of Human Subjects – institutions are provided a set of guidelines for assuring compliance with policy 46.101-2. The section §46.103(a) dictates that institutions must provide written assurance that they will comply with the requirements set forth in the policy, while the subsections of §46.103(b) delineate what this assurance must include.¹³² The subsections include requirements for the assurance, such as a statement of principles, the designation of one or more IRBs and sufficient staff to comply with the requirements, a list identifying IRB members and their qualifications, and written procedures which IRB will follow. It is

¹³² Ibid.

important to note that institutions design their own written procedures, including what the initial and continuing review includes, and which projects require more review. In other words, it is up to each institution to create its own IRB process and requirements for researchers.

Chapter VI: Recommendations

The findings express three key points: firstly, that there is a significant lack of cultural competency and understanding of Native practices and communities among researchers who choose to work with Native subjects; secondly, that consent at the community level is absent from IRB policy at the federal, state, and institutional levels; and thirdly, Native communities have little information on their rights and the regulations for research, and therefore, little possibility to control what research conducted within their community.

The following recommendations are split into two sections. The first section (A) includes recommendations that relate directly back to primary research, or recommendations for policy and protocol in research in Native communities. The purpose of section (A) is to address the concerns and needs of Native American research subjects. The second section (B) utilizes principles from the previous section's recommendations, as well as findings from the review of literature, to create recommendations for the principle of Free, Prior and Informed Consent. As stated in the research question, this investigation assessed whether and how community-based

participatory IRBs or a Community Review Board might serve as a vehicle through which FPIC is operationalized at the local level.

Section A: Research in Native American Communities

Note: The following recommendations for Research in American Communities in Section (A) do not include the crucial recommendations for Community Review Boards and the withholding of funding for projects that do not receive community approval. Since both of these recommendations are valuable to a broader range of indigenous communities and are not specific to the United States, they will be further explained in Section (B).

A.1 – Researchers entering Native communities need cultural training

The interview with Julie Raymond-Yakoubian of Kawerak Inc. supported the conclusions from the review of literature that often researchers working with Alaska Native communities are uneducated with respect to Native culture. Raymond-Yakoubian attests to the fact that researchers fail to create relationships with the community, while she strives to spend time and integrate herself into each village where she gathers research.¹³³ This recommendation is also relevant to Finding 4.1, which observes that Native tribes can suffer from research fatigue. Inherently existent in this observation is the fact that Native peoples are over studied, and subject volunteers are overworked. There is certain disrespect for the community when members are asked to contribute to research investigations – that usually intend to serve or benefit the community – to the point where they do not have the time and energy to do so anymore.

Gretchen Hundertmark of the UAF IRB mentioned in her interview the paper “Walk Softly and Listen Carefully”, which advises researchers to be conscious of Native ways of being when entering and interacting with Native communities. This paper

¹³³ Raymond-Yakoubian, Interview.

contains a wide variety of personal stories, from “Reflections of a Native Researcher” to a section on “Understanding the Value of Indigenous Knowledge in Research”.¹³⁴

Although a possible implementation of this recommendation could include mandated training for researchers, similar methods already exist: HHS provides a wide variety of webinars and training videos, addressing the ethics Belmont Report among other considerations for subjects.¹³⁵ These quick tutorials are minutes, and do not necessarily create an understanding in the researcher for the importance of respect for subjects.

This recommendation suggests that cultural training may include a Community Advisory Board or Community Review Board that would instruct researchers on basic processes for working with communities in their region. The value and structure of these Boards is further described in Recommendation B.2.

A.2 – Researchers need time to create a relationship with the community before moving forward with research. This need could be met with a mandated period of relationship building before research commences

In “Walk Softly and Listen Carefully”, the importance of creating “trusting relationships” between researchers and communities is emphasized.¹³⁶ This recommendation may be one of the more ambiguous, since positive and trusting relationships are not built off of law, protocol and processes. Despite the ambiguity, it is

¹³⁴ “‘Walk Softly and Listen Carefully’: Building Research Relationships with Tribal Communities” (NCAI Policy Research Center and MSU Center for Native Health Partnerships, 2012).

¹³⁵ Office for Human Research Protections, “Training Videos and Webinars,” *U.S. Department of Human Health Services*, accessed April 11, 2014, <http://www.hhs.gov/ohrp/education/training/>.

¹³⁶ “‘Walk Softly and Listen Carefully’: Building Research Relationships with Tribal Communities.”

one of the most important. Relationships are built off of time, communication, and ability to understand what is first seen as the 'other'. The disconnect between researchers and the researched emphasizes unequal power relationships; as seen in the Barrow Alcohol Study, the community was only allowed access to the results of the study the same day it was published nationwide. Therefore, findings were published before consent was given and before the community had the ability to control what was said publically about their specific community.

Gretchen Hundertmark of UAF recommends that researchers contact the Tribal Council or Tribal Board before contacting any community members, which is a positive step in relationship building. However, this step does not guarantee a trusting relationship. Often researchers are under time or funding constraints, and feel pressured to move forward with research as quickly and efficiently as possible. These funding and time constraints were some of the obstacles that the research team in "Unheard Alaska" had to overcome to create a truly participatory research study with their community. Since "quick" and "efficient" are privileged Western ideals, they may not sit well with the cultural fabric of native communities. Cultural training needs to be more than a quick tutorial or conversation by phone; it needs to be a commitment from the researcher.

This recommendation posits that both researcher and community would benefit from a legally or funder mandated period for relationship building. This period would be a set number of weeks where the researcher or team would be free to meet with the elders, leaders, and potential subjects to converse and share ideas. This period would be

built into the proposal, so funders and institutions would respect this period as simply a part of the research process.

A.3 – 45 CFR 46 should be amended to consider Native American or indigenous US citizens as vulnerable populations

Currently, 45 CFR 46 considers children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disabled persons to be vulnerable populations.¹³⁷ Native populations are not considered protected populations, and are not guaranteed any further protections than the average layperson. Gretchen Hundertmark of the University of Alaska Fairbanks IRB attests to the fact that under her institution's IRB policy Alaska Native peoples are considered *special* populations in IRB review, though there is no formal designation as a protected population.¹³⁸

This paper recommends that along with specific protocol for approving research on pregnant women and prisoners, 45 CFR 46 should be amended to include an additional set of protections for Native American and Alaska Native populations. Protocol should include cultural training for researchers, as well as prompting full rather than expedited review for all research on Native peoples. According 45 CFR 46, IRBs reviewing research to be conducted with prisoners must have at least one prisoner, former prisoner, or prisoner expert on the board.¹³⁹ So should be the law for IRBs reviewing research on Native populations; there should be at least one person on the board who is a regional tribal member, elder, or integrated cultural expert on Native

¹³⁷ "45 CFR 46."

¹³⁸ Hundertmark, Interview.

¹³⁹ "45 CFR 46."

issues. The addition of Native persons as vulnerable subjects would in theory create a more powerful legal protection against research malpractice in Native communities.

Section B: Processes for Community Consent for Indigenous Peoples

B.1.1 – The United Nations must clarify the meaning and implications of the term “consent”

“Free Prior and Informed Consent” needs to be changed to imply “Free, Prior and Informed Consent or Refusal”. The term ‘consent’ needs to be redefined within the UNDRIP and consequent literature to explicitly describe consent as the right to accept or refuse. Communities need to have clear authority to say ‘no’ to any action that may affect them or their land. The community’s rejection of development can be due to the risk to livelihood or health, but should not even need to warrant an explanation. Just as we describe consent for human subjects research to be a simple ‘yes’, ‘no’, or ‘yes with conditions’ – which opens up a conversation for further deliberation on the action that will ensue – so should proposals for consent require for issues of development on indigenous land.

B.1.2 – The United Nations must include a process for not only prior but continuing free, informed consent

Although this paper maintains the absolute importance of prior consent, communication between the developers and the indigenous community should be a process of *continuing consent*. That is to say that as project plans evolve and construction is underway, there are always unseen changes in what was originally

planned. It might be later discovered, for example, that drilling in a specific area might taint the community's water source.

The issue of continuing consent might be implicit with the United Nation's definition of the principles of FPIC – if you are going to begin a conversation or relationship with a community, you should update them with any new information as you go along. However, this continuation of information is not explicitly promised in the principles of FPIC. Models of Community-Based Participatory Research like that of the study “Unheard Alaska”¹⁴⁰ show the value of frequent updates and *continuing* conversations; the community's voice should be heard throughout the entire process to lead administrators on the path that is respectful and beneficial.

B.2 – Creation of a new institution for overseeing processes of FPIC: CRB

In order to ensure that the rights guaranteed in FPIC are granted to indigenous peoples, the United Nations must create a new system that will execute justice for these communities. Just as the HHS OHRP created the principles of the Belmont Report and mandated the IRB to oversee processes for consent for research on human subjects, the United Nations must create a plan for review boards to enforce the principles of FPIC for the consent of development on indigenous land. The United Nations must work past writing theoretical principles to develop methods for consultation, consent and refusal. United Nations programs with operational structure, such as the UN-REDD+ programs, fail to fully implement FPIC because they do not allow the community to make an

¹⁴⁰ Mohatt et al., “Unheard Alaska: Culturally Anchored Participatory Action Research on Sobriety With Alaska Natives.”

autonomous decision. REDD+ programs are often implemented at the state or provincial level, and do little to empower indigenous communities with a voice to decide.¹⁴¹ The REDD+ programs also give weight to economic interests, which in theory negate the purpose of FPIC: to give indigenous communities a voice in their own self-determination.

The idea for this recommendation came from SEHN Director, Carolyn Raffensperger, who suggested the option of a Community Review Board (CRB). The CRB would be an advisory council composed of members of the community, regional experts, and other related scientists or academics in the field. The function of a CRB would be similar to that of an IRB in that it would review the proposed action on indigenous land, but would then function as a liaison between the community and the developer or corporation. The CRB – as a panel of experts on both community needs and socio-environmental impacts – would analyze the proposal and provide the community with recommendations. These recommendations would include accepting the proposal in full, outright rejection of the proposal, accepting the proposal with conditions, or accepting certain parts of the proposal and rejecting others. The final decision would be left to the community, and to no one else. This process adds a third party into the existing equation of community-to-developer, which is an inherently unequal relationship. The CRB may serve as a protective body for the vulnerable community to ensure that the community's interests are best served.

¹⁴¹ Ludivine Eloy et al., "Payments for Ecosystem Services in Amazonia. The Challenge of Land Use Heterogeneity in Agricultural Frontiers near Cruzeiro Do Sul (Acre, Brazil)," *Journal of Environmental Planning and Management* 55, no. 6 (July 2012): 685–703, doi:10.1080/09640568.2011.621021.

B.3 – Federal Environmental Protection bodies should inform indigenous communities

The ‘inform’ in informed consent is prejudiced towards who is providing the information, and what kind of information they are providing. In conversations with Carolyn Raffensperger, she mentioned the United States Environmental Protection Agency (EPA) as a powerful informer for all environmental risks for development. Raffensperger’s idea would have the EPA inform and advise on environmental impacts and implications for humans and natural resources, consistent with current protocol. However, it would not be the developer, government agency, or environmental NGO that would decide whether the project moves forward. Using the EPA’s findings, recommendations and advice, the community would make the decision on whether the development would occur on their land.

This recommendation is not fully developed, since research for this paper did not include processes with the EPA; the investigation focused the “consent” rather than “informed” part of FPIC.

B.4 - Withholding funding for projects that have not obtained community consent

The Review of Literature for this investigation examined the policy of the Royal Bank of Canada (RBC) for “free, prior and informed consultation” in procurement processes. This form of FPIC is found in RBC’s supplier management policy, which includes requirements in the procurement process to review environmental and social issues that could impact business or communities. This review concluded that although there were no publically available documents further delineating what this

“consultation” should entail, the social and environmental stance of a national bank is very powerful.

Since all federally funded – directly and indirectly – research on human subjects must first be subject to review by an IRB in the United States¹⁴², it is reasonable to suggest that funding or tax breaks for development first be subject to a review board for FPIC. Likewise, if banks are federally mandated to require FPIC for development on indigenous land, or choose to do so in their own best interest, few or no projects would proceed without a process of FPIC.

Chapter VII: Conclusion

The operationalization of the principles of Free, Prior and Informed Consent is essential to the respect of indigenous populations worldwide and the preservation of native culture and land. Similarly to regulation for the Institutional Review Board, these operations must be delineated in federally mandated policy that holds developers and authorities responsible for projects that administer respect, benefits and justice to the community. The efforts of researchers carrying out community-based research, projects and actions in Alaska Native communities create a powerful standard for what should be expected from relationships with indigenous communities. This paper found that time, communication, and cultural consideration are vital to creating healthy and trusting relationships.

¹⁴² “45 CFR 46.”

In continuing the conversation around consent, there is not only the question of what role authorities and corporations should play in assuring processes of FPIC but what power communities hold to ensure their own preservation. The model of the Community Review Board may enable the community to make an informed decision, by including a community voice within the research review process. While the IRB provides structure for consent to research, it neglects the affect research may have on the community. Both models must combine to create a board capable of facilitating community conversations with authorities, and to elevate community concerns to be respected as valid arguments for their own values and independence. It is imperative for the success of sustainable and respectful FPIC practices that indigenous voices and indigenous knowledge are recognized for their inherent value and power to preserve culture and protect the socio-environmental health of this planet.

For Future Research: Moving Forward

Although this paper aimed to investigate possible models for operationalizing FPIC, there are a few missing pieces of research. Gaps in primary research include interviews with Terry Powell, administrator of the Alaska Area IRB, additional Alaska area community-based researchers, and directors or administrators with Independent Tribal IRBs. Although there are no Independent Tribal IRBs in the Alaska area, the Indian Health Service lists many larger Nations such as Blackfeet, Cherokee, Chickasaw, Choctaw, Menominee, and Muscogee (Creek) that have federally established IRBs.¹⁴³

¹⁴³ "Human Research Participant Protection in the Indian Health Service," *Indian Health Service*, n.d., https://www.ihs.gov/Research/index.cfm?module=hrpp_irb#indie.

Examining the processes, practicality and community value of these Independent Tribal IRBs would benefit the Review of Literature in this paper, as well as possible interviews with officials involved with these boards.

An in-depth analysis of UN-REDD+ programs and policy would benefit the background research of this investigation. Although this investigation asserts that REDD+ programs are not the answer to operationalizing FPIC – that they cater to economic interest – that is not to say that their operations are without value, since they are the United Nations own programs that aim to implement concepts of FPIC.

The largest piece missing from this paper is the community voice. Time constraints for this investigation did not allow for interviews of tribal members themselves; these sorts of interviews would have prompted a full review of the research proposal, which can sometimes take months. This research was also conducted out of Los Angeles, CA with no funding; direct contact with Alaska Native peoples would have been logistically and financially improbable.

However, without this voice, this research is incomplete. The goal of this project was to examine processes for consent, and to argue that consent includes a conversation, and ultimately, the right of the community and its members to say no. If this project were to be expanded to include the voices of a variety of Native community leaders and members, its recommendations and conclusions would carry more weight and may change to reflect community needs. Additionally, an untainted collective community voice would make this research unique and far more valuable to the conversation on FPIC and to the question of indigenous consent worldwide.

Appendices

Appendix A – My Personal IRB Experience: Northwest Indian College (NWIC)

When I began the research process for this paper back in September of 2013, I knew I would need to go through the Human Subjects Research Review Committee (HSRRC) here at Occidental College in order to obtain the college's approval for my methodology for interviewing experts and academics working with AI/AN communities. From the beginning of this project I chose not to interview tribal members themselves, because a thorough review that is usually triggered for more vulnerable subjects – especially for the number of subjects I would need for that kind of project – would likely not fit into my project timeline.

After my research was approved by HSRRC, I did not expect that my work would prompt any further review. I was wrong. My selection of interviewees included a variety of academics and researchers, all of whom were formerly associated with a variety of institutions and IRBs. However, one of my subjects is currently working at the Northwest Indian College (NWIC). William Freeman is the Director of Tribal Community Health Programs at NWIC, and creator of the IRB at Indian Health Services (IHS). Although Dr. Freeman is not a tribe member, his work with NWIC elicited an additional review of my research.

With an email address provided by Puneet Chawla Sahota, I first contacted Dr. Freeman on January 14th of 2014, where I explained the goal and nature of the research and asked him for an interview. He responded that same day that he would be happy to

interview, and we planned to speak by phone the following Wednesday. On January 16, Dr. Freeman returned the informed consent form with an explanation that, “NWIC has a policy that all research done on/with NWIC employees must be reviewed & approved by the NWIC IRB”; if I wanted to use his name or title in my work, I would need to first go through the IRB process. This interview did not happen due to logistical issues (I forgot the 1 hour time difference). However, shortly after it became clear to me that if I wanted to do my full planned interview with Dr. Freeman, and use his name in my work, I would need to resubmit my proposal for review by the NWIC IRB office.

I had already completed the IRB process for Occidental College, which was expedited, since my research posed minimal risk to subjects. I assumed that since I had already completed this process, I would be swiftly moved through the paperwork and protocol for the NWIC IRB. To be honest, at first I was confused as to why my research proposal would prompt review: I thought the interview was pretty straight forward, and I was interviewing an academic and expert who has far more knowledge on this topic than I do. None of my other interviews prompted IRB review, so I was annoyed that this one interview would potentially take more time out of my schedule.

Once I had received the paperwork from Colleen in the NWIC IRB office, it became clear that I would need to fill out the NWIC IRB forms, and restate my research proposal (that had already been approved by Occidental’s IRB). Through a series of emails over a couple weeks, I completed the proposal process. Two weeks later, on February 16th, my proposal was approved with conditions. I then assured my compliance with these conditions, and arranged an interview with Dr. Freeman.

Reflections on NWIC IRB Experience

Although the process was frustrating for me at the time – it kept me from completing my crucial interview with Dr. Freeman – I came to realize through further research with this paper that this process, to be done correctly, takes time. As a student at an institution, I only have so much time to finish my work, so I get angry when something is standing in my way. The Western ideals of efficiency and fast paced processes are ingrained in my mentality as a student – I rarely take a step back to think about the way that other people might value time. Multiple of my recommendations mention how creating cultural understanding for researchers and building relationships with communities takes time and effort, and that both are integral to quality, ethical research. Additionally, this time and space to have conversations back and forth is what builds a mutual understanding of what should be accomplished with the research, or in the case of FPIC, with development. My emails back and forth with Colleen and Dr. Freeman – where I would submit and resubmit my proposal with edits – were a sort of conversation, before my direct contact (via phone interview). Looking back, these conversations were necessary for me to understand what was expected of me.

Appendix B – Interview Questions

- Tell me a little about your background.
 - Where are you working now?
 - What brought you to this job? Or to work in this field?
- How long have you been working at _____ ?
- What is the focus of your work at - _____ ?
- What is some of the research you are currently focused on?

Just to clarify, one of the focuses of my paper is to look at the issue of changing the individual consent required for research to a more inclusive form of community consent. This idea comes from the idea of Free, Prior and Informed Consent, which is the idea that indigenous or other native communities have the right to receive all information regarding any development or action on their land before it happens, and to be explained in detail all processes, possible effects, etc. and to then give or withhold consent. FPIC is not a signature on an informed consent form, but a process including the entire community or existing decision-making leadership, of review and communication between the community and the institution to make decisions that reflect and respect community needs.

Now lets talk a little about Community Based Participatory Research

- What are some examples from publically available cases you have encountered of Community Based Participatory Research for native or more specifically Alaska Native communities?
- How is Community Based Participatory Research important for indigenous communities?
 - What does it give the communities that regular research practices do not?
 - What are the most important upsides to CBPR?
 - What do you see as some of the downsides of CBPR?
- What do you consider to be some of the largest hurdles for these communities to executing community-based research?
 - Do these hurdles sometimes outweigh the benefits of CBPR?
- What is the role of the researchers within the community? Researchers outside the community?

I want to talk a little about the relationship between Institutional Review Boards and Native Communities, more specifically Alaska Native communities.

- First off, how would you describe this relationship?
- Would you say, in your experience, that many indigenous communities have a certain kind of mistrust for researchers and their institutions?
- What do you consider some of the greatest faults/strengths of current IRB processes for obtaining consent?

One of the cases I'm using in my research is the Havasupai Tribe case. In this case, one of the issues was that although individuals consented to the research, these individuals made up only 1/6th of the tribe. The research was published in articles using the Havasupai name with conclusions that were humiliating to both those who had consented and those who did not consent to the research.

- For you, how does the issue of community versus individual consent tie in to the idea of Community Based Participatory Research?

Do you have anything else to add?
Do you have any questions for me?

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