Principles and Models for Data Sharing Agreements with American Indian/Alaska Native Communities

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I. Introduction

Respect for human rights and dignity is a principle that is important in research. This respect is based on the paradigm that all humans have inherent worth and are deserving of respect and consideration. American Indian/Alaska Native (AI/AN) tribal governments are sovereign entities with inherent authorities to create laws and enact health regulations. AI/AN tribes and bands have the right to self-determination, and so regulate all affairs on their lands, including research. AI/AN tribes are increasingly asserting sovereignty over research and data collected from their citizens. Many AI/AN communities hold that data derived from health research conducted with their members are the property of the tribe. Ownership of data by AI/AN communities is an ideal to which many researchers and communities aspire. This ideal must be balanced with the requirements of funding agencies, including data sharing mechanisms. All research should endeavor to have benefit returning to the participating tribes.

This paper aims to provide guidance for researchers and their tribal partners on how to develop data sharing agreements. A glossary of terms is provided below. Tribal sovereignty over research and the history of research in tribal communities are then discussed. Next, ethical principles for conducting research with tribal nations are presented. Finally, principles and models for data sharing are discussed. The Appendix includes model data sharing agreements and a tribal resolution for establishing a data repository. These model tools were developed by the Northwest Portland Area Indian Health Board (NPAIHB) Tribal Epidemiology Center.

Glossary of Terms Related to Research Ethics and Data Sharing in Indian Country

Academic freedom – The collective freedom of faculty and students to conduct research, and to disseminate ideas or facts without religious, political, or institutional restriction. It includes freedom of inquiry, freedom to challenge conventional thought, freedom to express one's opinion about the institution, its administration, or the system in which one works, and freedom from institutional censorship.

Autonomy - Independence or freedom, as of the will or one's actions.

Biobank – A repository of human biological specimens collected for research studies. A biobank may also include associated health or demographic information about individuals from whom biological materials were collected.

Community – A group of people with a shared identity or interest that has the capacity to act or express itself as a collective.

Community customs and codes of research practice – may be expressed in written or oral form. Consistent with the worldviews of particular AI/AN community customs and codes of research practice may embody kinship networks and responsibilities that include multi-generational obligations to ancestors and future generations. Ethical obligations often extend to respectful relations with plant, animal and marine life (TCPS 2, 2010).

Community engagement - a process that establishes interaction between a researcher or research team, and the AI/AN community relevant to the research project. It signifies a collaborative relationship between researchers and communities, although the degree of collaboration may vary depending on the community context and the nature of the research. The engagement may take many forms including review and approval from formal leadership to conduct research in the community, joint planning with a responsible agency, commitment to a partnership formalized in a research agreement, or dialogue with an advisory group expert in the customs governing the knowledge being sought. The engagement may range from information sharing to active participation and collaboration, to empowerment and shared leadership of the research project. Communities may also choose not to engage actively in a research project, but simply to acknowledge it and register no objection to it (TCPS 2, 2010).

Confidentiality - Confidentiality has also been defined by the International Organization for Standardization (ISO) in ISO-17799 [1] as "ensuring that information is accessible only to those authorized to have access" and is one of the cornerstones of information security.

Cultural heritage – A dynamic concept which includes AI/AN relationships with particular areas, material objects, traditional knowledge and skills and intangibles that are transmitted from one generation to the next.

Justice – A core principle that refers to the obligation to treat people fairly and equitable.

Self-determination - the principle in international law that nations have the right to freely choose their sovereignty and international political status with no external compulsion or external interference. The principle does not state how the decision is to be made, or what the outcome could be, be it independence, federation, protection, some form of autonomy or even full assimilation. Neither does it state what the delimitation between nations could be — or even what constitutes a nation (Betty Miller Unterberger, Self-Determination, Encyclopedia of American Foreign Policy, 2002).

Sovereignty - Tribal sovereignty refers to the right of tribes or of federally recognized American Indian nations to exercise limited jurisdiction within and sometimes beyond reservation boundaries (wordiq.com)

Traditional knowledge - the knowledge held by tribal nations. Traditional knowledge is specific to place, usually transmitted orally, and rooted in the experience of multiple generations. It is determined by an AI/AN community's land, environment, region, culture and language. Traditional knowledge is usually described by AI/AN peoples as holistic, involving body, mind, feelings and spirit. Knowledge may be expressed in symbols, arts, ceremonial and everyday practices, narratives and, especially, in relationships. The word tradition is not necessarily synonymous with old. Traditional knowledge is held collectively by all members of a community, although some members may have particular responsibility for its transmission. It includes preserved knowledge created by, and received from, past generations and innovations and new knowledge transmitted to subsequent generations. In international or scholarly discourse, the terms traditional knowledge and Indigenous knowledge are sometimes used interchangeably (TCPS 2, 2010).

II. Tribal Sovereignty Over Research

Federal Indian law and policy have changed over the course of history. Prior to the treaty era, tribes were totally sovereign nations possessing all rights and powers that derive from being independent nations (Funke and Kickingbird, 1976; Pevar, 1992). It was and is the responsibility of sovereign nations to protect their own people from harm. Between 1787 and 1828, treaties were negotiated with tribes for land by the newly created United States of America. This time period is known as the treaty era (Pevar, 1992; Getches, 2006). Negotiations were often conducted hurriedly under adverse conditions, which included negotiation of ideas in languages meant for trade. As a result, the historical facts presented in treaty documents may not be accurate.

The United States has a unique legal and political relationship with AI/AN tribes as provided in the United States Constitution, treaties, federal statues, executive orders and memoranda, Supreme Court decisions and other case law (Bryan, 2009). The Indian Reorganization Act of 1934, landmark legislation in affirming the government to government relationship between tribal nation and the federal government, is part of the foundation for tribal self-governance as it exists today. In addition, the Indian Self-Determination and Education Assistance Act (Public Law 93-638) and the Indian Health Care Improvement Act, were passed in 1975 and 1976, respectively. Self-determination policies have enabled tribes to administer service programs and make decisions regarding tribal membership, as well as to regulate research on their lands.

Researching across cultures has ethical implications that begin with considering the balance of power between researchers and study participants throughout the research process, including informed consent, development of the research design, data ownership and data use (Marshall, 2004). Ethical conduct of researchers who have worked across cultures worldwide has a history of being criticized (Loff & Black, 2000; Shalala, 2000). Issues of community damage, exploitation, and inaccuracies have arisen from such work. Academic Western thinking and conceptualization are frequently not those of the community being studied.

Unfortunately, the long history of research in Indian Country has also included instances of harm to AI/AN communities (Sahota, 2007, available at http://www.ncaiprc.org/files/Research%20Regulation%20in%20AI%20AN%20Communities%20-%20Policy%20and%20Practice.pdf). These harms have eroded the trust of sovereign tribal nations in traditional research practices and have led to a call for greater tribal control of research. Because data collection has frequently been imposed by outside authorities such as the federal government, it has been met with resistance in many quarters (Canada, Royal Commission on Aboriginal Peoples, Report of the Royal Commission on Aboriginal Peoples 1997). It is in the context of this difficult history that new ethical frameworks are emerging for working with tribal nations.

Background of Research Injstices

Topic of Concern
Tribal nations have been subject to too much research.
Researchers have selected subjects of personal or academic interest without consideration of tribal interests and priorities.
Researchers have often pre-empted meaningful community involvement by presenting fully designed and funded projects to the community rather than using participatory methodology early on in the research design process.
Researchers have treated AI/AN tribes and peoples as merely a source of data.
Researchers have failed to explain their studies in a language or manner that adequately

insures fully informed participation and consent.
Research has disrespected human dignity of participants, including, but not limited to their religious, spiritual or cultural beliefs. (Warne, 2010)
Researchers have collected genetic materials for purposes not originally identified to the community and/or individuals (e.g., the lawsuit filed by the Havasupai Tribe against the Arizona Board of Regents).
Human remains and cultural property have been taken for storage, display in museums, or for sale to individuals.
Researchers have used leftover portions of blood samples for secondary research without consent of the donor.
Researchers have described problems with a disregard to their impact on communities.
Researchers have often focused on problems without examination of positive, resiliency factors.
Research has not been returned to the community in ways which benefit the community.

Past problems with research have generally revolved around control. What gets done, how it gets done, and what is transmitted about discoveries often lies outside of the control of the AI/AN tribes and people participating.

In response to this difficult history, many tribes have established their own tribal research review boards, including tribal IRBs. Tribes are sovereign governments with the power and responsibility to regulate research conducted with their citizens. Tribes have diverse processes for research review, including tribal Institutional Review Boards (IRBs), community advisory boards, and tribal governmental review (i.e., the tribal council serves as the review board). These tribal boards have been established to review proposed research protocols, and in so doing, help prevent research-related abuses of individuals and tribal communities, protect human subjects and traditional knowledge, and identify research-related benefits and risks to the tribe. Tribal research review boards serve to: (1) protect the people, culture, and natural resources of tribes from unauthorized scientific research; (2) reduce the adverse effects of research on tribal communities; (3) ensure that researchers recognize tribal control of research activities; (4) establish and provide a statutory basis to review and govern any research, database, or publication undertaken on their reservations; and (5) provide a mechanism for tribes to enforce their decision making outside of federal regulations and university IRBs. As required by the reviewers, data can only be gathered with tribal consent. Permission to carry out research can be granted by both the tribal research review entity and the tribal government, often in the form of a tribal resolution, which specifically outlines how the data will be used, reported, and disseminated. Many tribes have some process for research review, even if they do not have their own tribal review board. Not all tribes have a formal board, but may have a research review process involving staff, tribal health board, tribal council review, or another mechanism for the review of research.

III. Research Ethics

Ethical principles for working with AI/AN communities include some of the same principles used with other ethnic communities. However, the challenging history of research in AI/AN communities and the sovereignty of tribal governments result in some unique ethical considerations as well. In this section, traditional Western principles of

ethical health research will be discussed along with new, emerging ethical frameworks for working with AI/AN communities.

Principles for Ethical Research

Research should be based on three core ethical principles (The Belmont Code 1978) :

- Respect for Persons and Communities
- Concern for Welfare (Beneficence)
- Justice

Respect for Persons and Communities

Respect for persons and communities acknowledges the inherent value of not only the individual, but the community to which they belong. The Belmont Report was originally written to protect individual research subjects, but scholars like Bill Freeman and Francine Romero have extended these three values to also apply specifically to tribal communities (Freeman and Romero, 2002, accessible at*:* http://www.npaihb.org/images/epicenter_docs/irb/docs/guidelines.pdf).The original Belmont Report does not mention research protection for communities, but this level of protection is critical in Indian Country.

The principle of respect for persons and communities also includes the obligation to respect the autonomy and sovereignty of tribal nations as governments (Freeman and Romero, 2002, accessible at*:* http://www.npaihb.org/images/epicenter_docs/irb/docs/guidelines.pdf).

Autonomy includes the ability to deliberate and choose based on deliberations. Autonomy gives due deference to the person's and the community's judgment, thus allowing the freedom to choose. In order for autonomy to be fully respected, all relevant information about a study needs to be provided to tribal members, which may require translating informed consent forms and study recruitment materials into a tribe's native language(s).

Beneficence (Concern for Welfare)

Beneficence emphasizes maximizing possible benefit to individuals and communities, while minimizing potential risks, of a research study. "Benefit" may be defined both in the short term and long term. Possible short-term benefits for communities include capacity building and training for tribal members who join the research team. One long-term benefit may be the generation of data that helps inform community policies and practices. The concept of beneficence can be viewed as valuing the quality of an individual's or community's experiences in all aspects of a research project. It includes, but is not limited to, concern for physical health, mental health, and spiritual health, in addition to determinants of social health (e.g., housing, socioeconomic and security considerations).

Justice

Justice refers to the obligation to treat all people fairly and equitably. Fairness entails treating all people with respect and concern. Equity requires distributing the benefits and burdens of research participation in such a way that no segment of the population is

unduly burdened by the harms of research or denied the benefits of the knowledge generated from it (TCPS 2, 2010)

Treating people fairly and equitably does not always mean treating people in the same way. Differences in treatment or distribution of resources may be justified when failures to take differences into account may result in the creation or reinforcement of inequities. Academicians have traditionally been members of colonial cultures; that is, researchers have held power in forms of money, knowledge and perceived expertise over their human subjects. The relationship between tribes and researchers is now moving towards a more equitable place, honoring of traditional knowledge and even distribution of resources.

Justice may be compromised when a serious imbalance of power prevails between the researcher and participants. Resulting harms are seldom intentional, but nonetheless real for the participants. In the case of AI/AN peoples, abuses stemming from research have included: misappropriation of sacred songs, stories and artifacts; devaluing of AI/AN peoples' knowledge as primitive or superstitious; violation of community norms regarding the use of human tissue and remains; failure to share data and resulting benefits; and dissemination of information that has misrepresented or stigmatized entire communities (TCPS 2, 2010).

Emerging Ethics

Academic freedom is the collective freedom of faculty and students to conduct research, and to disseminate ideas or facts without religious, political, or institutional restriction (Amercian Association of University Professors 1940). It includes freedom of inquiry; freedom to challenge conventional thought; freedom to express one's opinion about an institution, its administration, or the system in which one works; and freedom from institutional censorship. Academic freedom exists to encourage innovation and inquiry, as well as to provide an open space from which to raise questions that might guide social and political decision making. However, academic freedom may be challenging in research with small populations, such as tribal nations, where individuals or groups could be harmed when data are interpreted without community involvement. It is in this environment that emerging ethics could take precedence over traditional academic practices in working respectfully with tribal communities.

The highest ethical standards are recommended when working in partnership with tribal communities. Working in this way generally takes more time than conventional research approaches have in the past. However, it is important to do what is ethically correct, which is not necessarily the most expedient. This is especially true in light of the difficult history of research mentioned previously.

Emerging ethical practices that are recommended are summarized in the table below:

Ethical Practice
Strict adherence to the usual and customary ethical requirements for research – informed consent and confidentiality, including consideration of whether anonymity is needed both for individuals and the tribe as a group.
Community involvement, participation and consultation, including appropriate approvals by tribal councils.
Negotiated research relationships in writing, which are agreed upon by all parties.
Meaningful tribal capacity building; the ability of the Tribe to either conduct independent

research or implement the findings of research to enhance tribal capacity.
Meaningful protection of the individual and the tribal community including the respect of tribal protocols and customs.
The return of data and reports to the community.

IV. Data Sharing

In this section, principles for data sharing are recommended. Detailed discussions are provided about data sharing, ownership, access, and control. Finally, considerations for intellectual property are presented.

Principles for Data Sharing

There are several important principles that relate to data sharing agreements in AI/AN communities:

1. Participatory Research, also known as community-based participatory research (CBPR) is research that is conducted as an equal partnership between traditionally trained experts and members of a tribal community. The community participates at varying degrees in all aspects of the research process, from development and implementation to analysis and publication. In participatory research models the community is respectfully afforded equal power to that of the traditionally trained experts. Tribes are sovereign governments, and therefore also have oversight and decision making power over research studies conducted with their citizens.

2. Ownership of Data The rights and responsibilities surrounding ownership, access and retention of data as well as the definition of research data may vary based upon sponsorship of the project, nature of the award, and general context of each situation. For the purposes of a specific research agreement, the investigator and tribe may review the funders' expectations. The use, ownership, and stewardship of data is a point of negotiation for both tribes and researchers when conducting research in the community.

3. Obligation to Follow-Up An obligation is a requirement to take some course of action, whether legal or moral. In the contexts of research in tribal communities, an obligation could exist to follow up with the community on the results and needed actions suggested by experts or community analysis. The obligation to follow up with communities suggests considering policy and practice implications of data rather than just collecting data and leaving the community. Follow up with communities provides an additional level of equity of power between experts and the community.

4. Future Participation Sustaining the benefits of a research project may require researchers to be involved with the community after the immediate research project is completed. Such future involvement may include potential uses of data derived from a particular project. It is useful to define and clarify issues around long-term relationships between researchers and communities during initial negotiations between the research team and the community. Research agreements may need to be revisited at the end of the project to ensure emergent community needs are addressed.

A data sharing agreement offers a helpful mechanism for negotiating terms of data ownership and access between tribes and researchers. Such an agreement could be

drafted between the two partners at the post-award phase of funding. Ideally tribal entities could be involved in the development of any proposed research prior to the development of the grant proposal. The Appendix at the end of this paper includes a model data sharing agreement from the Northwest Portland Area Indian Health Board.

Data Sharing and Ownership

Federally recognized tribes are sovereign nations, and so they often make collective claims to their traditional knowledge, biogenetics resources, and intellectual property. Some tribes may also claim ownership over data collected in research studies conducted with their citizens. There are a variety of options for tribes to maintain control over data, as discussed in another section of this resource guide. One helpful framework for understanding tribal views on data control has been developed by the First Nations of Canada. Ownership, control, access and possession (OCAP) is self-determination as applied to research, according to First Nations of Canada (Schnarch, 2004).This framework applies to any collection of data, including research, program evaluation, development of surveys and statistics, the use of cultural knowledge, etc. It is broadly concerned with all aspects of information creation and management.

Ownership

Data ownership refers to both the possession of and responsibility for information and can be considered at both the individual research participant and collective tribal level. Ownership implies power as well as control over the use of data. The ownership of information includes not just the ability to access, create, modify, package, derive benefits from, sell or remove data, but also the right to assign these access privileges to others (Loshin, 2002). Data ownership has been increasingly articulated as a major concern of participants in research projects. Darou et al. (1993) were among the first to suggest that some ethical issues can be avoided by sharing results and ownership with participants. Scofield (1998) suggested replacing the term ownership with stewardship, because it implies broader responsibility where the user considers the consequences of making changes over "his" data.

Ownership refers to the relationship of a tribal community to its cultural knowledge/data/information. The principle means that a community owns information collectively in the same way that an individual owns their own personal information. In other words, the information belongs to the community and is the tribe's "property." Ownership is distinct from stewardship. Stewardship is care taking of data or information that is accountable to the group (Schnarch, 2004), regardless of who owns the data. It includes insuring the integrity and quality of data sets. Data may be stewarded though a variety of mechanisms, including preservation by tribal entities, funding agencies, academic institutions or in data repositories that are established to maintain data sets. Ownership and stewardship roles may be assigned to tribes, universities, or other organizations depending on the interests and needs of the parties involved.

Control

The principle of control asserts that tribal members and representative bodies are within their rights in seeking to control all aspects of research and information management processes which impact them. The principle of control is focused on a tribe's right to determine how data are used, including who will collect the data, how will it be shared between the partners (university and tribe), who will be the primary holder of data, how

will the tribe be identified, and how will the data be used, including approval of any secondary data analysis. Secondary use of data is defined as use for a study outside the original research project. There are many issues related to data control, among them access, ownership and disposition of data. All of these issues can be negotiated during the research development phase. However, some data uses may be unanticipated at the beginning of a research study, and for certain types of research, the specific ways data will be used are determined during the project. Tribes can choose to maintain oversight throughout data analysis, and to require that researchers seek specific approval prior to secondary uses of data. Tribal control over data may be a foreign concept for some researchers new to Indian Country, and may appear at first to contradict the value of academic freedom. However, ethics and values are culturally defined (Sampson and Groves, 1989). The status of tribes as sovereign governments also gives these communities unique kinds of legal and political authority, including over research and data collection activities.

The principle of control also includes interpretation and publication of data. Tribal control over data interpretation can occur through a range of options. Minimally, tribes should be given the opportunity to review interpretations and conclusions drawn by researchers. If the tribe disagrees, the tribe could author a section of the resulting research article or a companion article presenting their views. Tribes that assert tighter control over data interpretation may require that researchers submit their manuscripts for tribal approval before submission to any publisher. In these cases, some tribes retain the right to deny permission to publish if the manuscript is viewed as stigmatizing or harmful to the community. More information on tribal options for review of publications is available in the Research Regulation Toolkit developed by the National Congress of American Indians Policy Research Center (NCAI PRC). The toolkit also includes papers on options for tribes wishing to create their own research regulation structures (e.g., IRBs versus community advisory boards) and checklists for reviewing research proposals. In sum, a key challenge in data sharing is how to maximize benefits and minimize potential harms to specific AI/AN tribes and their citizens.

Access

Tribes often desire access to information and data about themselves and their communities, regardless of where such data are currently held. Tribes also have the right to manage and make decisions regarding access to their collective information (Schnarch, 2004). It is important for tribes to have access to datasets, including federal datasets, which contain information about their tribal members and service users. This kind of access aids in enhancement of decision making and policy development. Such access also aids in the movement toward health equity (Health Research Advisory Council, 2009 and 2010, http://minorityhealth.hhs.gov/HRAC/Assets/HRAC%202010%20Recommendations%20to%20HHS.pdf).

Access to data for tribes also means including them in large, national studies. National data sets, such as those held by the Centers for Disease Control and Prevention (CDC) have "small number" cutoffs for reporting. As a result, AI/ANs are often not included in national data sets because of their small population as a percentage of total samples. In other cases, data sets may not include a race or ethnicity variable. Small numbers are of concern in many public health assessments, and oversampling of AI/AN communities may help to address this issue. Health policy decisions are often based on public health

data sets. For this reason, inclusion of AI/ANs in national studies is important. Balancing this need for inclusion with concerns tribes have about data sharing is an ongoing challenge.

Continued dialogue between tribal nations and federal agencies that collect national data is critical to ensure that AI/AN peoples are included in vital data collection while also maintaining the confidentiality of individuals and tribes as groups. The small size of some AI/AN communities can also pose challenges around confidentiality of individuals. For example, a member of a single AI/AN community with distinctive characteristics (e.g., an elder with a specific disease) could be identified in a tribal data set even if her name or other identifying information were not included. Problems with confidentiality can arise when small numbers of individuals have a particular condition, particularly within a small ethnic group. Problems with confidentiality breaches can occur much more easily in small populations. In large data sets, small numbers are assumed to be less than 300 individuals (Assessment Operations Group). Tribal nations may also sometimes request group anonymity, or not to be named, in certain research reports that are viewed as potentially stigmatizing.

Historically, data not being returned to AI/AN communities has hampered efforts to better the situation in these communities. Return of data can be viewed as a form of repatriation of information, similar to tribes regaining sacred materials from museums or having their lands returned. Tribes' requests for return of data generally refer to collective, aggregate data at the tribal level, not the data for individual tribal citizens. When data are returned to tribes, the confidentiality of individual research participants should be ensured. Access to data and interpretation of aggregate data at the tribal level is also important for tribal nations to have input on how research findings are presented to the public. Tribes can help to ensure accurate interpretation of data as research partners. One potential mechanism for entering into such a research partnership is the concept of tribes or their authorized representatives (e.g., a tribe's physician) as co-Principal Investigator. This framework allows tribes and their research partners to have equal authority over data collection, use, and interpretation.

The issue of access also relates to data collected by tribes themselves such as for program evaluation. Tribes do not always want to share their data for a variety of reasons, like stigmatization, fear of misuse of data, concern about anonymity of tribal members, among others.

 Tribes wrestle with funders' requirements for access to data. For example, some funding agencies require that grantees share data or program evaluations with the funder, which may be problematic for tribes concerned about data confidentiality. Some tribes have also expressed concerns about secondary data analysis conducted without tribal authorization. Although there have been some cases of problems with secondary analysis, sharing data or providing outside researchers with access can also result in new research findings that are beneficial to tribes.

Possession

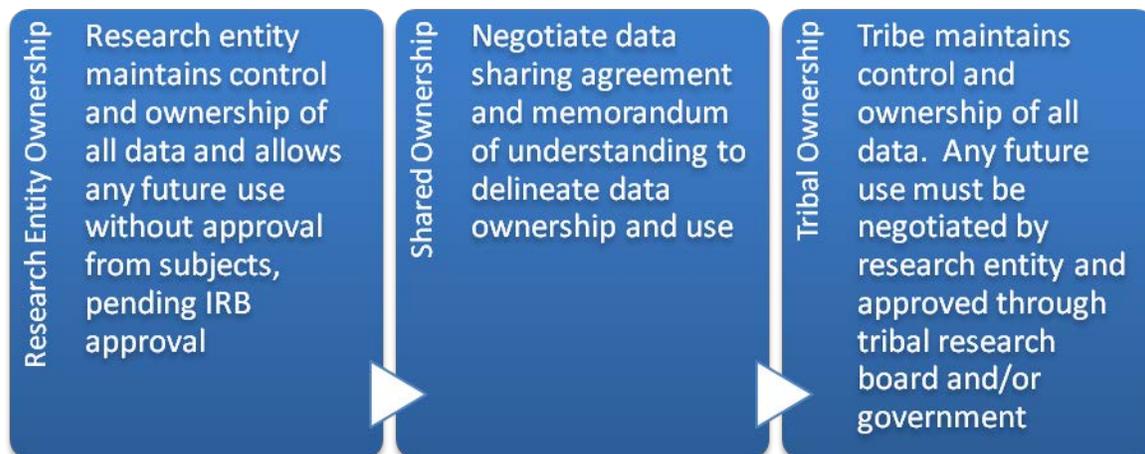Data collected from tribal citizens should ideally be returned to the community from which the data were obtained. Some tribes may wish to retain possession of data throughout a research study. Data can be stored on tribal lands, or electronic databases can be primarily housed in tribal information systems. Access to data sources can also be restricted through electronic security measures, such as password protection of

databases with tribal representatives as primary users. The location of data may be particularly important for culturally-sensitive matters, such as in archaeology studies dealing with sacred artifacts or oral history projects regarding traditional tribal knowledge. Tribes that wish to maintain possession of their data might consider setting up a data repository. This model is discussed further below.

Range of Options in Data Sharing

There is a range of options which may be employed for tribal control of data (see the figure below). Plans for data management should seek to ensure data integrity, including confidentiality and anonymity. Minimally, data collected from tribal members within the community setting should be returned to the community from which it was obtained. The return can be through reporting or return of primary data sets.

Available options for data sharing may depend on the funding source for the work, the established research protocol, and memoranda of understanding or data sharing agreement developed between the tribe and research team. Data and/or biological specimens could be held primarily by either the researcher's institution or the tribe. Tribal storage of data offers the potential of greater tribal control over data and how they are used. Capacity for tribal storage of biological specimens or data needs to be considered, however. For example, biological samples may need to be stored in special refrigeration units, etc. that may not always be available on tribal lands. Thus, data management plans can range on a spectrum from research institution control of data to tribal control, as shown in the figure below.

Research Entity Ownership	Shared Ownership	Tribal Ownership
Research entity maintains control and ownership of all data and allows any future use without approval from subjects, pending IRB approval	Negotiate data sharing agreement and memorandum of understanding to delineate data ownership and use	Tribe maintains control and ownership of all data. Any future use must be negotiated by research entity and approved through tribal research board and/or government

Grants funded by the National Institutes of Health require plans for sharing data if the funding for such grant is greater than $500,000 of direct funds in one year. Data sharing can be accomplished through a variety of mechanisms that allow different levels of tribal control. Sample NIH data sharing plans involving tribal control of data and further options for tribal data control in federally-funded grants are available here. The AI/AN Health Research Advisory Council (HRAC) may also be a helpful resource for tribes in navigating federal funders' requirements for data sharing (http://minorityhealth.hhs.gov/hrac). The AI/AN HRAC was established in 2006 to provide the U.S. Department of Health and Human Services a venue for consulting and

collaborating with tribes about health research priorities and needs in AI/AN communities. Tribal leaders who serve on the AI/AN HRAC recently recommended that the Department of Health and Human Services adopt department-wide minimum standards and requirement for a tribal data sharing agreement for federally funded grants (Health Research Advisory Council, 2009 and 2010 http://minorityhealth.hhs.gov/HRAC/Assets/HRAC%202010%20Recommendations%20to%20HHS.pdf).

One option for tribal control of data is a **data repository**. These repositories are subject oriented computerized warehouses of data sets related to research or public health practice. The data come from multiple sources, and are presented from the perspective of the groups that contribute the data.   Data are added, but never deleted, providing a historical perspective on participating organizations' work. Data in repositories can be structured so that no individual identifiers are present in the data set, thus protecting anonymity and confidentiality. Tribes can require that the use of data from their repositories is subject to approval from an IRB, tribal research board, and/or the tribal government. Data repositories can also be held by tribes themselves, or consortia of tribes. Thus, data repositories provide a possible mechanism for tribal control of data. For example, the Northwest Portland Area Indian Health Board has established a data repository through passing a recent resolution (http://www.npaihb.org/images/policy_docs/resolutions/FY11/11-02-04%20NW%20Tribal%20Data%20Repository.pdf).

Intellectual Property Related to Research

In collaborative research, intellectual property rights should also be discussed by researchers, communities and institutions. The assignment of intellectual property rights, or the granting of licenses and interests in material that may flow from the research, should be specified in a research agreement (as appropriate and if possible) before the research is conducted. Researchers, communities and institutions should be aware that all knowledge and information is not necessarily protected under existing law. Existing intellectual property legislation generally protects works and inventions. Strict criteria are used to define intellectual property rights. Understanding and communicating what qualifies, or does not qualify, as intellectual property for the purposes of research is a joint responsibility of communities, researchers, and institutions. Research agreements provide an important mechanism for ensuring transparency and accountability between research partners.

Some knowledge collected as a result of the research may have commercial applications, and lead to the development of marketable products. With respect to commercialization of results of collaborative research, researchers and communities could discuss and agree on the use, assignment or licensing of any intellectual property (e.g., any patents or copyright) resulting from the marketable product, and document mutual understandings in a written agreement. If the proposed research has explicit commercial objectives, or direct or indirect links to the commercial sector, researchers and communities may want to include provisions related to anticipated commercial use in research agreements. These provisions should be clearly communicated to all parties in advance, consistent with a transparent informed consent process (TCPS 2, 2010). Regardless of which party legally holds intellectual property rights in data, specific issues related to data control and use can be specified in a research agreement

V. Research Agreements

When a community has formally engaged with a research team, the roles, rights, and responsibilities of both the researcher and the community should be set out in a research agreement prior to any activities taking place. Terms of data sharing are particularly important to include in a research agreement. Research agreements should precede recruitment of individual participants and collection of, or access to, research data. The scope of the agreement will depend on the level of engagement which the community desires, and the availability of resources to support community participation. There is a spectrum of how involved communities are in day-to-day workings of research projects, even in what is termed "community-based participatory research" (CBPR) (Sahota, 2010, available at http://www.ncaiprc.org/files/CBPR%20Paper%20FINAL.pdf).

At a minimum, the research agreement can address how ethical protections that normally apply to individual informed consent will also be applied to the tribal community. For example, this would include procedures for securing group consent from tribal governments for study participation. Terms should also be included related to sharing of research benefits, ongoing tribal review of the study, and procedures for modifying the agreement in the future. Agreements typically set out the purpose of the research and detail mutual responsibilities in project design, data collection and management; analysis and interpretation; credit due to knowledge holders (e.g., authorship of publications); protection (and non-disclosure) of restricted knowledge; sharing of benefits or royalties flowing from intellectual property where applicable; production of reports; co-authorship; dissemination of results; and a conflict resolution process. Provisions for any anticipated secondary use, or use of specimens/data for purposes outside of the original study design, could also be addressed and documented in the research agreement (TCPS, 2010). Research agreements can also include provisions for tribal review of reports and manuscripts prior to publication, or limits on the release of and access to research results.

Research agreements are increasingly being recognized by academic institutions (and the researchers associated with them) as providing reference points for the research ethics review process and approval on such elements as consent, confidentiality, and access to and use of information. Research agreements can be included in applications submitted to university IRBs. These agreements can provide contextual information and guidance for IRBs conducting their initial review of applications and continuing research ethics review throughout the project.

Building relationships, clarifying the goals of a project, and negotiating agreements requires substantial investment of time and resources on the part of the community and the researcher. Development and participation costs incurred by the community and the research team could be factored into grant proposals to the extent possible within funding guidelines. Pilot funding could also be applied for in order to establish a research partnership with a tribal community.

Conflict may arise with academic institutions if a university will not accept tribal ownership of data or tribal review of publications. One method of dealing with these types of issues is to establish a scientific advisory board made up of community members and scientists to advise on ethical and scientific matters. Having a balanced team of interested individuals can pave the way for productive negotiations between research institutions and tribes. Throughout the duration of a research project, as trust is built within the community, amendments to research agreements can be negotiated. It is fair for a tribe to ask how they will be represented in the research. It is also reasonable

for researchers to expect that factual research findings in publication manuscripts may not be altered during the tribal review process.

University IRBs that are familiar with AI/AN tribes look closely at the negotiation between the researcher and each potential research participant during the "informed consent" process. Due to concern about tribal sovereignty and self-determination, the IRB examines the negotiation both between the researcher and each potential volunteer, and also between the researcher and the tribal community. That is, the IRB helps ensure that all research observes the same principles—respect for persons, beneficence, and justice—as it applies to tribal communities. Tribal consent to participate in a study is given through executing a research agreement, while individual participants sign informed consent forms. If communities are to have access to an individual's personal data during the project, each participant can be made aware of this as part of the informed consent process. Access to confidential information provided by an individual may be subject to privacy laws, such as the Health Insurance Portability and Accountability Act (HIPAA) (TCPS, 2010). Key components of research agreements regarding data sharing include:

The purpose of the data collection and why it is important to the tribe.
The expected outcome of the project.
The variables will be collected and why.
Who will have access to the data and for what purposes.
How the data will be managed – storage, security, exchange, length of data storage and method of destruction or return to the tribe.
How data will be stored or handled according to US governmental regulations which apply (e.g., the Freedom of Information Act and amendments relating to federally funded research; HIPAA regulations)
How the results will be shared and who will approve the documents to be shared.

Below is a suggested outline for a research agreement:

- Introduction including the relevance of the project; why tribal involvement is important; potential risks, burdens, and benefits of research; the impact of research and data collection on the tribe; and any compensation for participants involved in the study or project.
- Clear description of study design including timing, materials to be used, where the study will occur and study procedures that are mutually understood.
- Potential risks and benefits of the study including anticipated benefit to tribal community; steps taken to minimize risks and maximize benefits; and assessment of balance of risks and benefits which will be continual and on-going.
- Adverse events handling.
- Confidentiality of research data.
- Plans for data analysis.
- Anticipated reporting of data and publications.
- Process for resolving conflicts between research partners (e.g., arbitration).

Model research agreements are available from the American Indian Law Center, Inc. (http://www.nptao.arizona.edu/research/NPTAOResearchProtocolsWebPage/AILawCenterModelCode.pdf), the Indigenous Peoples' Council on Biocolonialism (http://www.ipcb.org/publications/policy/index.html) the Canadian Aboriginal AIDS

Network
(http://depts.washington.edu/ccph/pdf_files/Principles_of_Research_Collaboration_Template.doc.pdf), and the Indigenous Wellness Research Institute (IWRI) at the University of Washington (http://www.iwri.org/methods). The Appendix at the end of this paper includes a model research agreement template from the Northwest Portland Area Indian Health Board. Other model research agreements may also be obtained from Tribal Epidemiology Centers, tribal leaders, and organizations working on a regular basis with tribes in the area of public health.

VI. Conclusion

Tribes should have the authority to decide how research data will be used in the future. Without the tribe and its collective consent to participate, there would be no data. Research agreements can be developed in a way that satisfies the requirements of the tribe, university, and funder regarding ownership and control over the data. In addition to data ownership and control, tribes and researchers should be aware of key issues of concern, such as anonymity and confidentiality for both individual research participants and the tribe as a whole. In sum, key recommendations for conducting research with tribes include:

1. A meaningful ethical framework needs to be maintained by all parties seeking to work with tribes and tribal organizations. This includes a mindfulness toward traditional harms of research, cultural knowledge that is both historic and current, and acknowledgement of the worldview of each participating partner in the research proposal.

2. The community needs to be a part of the research study from study conception to publication. The community may choose participate to varying degrees in all aspects of study design, data analysis, and interpretation.

3. Research agreements are a useful tool for lending clarity to the research process. Potential risks and benefits to the tribe or tribal organization can be delineated in these agreements. The roles and responsibilities of all research partners can also be included. Finally, provisions related to data ownership, control, access, and possession can be specified, along with procedures for publication review.

APPENDIX

This appendix includes a model data sharing agreement developed by the Northwest Portland Area Indian Health Board for use with tribal partners. Following the model data sharing agreement, there are templates for confidentiality agreements to be signed by research staff. Finally, a resolution from the Northwest Portland Area Indian Health Board for establishing a tribal data repository is also available here: http://www.npaihb.org/images/policy_docs/resolutions/FY11/11-02-04%20NW%20Tribal%20Data%20Repository.pdf. Within the model data sharing agreement there are a number of important areas to consider. Data sharing agreements should generally include the following topics: parties involved, including contact information; the purpose or need for the data sharing agreement; nature of the data to be collected; access and confidentiality of data; how the data are to be used; how and in what situations the agreement can be severed by either party; and relevant legal authorities (tribal, state, national). Notably, the model data sharing agreement below offers options for tribes regarding which specific types of data they wish to share or not (see section III.B, *Description of Data/Data Workplan, Data Provided Under this Agreement*). Please note that this model agreement is provided as a sample only and that tribes should consult their legal counsel before using this template agreement. For more information on this model data sharing agreement, please contact Dr. Victoria Warren-Mears, Director, Northwest Tribal Epidemiology Center at the Northwest Portland Area Indian Health Board (vwarrenmears@npaihb.org).

Model Data Sharing Agreement

<div align="center">

DATA SHARING AGREEMENT

between

(NAME OF TRIBE)

and

THE NORTHWEST TRIBAL EPIDEMIOLOGY CENTER (EpiCenter),

NORTHWEST PORTLAND AREA INDIAN HEALTH BOARD (NPAIHB)

</div>

I.   ENTITIES RECEIVING AND PROVIDING DATA

ENTITY RECEIVING DATA:	NPAIHB
OFFICE:	Northwest Tribal Epidemiology Center
CONTACT PERSON:	Victoria Warren-Mears
TITLE:	Director, NW Tribal EpiCenter
ADDRESS:	2121 SW Broadway Dr. suite 300
	Portland, Oregon 97201
PHONE NUMBER:	(503) 228-4185
EMAIL:	vwarrenmears@npaihb.org
FAX NUMBER:	(503) 228-8182
ENTITY PROVIDING DATA:	
OFFICE:	
CONTACT PERSON:	
TITLE:	
ADDRESS:	
PHONE NUMBER:	
EMAIL:	
FAX NUMBER:	

II.   PURPOSE, AUTHORITY AND TERM OF AGREEMENT

A. PURPOSE
   To facilitate the health of Indian tribes and individual American Indians and Alaska Natives in the Northwest, the Northwest Tribal Epidemiology Center (The EpiCenter) of the Northwest Portland Area Indian Health Board (NPAIHB) and {NAME OF TRIBE} are entering into an agreement which will allow the exchange of data and clarification of data access and utilization.

B. LEGAL AUTHORITY
   1. The NPAIHB is an Indian Organization as defined by federal law in the Indian Self-determination and Education Assistance Act, 25 U.S.C. §450b(1). NPAIHB has established The EpiCenter, whose mission is, in part, to provide timely and accurate health status information to northwest tribes.
   2. The {NAME OF TRIBE} is an Indian tribe as defined by the Indian Self-Determination and Education Assistance Act (25 U.S.C. § 450 et seq.

C. PERIOD OF PERFORMANCE
   This agreement shall be effective when signed by both parties and shall continue until terminated pursuant to the termination clause contained herein, or a period of 5 years, whichever is earlier. Modifications to this agreement may be made at any time at the request of {NAME OF TRIBE}.

III. **DESCRIPTION OF DATA/DATA WORKPLAN**

A. JUSTIFICATION FOR EPICENTER ACCESS TO SPECIFIC DATA OPTIONS
   Access to the following data sources is requested for the purpose of tracking population-level statistics, for example, disease rates, screening rates and level of care provided.

   1. **IHS Epi Data Mart** – The Indian Health Service (IHS) Epidemiology Data Mart is a subset of the central data warehouse database known as the IHS National Data Warehouse. These were established by the IHS to gather, store, and report health information from various sources throughout the Indian Health system. The EpiCenter will use this data for public health surveillance and health status assessment and reporting on behalf of NW tribes. This data will be de-identified and only available at the Area level (i.e., no tribal affiliation information will be available). The EpiCenter will only have access to data pertaining to the Portland IHS Area (Idaho, Oregon, and Washington tribes).

   2. **Patient Registration** – Patient registration data will be used to conduct record linkages with various public health data systems. Record linkages are important for identifying inaccurate and missing race data for AI/AN, and result in much more accurate disease and mortality estimates at the state level. This activity grants the EpiCenter, and by extension,

northwest tribes, access to data sources that are not routinely available to tribes, such as cancer, trauma, and hospitalization registries that are administered by the states. These activities directly benefit both state partners and tribes by: (1) improving the accuracy of race data in state surveillance data systems, and (2) providing more accurate and complete health status data for northwest tribal communities. Direct identifiers are accessed only during the linkage, and never exchanged with the state or any other party. Furthermore, linkages will only be completed after review and approval of the Portland Area IHS Institutional Review Board (IRB) and relevant state IRBs. Data with direct identifiers will be handled according to more stringent security measures than de-identified data, as outlined in Section V of the Agreement**.**

3.   **Encounter and Claims Data** – Patient encounter and claims level data may be used for a variety of purposes, for example, surveillance of reportable conditions, reports of top diagnoses, immunization and screening coverage, and providing general technical assistance. Whenever the EpiCenter wishes to access encounter and claims level data from {NAME OF TRIBE}, the EpiCenter shall provide a written request to the Point of Contact listed in Section VII, below. This request will contain, at a minimum, the proposed use of the data, list of data elements required, and intended audience. Appendix I contains examples of possible encounter level data options and packages available in the RPMS system**.**

4.   **Portland Area-Level Reports** – Some reports are collected by IHS at the Area level, such as those from GPRA, the diabetes audit, suicide reporting, immunizations, women's health, and Contract Health Services. Data contained in these reports is aggregated by tribe/site as well as at the Area and national levels. These reports contain measures that are standardized nationally and allow for comparison of local results to larger aggregate results. Reports from previous years contain historical information that may no longer be available locally. The EpiCenter will use this data for general health status assessment and tracking of clinical measures within the Portland Area.

B. DATA PROVIDED UNDER THIS AGREEMENT

	Data Options	Yes	No	Signature
1.	IHS Epidemiology Data Mart access (Area-level aggregated and de-identified data)			

2.	Patient registration list from RPMS and/or other patient management system (full name, date of birth, sex, race social security number, address, tribe, Indian blood quantum, classification/beneficiary code, primary facility and facility HRN, current community, date of last update, date of death, Medicaid ID number, Medicare ID number)			
3.	Encounter and claims level data			
4.	Portland Area-level reports			

IV. __ACCESS TO DATA__

A. METHOD OF ACCESS AND TRANSFER

Depending on the specific data types authorized under this Agreement, data will be obtained by the EpiCenter in one or more of the following manners:

- Remote (web-based) password-authenticated access to Epidemiology Data Mart (option #1)
- Remote password-authenticated access to local RPMS server (options #2-3)
- For sites/programs not using RPMS, an alternative method of data exchange will be arranged with {NAME OF TRIBE}; for example, on-site face-to-face exchange to a designated staff member (options #2-3)
- Existing reports either from {NAME OF TRIBE} or from the Portland Area IHS Office (PAO) in accordance with PAO policies and procedures (option #4)

B. PERSONS HAVING ACCESS TO DATA
Data access shall be restricted to the minimum number of individuals necessary to achieve the purposes set forth in this Agreement, to be assigned by the Director of the EpiCenter. All persons who will have access to data must complete a data privacy training provided by NPAIHB. Prior to the transfer of any data, staff members and researchers who will have access to the data shall sign the Use and Disclosure of Client Information. Signed copies shall be provided to {NAME OF TRIBE} by request.

C. FREQUENCY OF DATA EXCHANGE
Data will be exchanged as needed to meet reporting requirements as well as on an ongoing basis between the EpiCenter and {NAME OF TRIBE} staff for the entire length of the project.

V. __SECURITY OF DATA__

Data access shall be restricted to a minimum number of individuals, and individual access shall be authorized by the Director of the EpiCenter. The EpiCenter shall establish an internal system to monitor the access of data by individual staff under this Agreement. All reasonable precautions shall be taken to secure the data from individuals who do not specifically have authorized access.

All reasonable efforts will be made to de-identify data, but we will retain a link to chart numbers in analytic data sets in order to resolve errors. Some data sets will by necessity contain direct identifiers (e.g., registration data listed in Section III, option #2 above), and these shall be stored as encrypted files with a separate level of access, as assigned by the EpiCenter Director.

All other data (options #1, 3-4 in Section III above) shall be kept on a password-protected file server located in a secure environment at NPAIHB. Data obtained under this agreement will be kept in a separate directory on the server which is also password-protected and will be accessible only by individual staff-members specifically authorized access as provided in this Agreement. The EpiCenter follows all other IHS security protocols.

VI. **CONFIDENTIALITY**

A. REGULATIONS COVERING CONFIDENTIALITY OF DATA
The use and disclosure of information obtained under this contract shall be subject to privacy and security regulations, including those in 42 CFR Part 476, HIPAA, and the HITECH Act. The EpiCenter shall maintain the confidentiality of any information which may, in any manner, identify individual patients.

B. NON-DISCLOSURE OF DATA
The EpiCenter staff shall not disclose, in whole or in part, the data described in this Agreement to any individual or agency not specifically authorized by this Agreement, except in aggregate without personal identifiers. Aggregate data also shall not be released where the cell size is less than 5, or where there is a reasonable possibility of an individual being identified by the release of the data.
Data shall be provided on a timely basis, subject to staffing. The EpiCenter will document uses and users of the data and will report this information upon request to {NAME OF TRIBE}.

VII. **PAYMENT**

No compensation will be required by either party.

VIII. **PROPERTY RIGHTS**

A. APPROVAL PROCESS FOR SPECIFIC DATA ACCESS AND USE
Data access and analyses undertaken by the EpiCenter shall be subject to approval by the specified Points of Contact (POCs) listed in the table

below, depending on the level aggregation, tribal identification, and intended audience for the report. Prior to granting permission, the POC is expected to follow all usual and customary practices for approval according to {NAME OF TRIBE}. Possible POCs include Clinic Director, Tribal Health Director, and Tribal Council (with attention to a specific individual and role). Alternately, for some analyses no additional permission may be deemed necessary. Appendix II presents an example table with POCs listed for the various types of data.

Approval requirements for EpiCenter-initiated data analyses			
Intended audience	**Type of data**	**Permission to access data POC**	**Permission to release report POC**
Clinic management	Local clinical outcomes and/or activities, survey results, etc.	Title: Name: Contact info:	Title: Name: Contact info:
Clinic staff	Same as previous	Title: Name: Contact info:	Title: Name: Contact info:
Tribal Council	Same as previous	Title: Name: Contact info:	Title: Name: Contact info:
General community	Same as previous	Title: Name: Contact info:	Title: Name: Contact info:
Local press	Same as previous; intended for instances when local programs are seeking publicity	Title: Name: Contact info:	Title: Name: Contact info:
Granting agency	Local outcomes – tribes named	Title: Name: Contact info:	Title: Name: Contact info:
	Local outcomes – tribes not named	Title:	Title:

Approval requirements for EpiCenter-initiated data analyses			
Intended audience	**Type of data**	**Permission to access data POC**	**Permission to release report POC**
		Name: Contact info:	Name: Contact info:
	Aggregate outcomes over several tribes—tribes named but not tied to specific outcomes	Title: Name: Contact info:	Title: Name: Contact info:
	Aggregate outcomes over several tribes—tribes not named	Title: Name: Contact info:	Title: Name: Contact info:
Conference or scientific publication	Local outcomes – tribes named	Title: Name: Contact info:	Title: Name: Contact info:
	Local outcomes – tribes not named	Title: Name: Contact info:	Title: Name: Contact info:
	Aggregate outcomes over several tribes—tribes named but not tied to specific outcomes	Title: Name: Contact info:	Title: Name: Contact info:
	Aggregate outcomes over several tribes—tribes not named	Title: Name: Contact info:	Title: Name: Contact info:
Any other audiences/data not covered in this table		Title: Name: Contact info:	Title: Name: Contact info:

B. DATA USE AND OWNERSHIP

Whenever tribe-specific data are reported with tribal approval, {NAME OF TRIBE} shall be cited as the source of the data in all tables, reports, presentations, and scientific papers, and the EpiCenter shall be cited as the source of interpretations, calculations, and/or manipulations of the data. The EpiCenter may use, reuse and analyze, for teaching and research purposes, the data and findings as reviewed by and approved by {NAME OF TRIBE}.

The EpiCenter agrees to provide copies of any research papers or reports prepared as a result of access to {NAME OF TRIBE} data under this Agreement, and to allow {NAME OF TRIBE} to reprint or distribute same without charge, to the extent permitted under copyright protection laws and any applicable agreements as to copyright or related intellectual property rights.

IX.   SEVERABILITY

If any provision of this Agreement or any provision of any document incorporated by reference shall be held invalid, such invalidity shall not affect the other provisions of this Agreement which can be given effect without the invalid provision, if such remainder conforms to the requirement of applicable law and the fundamental purpose of this Agreement, and to this end the provisions of this Agreement are declared to be severable.

X.   TERMINATION

Either party may terminate this Agreement upon 30 days prior written notification to the other party. If this Agreement is so terminated, the parties shall be liable only for performance rendered or costs incurred in accordance with the terms of this Agreement prior to the effective date of termination.

No data may be used by the EpiCenter after the termination of this Agreement.

XI.   WAIVER OF DEFAULT

Waiver of any default shall not be deemed to be a waiver of any subsequent default. Waiver of a breach of any provision of the Agreement shall not be deemed to be a waiver of any other or subsequent breach and shall not be construed to be a modification of the terms of the Agreement unless stated to be such in writing, signed by the EpiCenter Director and Executive Director of {NAME OF TRIBE}, and attached to the original Agreement.

XII.   RIGHT OF INSPECTION

The EpiCenter shall provide the right of access to its facilities at all reasonable times, in order to monitor and evaluate performance, compliance, and/or quality assurance under this Agreement on behalf of {NAME OF TRIBE}.

XII.   ALL WRITINGS CONTAINED HEREIN

This Agreement contains all the terms and conditions agreed upon by the parties. No other understandings, oral or otherwise, regarding the subject matter of this Agreement shall be deemed to exist or to bind any of the parties hereto.

IN WITNESS WHEREOF, the parties have executed this Agreement.

{NAME OF TRIBE}   Northwest Tribal Epidemiology Center
                                         Northwest Portland Area Indian Health
Board

_____   _____

DESIGNEE   Victoria Warren-Mears, Director

_____   _____

Date   Date

USE AND DISCLOSURE OF CLIENT INFORMATION

Staff with access to confidential client information are responsible for understanding rules for use and disclosure of the information. Outlined below are key elements for staff to remember:

A. CONFIDENTIALITY OF CLIENT DATA

1. Individually identifiable client data is confidential and is protected by various state and federal laws.

2. Confidential client information includes all personal information (e.g., name, birth date, social security number, diagnosis, treatment, etc.) which may, in any manner, identify the individual.

B. USE OF CLIENT DATA

1. Client data may be used only for purposes directly described in the data sharing agreement between X, Y, and Z

2. Any personal use of client information is strictly prohibited.

3. Access to data must be limited to those staff whose duties specifically require access to such data in the performance of their assigned duties.

C. DISCLOSURE OF INFORMATION

1. Identified client information may not be disclosed to other individuals or agencies.

2. Questions related to disclosure are to be directed to X.

3. Any disclosure of information contrary to 1 above is unauthorized and is subject to penalties identified in law.

Name:_____

Signature:_____ Date:_____

Date:_____

Approved By:_____

Executive Director, Tribal Organization

Signature:_____ Date:_____

Sample Confidentiality Pledge:

TRIBE X
CONFIDENTIALITY PLEDGE

All persons having access to the Epidemiology Study data must agree with and affix their signature to the following:

"I hereby swear or affirm to comply with the Northwest Tribal EpiCenter's and Tribal policies for data use and disclosure when working with *The Epidemiology Study*. I further agree to the following provisions:

- To obtain approval from the Portland Area IHS IRB and any other applicable review boards prior to conducting any research activity utilizing *Tribal data*;
- Not to use nor permit others to use data in any way other than for approved activities and statistical reporting and analysis for research purposes;
- To release no data or information that is identifying or which can lead to the identification of an individual or group of individuals;
- To only report data derived from *The Epidemiology Study* in aggregate, and not to report any statistics generated from data representing less than 5 individuals;
- To report to Portland Area IHS IRB any unapproved use or disclosure of data or information from *The Epidemiology Study*;
- To use appropriate safeguards to protect the confidentiality of the information contained within *The Epidemiology Study*, including password protection of desktop and laptop computers, file encryption, and ensuring permanent deletion of outdated files.

I will assure that all persons with approved access to *Tribal* data will sign appropriate confidentiality pledges."

Signature:_____

Date:_____

Supervisor Signature:_____

Date:_____

Annotated Bibliography

References cited in the paper are listed below, with abstracts or summaries of many publications.

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. (1978). D. P. N. O. 78-0012.

Brugge, D. and M. Missaghian (2006). "Protecting the Navajo People through tribal regulation of research." <u>Sci Eng Ethics</u> 12(3): 491-507.
>   This essay explores the process and issues related to community collaborative research that involves Native Americans generally, and specifically examines the Navajo Nation's efforts to regulate research within its jurisdiction. Researchers need to account for both the experience of Native Americans and their own preconceptions about Native Americans when conducting research about Native Americans. The Navajo Nation institutionalized an approach to protecting members of the nation when it took over Institutional Review Board (IRB) responsibilities from the US Indian Health Service (IHS) in 1996. While written regulations for the Navajo Nation IRB are not dissimilar, and in some ways are less detailed than those of the IHS IRB, in practice the Navajo Nation allows less flexibility. Primary examples of this include not allowing expedited review and requiring prepublication review of all manuscripts. Because of its broad mandate, the Navajo Nation IRB may also require review of some projects that would not normally be subject to IRB approval, including investigative journalism and secondary research about Navajo People that does not involve direct data collection from human subjects.

Bryan, R. T., R. M. Schaefer, et al. (2009). "Public health legal preparedness in Indian country." <u>Am J Public Health</u> 99(4): 607-14.
>   American Indian/Alaska Native tribal governments are sovereign entities with inherent authority to create laws and enact health regulations. Laws are an essential tool for ensuring effective public health responses to emerging threats. To analyze how tribal laws support public health practice in tribal communities, the authors reviewed tribal legal documentation available through online databases and talked with subject-matter experts in tribal public health law. Of the 70 tribal codes found, 14 (20%) had no clearly identifiable public health provisions. The public health-related statutes within the remaining codes were rarely well integrated or comprehensive. The findings provide an evidence base to help tribal leaders strengthen public health legal foundations in tribal communities.

Buchanan, D. R., F. G. Miller, et al. (2007). "Ethical issues in community-based participatory research: balancing rigorous research with community participation in community intervention studies." <u>Prog Community Health Partnersh</u> 1(2): 153-60.
>   PROBLEM: Concerns have been raised that community participation might compromise scientific rigor in community-based participatory research (CBPR). PURPOSE: The purpose of this paper is to identify potential sources of tension between the values of scientific rigor and community participation in CBPR. KEY POINTS: CBPR lies at the nexus of two major underlying ethical concerns--respect for community autonomy and the fair allocation of limited public

resources--which have generated considerable controversy about appropriate criteria for evaluating CBPR grant proposals. The complexity of evaluating CBPR proposals is compounded by the multiple purposes that it serves: (1) an ethical function of demonstrating respect for community autonomy; (2) a research method for eliciting ideas for interventions to improve population health; and (3) an intervention in itself, seeking to enhance the capacities of community participants. CONCLUSIONS: Growing use of CBPR raises two new ethical issues that deserve greater public attention: first, the problem of securing informed consent and demonstrating respect for community autonomy when the locus of research shifts from the individual to community level; and second, fair distribution of scarce public resources when practical constraints make the most rigorous research designs for assessing the effects of community interventions virtually impossible. In light of recent federal initiatives, it is critical to achieve a common understanding of appropriate ethical and scientific standards for assessing the merits of CBPR.

Burhansstipanov, L., L. Bemis, et al. (2005). "Sample genetic policy language for research conducted with native communities." J Cancer Educ 20(1 Suppl): 52-7.
BACKGROUND: [corrected] We have been repeatedly asked to clarify genetic issues that have cultural ramifications for Native communities. METHOD: In the following commentary, we explain selected genetic issues that may vary among tribal nations; nonetheless, scientists should allocate sufficient time to meet with the tribal leaders and/or members of the tribal institutional review board prior to designing a genetic study to learn how selected issues are perceived by that specific tribal nation. RESULTS: Tribal nations generally encourage and mandate community-based participatory research methodology. CONCLUSIONS: We have included in this commentary draft language for study protocols to support researchers and tribal nations when developing studies pertaining to genetic issues.

Burhansstipanov, L., L. T. Bemis, et al. (2002). "Native American recommendations for genetic research to be culturally respectful." Jurimetrics 42(2): 149-57.
This article describes genetic research issues and recommendations identified by inter-tribal Native American groups in meetings with tribal leaders from 1995 through 1999.

Burhansstipanov, L., S. Christopher, et al. (2005). "Lessons learned from community-based participatory research in Indian country." Cancer Control 12 Suppl 2: 70-6.
The purpose of this article is to share lessons learned from implementing community-based participatory research (CBPR) in Indian Country that may be generalizable to other medically underserved communities. CBPR is currently included in multiple grant announcements by the National Institute of Health and Centers for Disease Control and Prevention, but information about this methodology vs. traditional research methodology is often misleading. This article addresses some common mistakes made by academic research institutes by sharing what we have learned about how CBPR can be implemented in a respectful manner. The majority of tribal nations prefer, if not mandate, that CBPR be used in most proposed studies involving their communities today.

Caldwell, J. Y., J. D. Davis, et al. (2005). "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." <u>Am Indian Alsk Native Ment Health Res</u> 12(1): 1-21.

> This article describes the collective experience of a multidisciplinary network of researchers, practitioners, and program evaluators who support appropriate research and evaluation methods in working with Native peoples. Our experience underlines the critical importance of culture in understanding and conducting research with the diverse populations of American Indians and Alaska Natives, and documents the need for community-based, collaborative, participatory action research. We discuss the major findings of the first American Indian Research and Program Evaluation Methodology national symposium, and articulate a set of 20 guiding principles for conducting research and program evaluation.

Duran, B. and K. L. Walters (2004). "HIV/AIDS prevention in "Indian country": current practice, indigenist etiology models, and postcolonial approaches to change." <u>AIDS Educ Prev</u> 16(3): 187-201.

> Many tribal and urban American Indians and Alaska Native communities have initiated HIV/AIDS prevention and treatment services. The richness, depth, and scope of these efforts, however, are not well known and have not been sufficiently documented in the academic literature. In this article we assess the strengths and weakness of the published literature using the constructs of the socioecological framework. We discuss the need to apply an "indigenist" etiology paradigm to HIV/AIDS risk and protection. Finally, we define and discuss the varied postcolonial approaches to HIV/AIDS prevention, treatment, and healing.

Eyre, R. and R. Gauld (2003). "Community participation in a rural community health trust: the case of Lawrence, New Zealand." <u>Health Promot Int</u> 18(3): 189-97.

> Since the mid-1980s, the New Zealand health sector has been in a state of continual change. The most radical changes were in the early 1990s, with the creation of an internal market system for public health care delivery. Rural health services, seen to be unviable, were given the option of establishing themselves as 'community trusts', owning and running their own services. Community trusts have since become a feature of rural health care in New Zealand. An expectation was that community trusts would facilitate community participation. This article reports on a study of participation in a rural community health trust. The 'pentagram model' of Rifkin and coworkers, with its five dimensions of participation-needs assessment, leadership, resource mobilization, management and organization-was applied. High levels of participation were found across each of these dimensions. The research revealed additional dimensions that could be added to the framework, including 'sustainability of participation', 'equity in participation' and 'the dynamic socio-political context'. In this regard, it supports recent theoretical work by Laverack (2001) and Laverack and Wallerstein (2001). Finally, the article comments on the future of rural health trusts in the current round of health sector restructuring.

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Mail, P. D., S. Lachenmayr, et al. (2004). "Eliminating health disparities: focal points for advocacy and intervention." Am J Public Health 94(4): 519-20.

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        This book discusses, in a question-and-answer format, the powers of Indian tribes, civil and criminal jurisdiction on Indian reservations, Indian hunting, fishing, and water rights, taxation, the Indian Civil Rights Act, the Indian Child Welfare Act, and tribal jurisdiction over non-Indians. Also included are copies of the Indian Civil Rights Act, Public Law 83-280, The General Crimes Act, The Major Crimes Act, and the Federal statutory definition of "Indian country." The question-and-answer format is designed for use by the American Indian public, raising major issues and informing the nonspecialist of the basic law on a given subject. The author also makes an effort to note those parts of the law where change is taking place. Each chapter is followed by detailed footnotes.

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Sahota, P. (2007). Research Regulation in American Indian/Alaska Native Communities: Policy and Practice Considerations. Washington, DC, National Congress of American Indians Policy Research Center.
http://www.ncaiprc.org/files/Research%20Regulation%20in%20AI%20AN%20Communities%20-%20Policy%20and%20Practice.pdf

        This paper provides options for tribal leaders to consider regarding research regulation structures, including tribal IRBs, tribal community advisory boards, using established tribal committees, and other types of research review processes.

Sahota, P. (2010). Community-Based Participatory Research in American Indian and Alaska Native Communities. Washington, DC, National Congress of American Indians Policy Research Center. http://www.ncaiprc.org/files/CBPR%20Paper%20FINAL.pdf

        This paper provides an overview of community-based participatory research (CBPR) in American Indian/Alaska Native (AI/AN) communities. Five cases of exemplary CBPR conducted with AI/AN communities are presented, including studies on cancer screening, diabetes prevention, mental health, archaeology, and traditional Native fire practices.

Satter, D. E., A. Veiga-Ermert, et al. (2005). "Communicating respectfully with American Indian and Alaska natives: lessons from the California Health Interview Survey." J Cancer Educ 20(1): 49-51.

        Background. California is home to the largest number of American Indians in the United States, including large numbers of residents who are from tribes outside of the state, in addition to Alaska Natives. In 2000 to 2001, the California Health Interview Survey randomly surveyed, by telephone, approximately 54,122

households throughout the state, focusing on public health and access to health care. Methods. American Indian and Alaska Native cultural competency training materials were developed for the data collection interviewers. Unique cultural and linguistic issues identified were (1) reservation dialect English, (2) the long pause, (3) slow speaking, (4) "walking on words," and (5) a brief review of the importance of collecting tribal heritage information. Conclusions. Since the successful implementation of the competency training, several researchers, practitioners, state agencies, and others have requested and implemented the training materials in their work. In this article, we review the training materials. We hope that these few tips will help others have successful experiences communicating respectfully with American Indian and Alaska Natives.

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> This article articulates the theoretical construct of empowerment and its importance for health-enhancing strategies to reduce health disparities. Powerlessness is explored as a risk factor in the context of social determinants, such as poverty, discrimination, workplace hazards, and income inequities. Empowerment is presented and compared with social capital and community capacity as strategies to strengthen social protective factors. A case study of a youth empowerment and policy project in New Mexico illustrates the usefulness of empowerment strategies in both targeting social determinants, such as public policies which are detrimental to youth, and improving community capacities of youth to be advocates for social change. Challenges for future practice and research are articulated.

Wallerstein, N. and B. Duran "Community-based participatory research contributions to intervention research: the intersection of science and practice to improve health equity." Am J Public Health 100 Suppl 1: S40-6.

> Community-based participatory research (CBPR) has emerged in the last decades as a transformative research paradigm that bridges the gap between science and practice through community engagement and social action to increase health equity. CBPR expands the potential for the translational sciences to develop, implement, and disseminate effective interventions across diverse communities through strategies to redress power imbalances; facilitate mutual benefit among community and academic partners; and promote reciprocal knowledge translation, incorporating community theories into the research. We identify the barriers and challenges within the intervention and implementation sciences, discuss how CBPR can address these challenges, provide an illustrative research example, and discuss next steps to advance the translational science of CBPR.

Wallerstein, N. B. and B. Duran (2006). "Using community-based participatory research to address health disparities." Health Promot Pract 7(3): 312-23.

> Community-based participatory research (CBPR) has emerged in the past decades as an alternative research paradigm, which integrates education and social action to improve health and reduce health disparities. More than a set of research methods, CBPR is an orientation to research that focuses on relationships between academic and community partners, with principles of

colearning, mutual benefit, and long-term commitment and incorporates community theories, participation, and practices into the research efforts. As CBPR matures, tensions have become recognized that challenge the mutuality of the research relationship, including issues of power, privilege, participation, community consent, racial and/or ethnic discrimination, and the role of research in social change. This article focuses on these challenges as a dynamic and ever-changing context of the researcher-community relationship, provides examples of these paradoxes from work in tribal communities, discusses the evidence that CBPR reduces disparities, and recommends transforming the culture of academia to strengthen collaborative research relationships.