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## Comparing Tribal Research and Specimens Policies: Models, Practices, and Principles

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## **Abstract**

This article reviews a range of tribal policies regarding the proper solicitation, collection, disposition, and return or disposal of biological samples, or biospecimens, which include not only the sample itself but also data, such as genetic information, derived from the sample. These policies are not always found within tribal regulation, and many that exist emerge from a discrete set of models, such as from the American Indian Law Center (AILC), the Canadian Institutes of Health (CIHR), and the Indigenous Peoples Council on Biocolonialism (IPCB). Some policies merge language from these national models and conceptual papers with tribally specific foci, including incorporating tribal language for specific principles to guide research with that community and their biospecimens. The article concludes with recommendations for principles that emerge as paramount in the review for directing research involving biospecimens.

## **Keywords**

research protocols, biospecimens, tribal principles

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## Comparing Tribal Research and Specimens Policies: Models, Practices, and Principles

This article reviews a range of tribal policies regarding the proper solicitation, collection, disposition, and return or disposal of biological samples or biospecimens. This includes not only the samples and specimens themselves but also data (such as genetic information) that have been derived from them. These policies are not always found within tribal regulations, and many emerged from a discrete set of models. While many tribal communities do not yet have specific policies on biospecimen usage, related policies and scholarship are useful for gauging the overall attitude toward biospecimens in Indian Country (Radin & Kowal, 2015). Thinking beyond the U.S., additional models and practices are useful for demonstrating not only the present approach but also additional forward-looking approaches to developing relevant policies that center Indigenous sovereignty (Beaton et al., 2017; Cunningham & Dunbar, 2007; Kowal, Greenwood, & McWhirter, 2015). This article reviews relevant policies, models, and practices from the U.S., Canada, and other countries across the world in order to highlight commonalities between different approaches and challenges to developing policy related to biological samples and biospecimens. By situating reviews alongside current scholarship on biological samples and biospecimens, this article seeks to inform potential best practices created from the cutting instead of the lagging edge of research and policy.

As research regulations have increased and achieved federal assurance and as specific policies governing biospecimens have been created, many guidelines have adopted the language found in the following codes and guidelines:

- *The Model Tribal Research Code* (now in its 3<sup>rd</sup> edition; the American Indian Law Center, Inc., 1999),
- The Indian Health Service (IHS) Guidelines for Implementing and Complying with HIS Policy on Specimens (Freeman, 2001),
- The Canadian Institutes of Health Research (CIHR, 2007) *Guidelines for Health Research Involving Aboriginal People*, and
- The Indigenous People's Council on Biocolonialism (IPCB, 2000) *Indigenous Research Protection Act*.

This review notes where some tribal policies can be extended regarding principles or return, for example, to provide information about what to do with remaining specimens in labs. Moreover, this review notes how research and sampling practices can be revised to address not only the collection and processing of biological samples and data but also issues surrounding consultation, ownership, and reciprocity. For a full comparison of protocols, see the Appendix.

Tribal research regulatory codes emerged prior to the establishment of tribal institutional review boards (IRBs) to protect traditional knowledges and guard against archeological research that communities may not invite, want, or find beneficial. In particular, these tribal research regulatory codes help to both guard against researchers taking tribal individuals' remains and, if remains have been taken, establish channels for their proper return through ceremonies. Historically, the bodies of deceased Indigenous persons have been disinterred from their resting places and "collected" by ethnologists, archaeologists, and others who saw financial value in them (Kowal, 2013). In the present, Indigenous Peoples' bodies have become sites of resource extraction insofar as the study of their genetic and biological materials is

touted as “beneficial to humankind.” These studies, however, rarely offer tangible benefits to those from whom specimens are taken (Mello & Wolf, 2010; Tsosie, 2007). Protections have emerged because of reactions to the encroachment on Indigenous Peoples’ bodies and lands; notably, these measures contain many of the same principles (and at least one of the same protocols) that have informed environmental protections as well as protections for human bodies and data derived from them. American Indian tribes created these codes both before and after the Native American Graves Protection and Repatriation Act of 1990 (NAGPRA) following generations of excavations done in the name of research and profit (Salzano & Hurtado, 2004). One limitation of these codes, which the NAGPRA sought to address, has been their enforceability outside of tribal land holdings. Broadly, however, these codes help us to consider how tribes have thought of “human subjects” who provide “specimens” as both living and non-living humans; moreover, these codes provide useful inferences regarding Indigenous communities’ preferred methods for the treatment, disposal, and/or return of samples in cases where specific research codes or policies are not available.

For example, the 1992 Cherokee Code stated, “the remains of Cherokee people shall not be subjected to destructive skeletal analysis” (Eastern Band of Cherokee Indians, 1992, Section 70-2c). This demonstrates that the technology used to date bone remains and obtain genetic material, which would destroy the remains themselves, is contrary to the explicitly stated preference of the Cherokee that remains be neither disturbed nor destroyed. Furthermore, it noted that remains should be reburied. The Cherokee Code also stated that any researcher permitted to perform a study on tribal lands or with tribal peoples should provide the tribe “a copy of all collected data, completed reports or publications, including copies of audio or video tapes or recordings obtained in the course of such study or research” and that “all such data . . . shall be deposited for permanent storage with the Museum of the Cherokee Indian” (Eastern Band of Cherokee Indians, 1992, Sections 70-3c-70-3d). This last point shows the importance of tribal governance over data created through research, particularly research involving human bodies (both “alive” and “remains”)—this is widely referred to as data sovereignty and has been evident in efforts undertaken by the National Congress of American Indians (Sahota, 2007), the Native Nations Institute (2016), and Te Mana Raraunga (2015). The 1992 Cherokee Code is both of its time and ahead of it. It highlights, for example, that both samples and the data derived from those samples should be dealt with according to both tribal preferences and reciprocal relationships between researchers and the tribe. The code is also useful for thinking about how tribal communities, either alone or collectively, may create biobanks and other large data repositories similar to the Alaska Area Specimen Bank, which will be discussed below (Hiratsuka, Brown, Hoefft, & Dillard, 2012; Hoeyer, 2008).

The Cherokee Code is also helpful for considering cases wherein samples have been obtained but there are neither living donors available to provide re-consent for the continuing use of the samples, processes for obtaining re-consent from the relations of the person from whom the samples were taken, nor processes or policies regarding the use of samples from a person who cannot be identified. There is relative consensus among graves protection and repatriation policies and legislation that remains should be returned to tribal nations for reburial. Similarly, when donors cannot be identified, or when detailed consent regarding how to care for samples (e.g., body parts with cultural significance, such as placenta) can be obtained beforehand, the Māori people of Aotearoa (New Zealand) have set precedent for the respectful disposal of specimens obtained through both research and the health system (Cunningham et al., 2007; Hoeyer & Hogle, 2014). For a sample to be taken, the Māori code requires consent, which asks

the participant, whether Māori or Pākehā (settlers), if s/he would like the sample returned (with the option of a particular blessing (known as *karakia*), disposed of, and/or used for future research. These guidelines have been shown to be effective in addressing the needs of this diverse group of Indigenous people. They may therefore provide useful methods to work with the diversity of thoughts, cultures, practices, languages, and approaches among American Indian and Alaska Native peoples in the U.S., as well as the diverse Indigenous Peoples in relationship with other settler colonial nation states around the world (Beaton et al 2017; Compton 2010).

### National Models and Theories

#### **American Indian Law Center (1999) *Model Tribal Research Code*, 3<sup>rd</sup> Edition**

The American Indian Law Center (1999) Model Tribal Research Code (MTRC) does not offer a prescriptive policy for tribes who are interested in establishing their own research codes; instead, it has provided historical information that explains why tribal research regulation is necessary. It included sections to guide tribes in creating their own protection codes by using questions and engaging with tribal leaders in ways that allow them to answer as they feel is appropriate, including defining important terms for the code. The research aims and methods should be stated explicitly. In addition, the code prompts the user to define “terms whose meaning might not be obvious to the community, to individual tribal members, or to researchers” (p. 20); this statement, in its attention to language, highlights the importance of transparency for all stakeholders, which emerged as an important principle in the tribe-specific protocols. One section of the MTRC explored the question, “Who will own specimens—human biological material—from the research” (p. 21)? In response, the code stated the protocol should provide assurances of confidentiality to participants, families, communities, and the tribe itself as necessary and appropriate. The statement also highlights the importance of determining who will own data produced by research. The MTRC do not provide answers to the questions posed, rather the questions are to be answered by tribes and communities. In approaching the issue in this way, the MTRC has invited necessary conversation regarding data and specimen ownership related to research with Indigenous communities. Another section of the MTRC offered a checklist that Indian Health Boards might use for contexts regarding “ownership and control of human biological material from . . . research” (p. 26). The checklist is noted as being of use to Indian Health Boards, it could be useful for IRBs and other regulatory bodies as well. The MTRC checklist queried: “How will the tribe’s interest in its cultural and community heritage for its future generations be protected” (p. 26)? The importance of protection is evident in the MTRC, and it indicates the necessity of considering what protection might look like from diverse, tribally specific perspectives—as opposed to those of researchers.

#### **Indigenous Peoples Council on Biocolonialism (IPCB, 2000) Indigenous Research Protection Act (IRPA)**

Following on the third edition of the MTRC, the Indigenous Peoples Council on Biocolonialism (IPCB, 2000) issued a model entitled the Indigenous Research Protection Act (IRPA), which actively engaged with concerns about specimens and samples taken for research. The Act provided normative responses outlining what tribes should do to protect themselves, while the MTRC and the National Congress of American Indians (NCAI; in their training for creating tribal regulation discussed below) offer questions to help tribal leaders formulate their own responses. The IRPA is one of the first models that has

provided a general response to Indigenous research regulation around biospecimens, which it defines in relation to “Traditional Indigenous Intellectual Property” (IRPA, 2000, Section 3.14). It bears a striking, though more legally based, similarity to the question posed by the MTRC regarding ownership and control of human biological material. The IRPA (2000) has defined “biogenetic resources that originate (or originated) on Indigenous lands and territories,” as well as “tissues, cells, biogenetic molecules including DNA, RNA, and proteins, and all other substances originating in the bodies of tribal members, in addition to genetic and other information derived therefrom” (Sections 3.14j-k), as particular forms of tribal Indigenous intellectual property that require explicit protection.

The IRPA (2000) noted that its guiding principles are: “Fully Informed Consent after Full Disclosure and Consultation,” “Immediate Risks and Benefits to Tribal Community,” “Confidentiality,” “Respect,” “Communication,” “Empowerment,” “Equity,” “Mutual Respect,” “Prior Rights,” “Self-Determination,” “Inalienability,” and “Traditional Guardianship” (Section 5). These principles are positioned centrally, which indicate that they can be used as a guide in making decisions in the face of new technologies or other changes in the research relationship. Respect is listed twice—once with reference to individuals and communities and again with reference to the mutual respect between researchers and Indigenous Peoples that is central to successful and robust science. In some instances, other principles are stated subtly or can be inferred from other principles. For example, the references to equity and empowerment also remind researchers and research participants that this relationship is reciprocal. In several instances, communication (and transparency) is embedded in codes regarding the return of results and samples to the community. However, the code also places emphasis on the importance of using the “local language” (Section 5.1e), which is itself a good research practice (see also Akwesasne Task Force on the Environment (ATFE, 1996).

With respect to biospecimens, IRPA (2000) emphasized specific limited consent for projects—i.e., consent that is free, prior, and informed—and the retention of intellectual property rights (pp. 14-15). IRPA’s ownership argument owes its language to the ATFE (1996; reviewed below). Considering the limited success of property arguments regarding biospecimens (see Lewis, 2013), this wording allows tribes both to choose “to require the deposit of raw materials and data, working papers or product” into repositories of their choice as well as for “duplicates of data or split samples . . . [to] be stored in such a local archive” (IRPA, 2000, Section 6.2m) during the course of research projects. Another of IRPA’s (2000) recommendations concerned the ability of tribes to elect to withdraw from a project and receive a full and complete return of all biological samples at the conclusion of a project. In addition, this recommendation concerned protections against the secondary use of biological samples without the tribe’s consent, expressly disallowing the patenting and commercialization of products based on the biospecimens.

### **Canadian Institutes of Health Research (CIHR, 2007) *Guidelines for Health Research Involving Aboriginal People* and Arbour and Cook (2006)**

In the Canadian Institutes of Health Research (CIHR, 2007) Aboriginal research ethics guidelines and an accompanying academic paper by Laura Arbour and Doris Cook (2006) have taken a different approach to the question of ownership vis-à-vis biological specimens. Arbour and Cook (2006) advanced the concept of “DNA on loan,” a model whereby DNA (both in sample and data derived therefrom) obtained through research is only loaned to researchers by participants. This concept is

different from U.S. legal approaches to biological specimens, which typically presume that a sample given (or taken) is a gift or donation. The principles of respect and reciprocity are central to Arbour and Cook's "DNA on loan" premise. As "stewards," researchers must care for samples and data with respect to ensure the integrity of samples and data. When researchers are not owners but rather custodians of samples and derivative information, certain abuses (such as patenting, reuse or secondary use without consent, improper storage, and/or destruction) are not as likely. Furthermore, under the DNA on loan model, researchers enter a reciprocal relationship with samples or data, since participants can withdraw from studies at any time and cancel the loan. As a result, researchers must consult with participants and/or return to communities to obtain re-consent if they wish to continue using samples or data. For many participants involved in research, the reciprocity they desire is simply to know what happened with their samples—that is, the results of research—and the DNA on loan premise enables and encourages this transparent sharing of information.

The CIHR (2007) Aboriginal research ethics guidelines have noted, "Co-ownership of data between researchers and communities is recommended because the Aboriginal community and the researcher are both integral to the production of data (pre and post-analysis), subject to the community's views on traditional or sacred knowledge" (p. 26). The guidelines have suggested that secondary research only happen with community consent (if samples are rendered anonymous), individual re-consent (if samples can be linked to identity), and/or through the use of a research review committee. This precondition not only stymies sample and data misuse, but it also promotes best practices in consent and participation insofar as Aboriginal (or American Indian) communities must be involved with and consulted about the research process. The CIHR guidelines also prohibit the transfer of samples to third parties, even for testing related to consented research, unless such transfer has been explicitly stated in the statement of consent itself. Importantly, the CIHR guidelines shifted responsibility regarding awareness of community policies and protocols away from research participants and to researchers. In doing this, the CIHR guidelines have offered a different way to think about "human subjects protection" as an issue that does not refer to whole bodies alone, but also the disaggregated parts of the human body that become samples and specimens.

The CIHR (2007) guidelines have emphasized that "for existing tissue banks, a series of consultations with Aboriginal stakeholders should be held to determine under what circumstances the samples can be used for future research" (p. 28). This indicates that many peoples may be willing to consent to continued research, but ultimately participation is the communities' decision, and all research should abide by the best practices concerning consultation and reciprocity.

**National Congress of American Indians (NCAI) *Research Regulation in American Indian/Alaska Native Communities: Policy and Practice Considerations* (Sahota, 2007)**

Written for the Policy Research Center (PRC) of the NCAI, Sahota (2007) demonstrated that the foundation for all research interactions with American Indian and Alaska Native (AI/AN) communities is based on the Belmont Report principles of respect for autonomy, beneficence, and justice, but emphasized that these principles must be applied to both the individual participants and the communities themselves. The Belmont Report (Department of Health, Education, and Welfare, 1979) highlighted the importance of data sharing considerations and emphasized that existing policy may allow AI/AN data to be made publicly available if protections are not in place at the beginning of research

projects. In the related *IHS Guidelines for Implementing and Complying with IHS Policy on Specimens*, Freeman (2001) clarified that “specimens for which IHS was or is involved in collection or storage are not anonymous for community because they are known to be from AI/AN people, with the group of Tribes also known” (p. 5). Freeman also noted that specimens can only be anonymous for individuals, and anonymous individual samples may still harm the community if it can be identified as the source. This attention to extending the Belmont Report principles to communities is necessary for tribes, but, arguably, it is useful for other communities as well.

Sahota (2007) reviewed how tribes or groups thereof may set up or partner with institutions to create IRBs, highlighting the importance of communication and tribal oversight. Likewise, Harding et al. (2012) reviewed the importance of data sharing and other agreements between communities, as a negotiated mutually respectful process that can produce the best outcomes for science and communities. In the creation of research policy and the development of model volunteer consent documents, Freeman (2000, 2007) emphasized language and how it helps one to translate and reconsider concepts, even if in non-technical English (or a version of English that is used as the “local language”) as opposed to an Indigenous language.

Sahota (2014), in a later study involving interviews with a small sample of participants from one tribal community, demonstrated the diversity of attitudes regarding biospecimens. The interviews with tribal members and leaders showed that it is important for communities to have guidelines for biospecimen disposal that include a range of options, such as returning samples to individuals, returning samples to community representatives, and/or clinical methods of disposing samples. Participants also suggested blessing the laboratory where handling and storage would occur in order to offer a culturally appropriate form of protection over the information and the piece of the participant. In the sample, most participants affirmed that they would want a sample destroyed after the study had finished. Many participants also expressed an inalienable connection between themselves and samples or specimens, which directly relates to the IRPA’s principle of respecting and upholding inalienability between participants and their specimens. Regarding the disposal of specimens following death, participants in Sahota’s (2014) study expressed different opinions about what constituted best practices. These opinions were tied to “how they understood traditions around both death and property” (p. 26). Most interviewees said “specimens should be used after death” (p. 26); however, the majority of those who said specimens should be used after death described themselves as traditional and felt that specimens should be cared for as other possessions of a deceased person (through burning or burial, for example).

This diversity of opinion regarding the disposal of specimens within and between communities is also evident in the Māori model (Cunningham et al., 2007). One advantage the Māori do have is a single language and recognition of their rights within the central governing document of the settler state. In related work in South Africa, Moodley, Sibanda, February, and Rossouw (2014) found that participants were concerned with the export of their specimens for secondary uses, the importance of re-consent for additional research, and benefit sharing between participants and researchers. They also reported diverse attitudes about participation in research and preferences for obtaining and using samples.



## **Alaska Area Specimen Bank (AASB)**

The Alaska Area Specimen Bank (AASB) is unique example of how to bridge multiple communities, languages, and ways of thinking. The AASB was created to help address the issue of biospecimens (largely AN) amassed from the healthcare system, and it focused on their maintenance, use, disposal, and return. These archival samples highlight the lack of informed consent typically given for secondary use of samples. With this in mind, Bathe and McGuire (2009) have proposed a framework for the secondary use of tissues in the AASB. The AASB has set up a formal network, which includes a community representative committee, to review proposals for research involving the samples. Proposal approval is required before specimens can be accessed. The network works with the larger governing structure of the bank to manage new deposits, withdrawals, and loans of samples and data.

Parkinson, Hennessey, Bulkow, Smith, and the Alaska Area Specimen Bank Working Group (2013) have similarly laid out a framework regarding access to specimens. Their framework has emphasized that new deposits must include informed consent and offer three options to participants:

- a. Storage of specimens with identifying information;
- b. Participation in current but not future projects (no deposit, only exchange of “currency”); and
- c. If foreseen, consent for secondary use of deposit, which may contain particular restrictions.

Central to AASB’s operation is the notion that ownership of specimens remains with participants, and that all resources in the AASB should “be used to benefit the health and well-being of the Alaska Native people” (p. 3).

Ongoing discussion is occurring around “the use of specimens from deceased persons” and other collections of human biological materials (Parkinson et al., 2013, Discussion section, para. 2). Hiratsuka et al. (2012) have noted, for example, that AN participants considered proper respect for participants to be of paramount importance; respect should be shown through appropriate care of samples; communication about dates of destruction; and respectful, non-cavalier destruction of samples.

## **Indigenous Nation-Specific Policies in U.S. Context**

### ***Navajo Nation Human Research Code (NNHRC; Navajo Nation, 1994) and Genetic Moratorium (Navajo Nation Council, 2002)***

The Navajo Nation Human Research Code (NNHRC; Navajo Nation, 1994) and Genetic Moratorium (Navajo Nation Council, 2002) have demonstrated a different approach towards research regulation and biospecimen use in Indian Country. The Navajo Nation (1994) noted in the NNHRC that research involving human subjects should be “beneficial, community-based, and consistent with the Navajo Nation priority and concerns” (p. 295). Importantly, the last part of this clause emphasizes the importance of mutual respect and community consultation for all research involving human subjects. Furthermore, the NNHRC expressly noted, “all data and research subject to this Code are the property of the Navajo Nation” (p. 296); the NNHRC also referred to the need to assure protection of data, thus implying that, even when samples are stored at another facility, they remain the property of the Navajo Nation. The NNHRC also highlighted the importance of both individual and national informed

consent, as well as the importance of the Navajo Nation reviewing manuscripts resulting from research with their people.

The Navajo Nation has subsequently established the Navajo Nation Data Resource Center whose research timeline lists the deposit of information derived from studies as its last step. In 2002, the Navajo Nation (Navajo Nation Council, 2002) issued a moratorium on genetic testing, which has limited but not halted the collection of biological specimens (including by the IHS) for purposes other than research. Given this moratorium, no secondary uses of samples would be permitted, and samples would be returned to the Navajo Nation or disposed of (with respect and possibly ceremony) after their use for research.

### **Akwesasne Task Force on the Environment (ATFE, 1996) *Protocol for Review of Environmental and Scientific Research Proposals (PRESRP)***

This ATFE's forward looking *Protocol for Review of Environmental and Scientific Research Proposals (PRESRP)* was not driven by the Belmont Principles, but rather by the community principles of *skennen* (peace), *kariwio* (good word), and *kasestensera* (strength). These community principles are all intended to support the goals of justice and unity. Coming from the Mohawk Nation community of Akwesasne, which has long been a leader in thinking about issues of concern to their community and Indian Country more broadly, the PRESRP emphasized respect, equity, and empowerment. While there is some overlap with the Belmont Principles, the Akwesasne principles center the interactions between researchers and participant communities as one characterized by reciprocity instead of simply protection. The PRESRP defined research as including "biogenetic" studies, a term that is similar to the language used in the MTRC and other codes.

In addition, the PRESRP included important safeguards regarding confidentiality, which permits the release of aggregate data only and allows data sharing only in accordance with community requirements. The PRESRP used the language of "fair and appropriate return" (ATFE, 1996, Equity section, para. 1) in combination with a data ownership statement, mirroring the IPCB's, to affirm that the community maintains rights to all samples and their disposal, intellectual property, and any data derived from samples.

The principles guiding the PRESRP suggest that the proper way to deal with samples from this community is to respectfully return them and, if they are not returnable, to respectfully destroy them. In either case, however, any data or information derived from the samples, as well as any papers or products created as a result of research using the samples, should be shared with the community.

### **Ho-Chunk Nation (2005) *Ho-Chunk Nation Code (HCNC)***

The Ho-Chunk Nation (Wisconsin) Code (HCNC) has offered explicit guidelines about the use and disposal of specimens in research, and it contains a broader definition of "human subject" than many federal IRBs. The HCNC defined "human subject" as:

[A] living or nonliving individual (including human remains) about whom a researcher (whether professional or student) conducting research obtains information or data through intervention or interaction with the individual, involving physical procedures by which data are

gathered (for example, blood draws) and/or manipulations of the subject or the subject's environment. (Ho-Chunk Nation, 2005, p. 4)

This definition extends past the typical bounds of human subject safeguards to protect remains (that may be unearthed) and the recently deceased. The HCNC also included a clarification for researchers, which includes students, that explicitly states acceptable or desirable methods for the clinical or biomedical sciences and psychological or educational research. "Specimens" in this code includes all "tangible and intangible data" (Ho-Chunk Nation, 2005, p. 4), which means that everything from data from computer codes to biological samples are to be treated similarly by researchers. The HCNC requires the completion of an application for the collection of specimens or data; this application must specify:

- How the specimens will be donated;
- How researchers plan to dispose of both specimens and derived data at the conclusion of the project;
- Any contemplated secondary research; and
- Informed consent procedures regarding the proposed study, saving of specimens, and future uses of specimens.

However, the HCNC only requires information to be presented; it does not dictate the answers. The HCNC has explicitly stated that research participants own their specimens, and thus current and future uses of specimens "must be disclosed and agreed to by the researcher and IRB prior to a [research] permit being issued" (Ho-Chunk Nation, 2005, p. 6).

### **Pascua Yaqui Tribal Council (2008) *Regulatory Code***

The principles highlighted by the Pascua Yaqui *Regulatory Code* include mutual respect, equity, empowerment, and working towards collaborative relationships (following the ATFE model). The principles that guide the review of research include those from the IPCB model. The language of the IPCB is used when the Pascua Yaqui regulatory code describes the regulation of biological samples (Pascua Yaqui Tribal Council, 2008, Section 170). The code has defined "biological samples" in a manner that was later mirrored by the Tohono O'odham, whereby ownership of samples remains with the tribe; this suggests that the proper disposal of samples would necessarily involve their return to the tribe.

### **Colorado River Indian Tribes (CRIT, 2009) *Human and Cultural Research Code***

The CRIT (2009) code focused on "protection of the CRIT property . . . such as blood and tissue samples" (p. 1), and it included provisions for obtaining informed consent from both living and non-living humans, with informed consent routed through non-living humans' heirs or relatives. The CRIT code asserted ownership of intellectual property generated from research and data. Although the code offers no specific provision or regulation regarding biological samples, future uses of samples would likely require either subsequent consent through the identification of donors or their heirs, or returning or disposing of the sample.

### **Fort Peck Tribes (2013) *Research Code of Ethics and Policy—Assiniboine and Sioux Research and Policies***

The tribes located on the Fort Peck Reservation in Montana have created a joint policy, which demonstrates the bridging of two Native American cultures in order to reach a consensus (as other models and the IHS Guidelines have also done). This code is linked to Fort Peck Community College, thereby bringing researchers into contact with the tribal people of the area. The code has noted, for example, “researchers and learners [must] accept a responsibility to share and practice the knowledge [given to them] in a manner consistent with its original use and teachings” (Fort Peck Tribes, 2013, p. 4).

Regarding specimens, the code stated, “the data collected . . . will be secured and owned by the people” (Fort Peck Tribes, 2013, p. 4). This provision may not be entirely feasible for a study involving biospecimens, insofar as there may be a need to build such capacity among communities and how such capacity can be tied to larger institutions is a question that the code does not address.

The code has noted that “free and informed consent” is necessary for research involving biospecimens, and it emphasizes that “the research project must make available support services for participants, including ceremony and counselling, that may be needed” (Fort Peck Tribes, 2013, p. 6). In line with the Māori guidelines, this point also relates to respectful, culturally appropriate storing and disposal of specimens. Given the background information contained in the code, the statement of “trust and respect as essential elements of the [research] relationship” (p. 1), and the implicit importance placed on transparency, the inference would be that all samples and their data would be returned to the community. The community would retain ownership over the information and any publications, but the details of research relationship would be negotiated with researchers.

### **Tohono O’odham Legislative Branch (2013) *Chapter 8—Research Code***

The Tohono O’odham Research Code (TORC) has defined biological samples inclusively, so that they include not only human subjects (living and nonliving), but also “microorganisms, bacteria, plant, animal, or any human biological materials, genetic samples, any copies of the original genetic samples, any cell lines containing copies of the original genetic samples, and data derived from those samples” (Tohono O’odham Legislative Branch, 2013, Section 8101). This is the most inclusive definition of biological samples among those in policies reviewed in this article. The emphasis on benefits to communities mirrors that of the HCNC. It includes requirements for protecting ownership of samples, data, and work products of the research, as well as specimens. Importantly, the TORC has noted the importance of both transparent communication and the use of the local language of O’odham, and it requires research to be explained in both O’odham and English. Per the TORC, future uses of biological samples must be disclosed before the initial collection of samples. The TORC’s regulation of biological samples section comes from the IPCB’s model, which necessitates appropriate return, prohibits sharing, and prohibits patenting or commercialization of samples.

## **Indigenous Nation-Specific Policies in Canadian Context**

The Canadian protocols reviewed below have been organized by region.

**Manitoulin First Nations *Guidelines for Ethical Aboriginal Research* (Aboriginal Health Research Review Committee [AHRC] & Manitoulin First Nations, 2003)—Ontario**

The Manitoulin First Nations *Guidelines for Ethical Aboriginal Research* has offered an innovative approach that resembles the ATFE insofar as both emphasize traditional teachings and the range of possibilities for engagement with research. The “seven grandfather teachings of respect, wisdom, love, honesty, humility, bravery, and truth” (AHRC & Manitoulin First Nations, 2003, p. 8) inform the guidelines. The guidelines emphasized:

- “Research should be owned by the local First Nations communities and organizations” (p. 7);
- Research should provide benefits, including capacity building and the production of documents useful to the communities; and
- Research should center respect for diversity within the community, for community ownership of data, and for Aboriginal knowledge and culture (p. 7).

The guidelines pull from the Tri-Council Policy Statement, the principles of respect for human dignity, respect for free and informed consent, respect for vulnerable persons, respect for privacy and confidentiality, respect for justice and inclusiveness, balancing harms and benefits, minimizing harm, and maximizing benefit. Regarding biological specimens, the guidelines have noted that ownership remains with the communities through intellectual property rights and other means. The guidelines also noted that values of the academic community, which include “openness, sharing of ideas, and scholarly activity” with the goals of “increas[ing] and disseminat[ing] knowledge” (p. 21) may or may not be commensurate with the values and goals of participant communities.

**Six Nations Council of the Grand River Territory (2014) *Conducting Research at Six Nations* — Ontario**

This code takes “mutual respect, understanding and trust” as its guiding principles (Six Nations Council of the Grand River Territory, 2014, Preamble section, para. 1). The reuse of data (and therefore samples from which that data was derived) is expressly prohibited without authorization from the research ethics committee. Communication through local media channels is emphasized as part of the research relationship, but the code’s section on storage and ownership does not expressly address biological samples; instead, it is focused on research products. However, the earlier prohibition on reuse of samples would require the researcher to store the samples until a mutually agreeable project is proposed and approved.

**Tl’azt’en Nation Chief and Council (1998) *Tl’azt’en Nation Guidelines for Research in Tl’azt’en Territory*—B.C.**

The Tl’azt’en Nation Guidelines (TNG) promoted respect (as opposed to protection) in research interactions, and prominently emphasized the diversity within their nation (Tl’azt’en Nation Chief and Council, 1998). This diversity is evident in other codes as well. This approach attends to different viewpoints and perspectives, but also to differing relations to norms, standards, and classifications, which encourages researcher to move beyond the classic categories and instead, in collaboration with the

community, create the best categories answer the questions of the community. Communication and the use of Dakalh, the Tl'azt'en language, are also emphasized by the TNG. The TNG noted that both individual and group consent are needed for projects. The community must be consulted regarding the design, implementation, and interpretation of the research. In addition, copies of the final report are to be made available to members of the community in cases where there are no conflicts in terms of privacy and confidentiality. Moreover, this information is to be made available in both Dakalh and English. The TNG has noted that commercialization can only benefit the people, and that local capacity building should be a part of research. While there is no explicit mention of biospecimens, the code suggests that traditional heritage is protected through the return of samples and data to the community.

**Nuu-chah-nulth Tribal Council Research Ethics Committee (2008) *Protocols & Principles for Conducting Research in a Nuu-chah-nulth Context*—B.C.**

The Nuu-chah-nulth have experienced ethical breaches in their relationships with researchers; as such, their code has called for protection and partnership in research, and includes a unique caveat regarding research participation or refusal (Nuu-chah-nulth Tribal Council Research Ethics Committee (2008)). Under the Nuu-chah-nulth's code, participants have a 24-hour minimum timeframe to consider the research before deciding to participate. The code emphasized that the community should benefit from the research, risks related to participation should be minimized, research data should be disseminated to participants and communities, and the community retains partial ownership of data. The principles governing this code break down the Belmont Principles: autonomy and protection as part of respect for persons; non-maleficence and maximum benefit and minimum risk as part of beneficence; and equality, equity, and fairness as part of justice. While this code does not, surprisingly, include reference to biospecimens, its principles and the Nuu-chah-nulth's historical relationship with researchers suggest that the community would require re-consent for future uses of samples, the respectful return of samples to communities, and/or the respectful disposal of samples in cases where future use and return are not possible.

**Mi'kmaw Ethics Watch (1999) *Mi'kmaw Research Principles and Protocols*—Nova Scotia**

The Mi'kmaw Ethics Watch (1999) code highlighted the importance of the Mi'kmaw language by using it at the beginning of the document. Throughout, the code has addressed how researchers and communities can be beneficial to one another. While this benefit is generally in terms knowledge, it is possible to infer biospecimens are included in the statement, "all research, study, or inquiry . . . belongs to the community and must be returned to that community" (Mi'kmaw Ethics Watch, 1999, p. 2). The code also emphasized the importance of "a negotiated partnership" which places participants as "equals in the research" (p. 3). The code emphasized the return of information, capacity building, and community consultation during the interpretation of data. Like the NNHRC, this code has expressly noted, "any research involving collection of human genes, Mi'kmaw genetic material, or involving the Human Genome Diversity Project shall be rejected or considered only as to its benefits to the Mi'kmaq people" (p. 4). This supports the contention that biospecimens should be returned to the community after their use and that very limited uses of those samples would be deemed acceptable.

### **Métis Centre at National Aboriginal Health Organization (2010-2011) *Principles of Ethical Métis Research***

This report proposed principles for ethical research involving Métis peoples, but does not indicate any specific policies for biospecimen usage. Indeed, it does not indicate or outline any specific policies at all. The principles highlighted are:

- Reciprocal relationships;
- Respect for . . . (a variety of such as individual and collective rights);
- Safe and inclusive environments;
- Recognize diversity;
- Research should . . . (normative statements regarding benefits, relevancy, and standards); and
- Métis context.

These principles, like those in other codes, are centered on diversity within tribal nations, which means that there is no single correct approach to research questions. Without clear policies, it is not possible to know how the Métis Centre at the National Aboriginal Health Organization would regulate the obtainment, use, return, and disposal of biospecimens. What is apparent from this code is that anything done to biospecimens should be respectful, and that communities should be consulted and informed about potential actions regarding biospecimens.

### **The Inuit Tapiriit Kanatami and Nunavut Research Institute (2007) *Negotiating Research Relationships with Inuit Communities: A Guide for Researchers—Nunavut***

The Inuit Tapiriit Kanatami and Nunavut Research Institute's (2007) guide for researchers is informed by the principles of honesty, humility, informed perspective, openness (including to new things), patience, willingness to learn, local capacity building (including supporting the local economy), communication, respect, and use of the local language. The guide specifies that control of data has to be addressed in negotiating the research relationship but no set policy is given. The guide implies that a properly negotiated research relationship will result in a reciprocal agreement developed between researchers and participants—as opposed to relying on prescribed policies for each aspect of research.

### **Additional Indigenous Policies in Other Settler-Colonial Contexts**

#### **Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS, 2012) *Guidelines for Ethical Research in Australian Indigenous Studies—Australia***

While the AIATSIS (2012) guidelines make little reference to biological specimens, it has presented a number of important principles, related to things such as the transformation of samples into data, that are related to samples and specimens. The 14 principles in this document included “rights, respect and recognition; negotiation, consultation, agreement and mutual understanding; participation, collaboration and partnership; benefits, outcomes and giving back; managing research: uses, storage and access; and reporting and compliance” (p. 1). The guidelines direct researchers and community partners

(who are to be equal partners) to negotiate in order to make decisions regarding the collection of samples, disposition, storage, and return of samples and data.

**Desert Knowledge Cooperative Research Centre (2008) *Desert Knowledge CRC Protocol for Aboriginal Knowledge and Intellectual Property*—Australia**

The Desert Knowledge Cooperative Research Centre's (2008) Desert Knowledge CRC Protocol for Aboriginal Knowledge and Intellectual Property (PAKIP) addressed "storage, access, and publication," (Section 5.2) and highlighted the importance of accessibility of information "by Aboriginal people with interests or rights in the data" (Section 5.2, para. 6) as an expression of continued partnership and benefit sharing. The PAKIP also noted that samples "must be destroyed on the request of the providers of the information or on the request of those who according to traditional law have the authority to make that decision" (Section 5.2, para. 7). This constitutes a novel system that covers various types of withdrawal and/or requests for destruction. This protocol prohibited commercialization and secondary use of samples without re-consent, which may be given by either individuals or the community as a whole. The return of results, as well as equitable benefit sharing, are also required.

**Supreme Community Council of Alto San Juan (ASOCASAN), United Nations Environment Programme (UNEP), Environmental Research Institute of the Pacific (IIAP), and Natural Justice (NJ) (2012) *Biocultural Community Protocol for the Territory of the Supreme Community Council of Alto San Juan*—Colombia**

This protocol specifically made reference to traditional knowledges and directly addressed the community concept of *zoteas*, which are "small, locally maintained gene banks" (ASOCOSAN, UNEP, IIAN, & NJ, 2012, p. 16). The protocol demonstrated a desire to protect and house knowledge of biology and nature within the community as much as possible, which is reiterated in the document's assertion of "the right of ownership over natural resources" (p. 33). This protocol also referenced the Nagoya Protocol of the Convention on Biological Diversity, which is focused on human interactions with environments and the rights associated to those interactions, with an emphasis on benefit sharing.

**Federación por la Autodeterminación de los Pueblos Indígenas (2010) *Propuesta de Protocolo para un Proceso de Consulta y Consentimiento con los Pueblos Indígenas del Paraguay*—Paraguay**

This protocol, available in Spanish, reiterated principles seen in other protocols, emphasizing justice, respect, equality, transparency, and Indigenous ownership (and benefit sharing) of research and other activities in their territory and involving their knowledges (Federación por la Autodeterminación de los Pueblos Indígenas, 2010). This protocol was not the result of debate and discussion among researchers, but rather emerged from consultation with and consensus between researchers and Indigenous people, and among Indigenous people.

**Traditional Health Practitioners of Bushbuckridge, Kruger to Canyons Biosphere, and Natural Justice (2010) *Biocultural Protocol of the Traditional Health Practitioners of Bushbuckridge*—South Africa**

This protocol focused on cultural and practical knowledge and it also encouraged the use of the local language and the translation of the protocol into the Indigenous language. Like other protocols that have



focused on traditional knowledges, this one is directed towards protecting knowledge and benefiting the communities who hold the knowledge. The protocol highlighted reciprocity, informed consent, and transparency as integral to research relationships. With regard to consent, research or other partnerships are to be regulated in part through “a process of community deliberation and ancestral consultation” (Traditional Health Practitioners of Bushbuckridge, Kruger to Canyons Biosphere, & Natural Justice, 2010, p. 5) that is similar to the Nuu-chah-nulth’s minimum reflection period for participants. Interestingly, this protocol expressed interest in welcoming “commercial bio-prospectors” who must apply “for any access to . . . [I]ndigenous biological resources” (p. 5). This approach further demonstrates the diversity of perspectives among Indigenous Peoples, and it offers an example of a community’s self-determination in research partnerships.

### **Principles that Inform Actions Regarding Specimens in Research and Laboratory Settings**

Both standard ethical principles and community-specific principles informed these protocols in establishing their conceptions of research relationships and preferences regarding the obtainment, use, return, disposal, and loaning of specimens. This article has presented community-specific policies, protocols, codes, and principles to allow for a coalitional understanding of ethical issues related to biospecimens. These principles provide guidance for both researchers who wish to partner with Indigenous communities (instead of either extracting specimens and conducting culturally-uninformed analyses or utilizing the remains of individuals whose relations do not want them to be analyzed), and for communities to reflect upon as they create their own policies going forward. Further, these policies can inform the research policies by drawing attention to the limits of current rules and the possibilities for interaction between the various stakeholders in the research.

Similar to the Belmont Principles, respect is central to the protocols and codes that we reviewed in this article, although the protocols and codes reviewed present a wider, more holistic understanding of respect that encompasses individuals, communities, samples, and data. Respect is thus necessary at every stage in the development of research relationships, from initial consultation to the presentation of the final research. This last point on presentation leads into the principle of beneficence, whereby attention must be paid through regulation or “common sense” to how the results of research will be interpreted and whether they pose risks for participants. There should also be benefit to participants and communities in terms of capacity building as a result of the research. This, in turn, extends to the need for transparency, including policies to allow access to and review of data, specimens, findings, and publications. Fair return of information and benefit to both parties in the relationship are both part of justice, equity, and empowerment of the community. In truth, many of these principles and practices are entangled, and they are often conjointly demonstrated through reciprocity, ownership, negotiation, protection, and communication. When those syncretic aspects are at the center the research, interactions with Indigenous Peoples, and/or decisions about specimens, the discussion will lead to best practices on how to proceed from within and between communities.

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## Appendix A

Table 1. Comparison of Regulatory Models and Indigenous Nation-Specific Policies

Steps in Process	MTRC (AIRC, 1999)	IRPA (IPCB, 2000)	CIHR (2009)	NCAI (Sahota, 2007)	AASB		Navajo Nation (1994) HRC	PRESRP (ATFE, 1996)	Ho-Chunk Nation (2005)	Pascua Yaqui (2008)	HCRC (CRIT, 2009)	RCEP (Fort Peck Tribes, 2013)	Tohono O'odham (2013)	Tl'azt'en Nation (1998)	Mi'kmaw (1999) RPP	AHRC & Manitoulin FN (2003)	Inuit Tapiriit Kanatami (2007)	Nuu-chah-nulth (2008)	Six Nations (2014)	Metis Centre (2010-2011)		Consensus	
Consultation/ Negotiation	S	Y	Y	Y	Y		Y	Y	Y	Y	S	Y	S	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Protection for	LH	B,K	LH	LH	LH		LH	B,K	H	B,K	H,K	LH	H,B	K	K,H	LH	K	LH	LH	H,K		LH, K	
Informed Consent	P,C	P,C	P,C	P,C	P,C		P,C	P,C	P,C	P,C	P,C, G	P,C	P,C	P,C	P,C	P,C	P,C	P,C	P,C	P,C	P,C		P,C
Confidentiality	P,C	P,C	P,C	P,C	P,C		P,C	P,C	P,C	P,C	P	P		P	S	P,C	S			P,C	S		P,C
Use & Storage																							
Potential Uses Defined	S	S	S	SD	Y				Y	Y			Y								S		YD
Withdrawal	S	P,C	P,C	S	P			P,C	P,C	P,C	P,C									P,C			P,C
Secondary Uses Consent	S	P,C	P,C	S	EC				P, EC	P,C			P,C							EC			P,C, EC
Return / On Loan/ Disposal																							
Of Results	R	R	R	R	R		R	R	R	R	R	R	Y	R	R	R	R	R	R	R	R		R

Steps in Process	MTRC (AIRC, 1999)	IRPA (IPCB, 2000)	CIHR (2009)	NCAI (Sahota, 2007)	AASB		Navajo Nation (1994) HRC	PRESRP (ATFE, 1996)	Ho-Chunk Nation (2005)	Pascua Yaqui (2008)	HCRC (CRIT, 2009)	RCEP (Fort Peck Tribes, 2013)	Tohono O'odham (2013)	Tl'azt'en Nation (1998)	Mi'kmaw (1999) RPP	AHRC & Manitoulin FN (2003)	Inuit Tapiriit Kanatami (2007)	Nuu-chah-nulth (2008)	Six Nations (2014)	Metis Centre (2010-2011)		Consensus
Of Data	R	R	SD	R	OL		R	R	OL	R	OL	OL	OL	R	R	R	R	R	R	R	R	D
Of Samples	SD	R	OL	OL	OL		DiB	OL	OL, Di	R, DiB	OL	OL	R		R	R, Di	R, OL	D				OL, R
Benefits																						
Commercial Possibilities		N	N	N	N		N		N	N	C		N	C	C							N, C
Local Capacity Building	Y	Y	Y	Y	Y		Y	Y	S	Y		Y	Y	Y	Y	Y	Y	S	Y	S		Y
Analysis Review	Y	Y	Y	Y	Y		Y	Y	Y			S	Y	Y		S	S	S		S		Y
Publication Review / Author	Y	Y	SD	Y	Y		Y	Y	Y	Y	S	S	Y	Y		S	S	S		S		Y
Language / Communication		Y	Y	Y	Y		Y		Y				Y	Y	Y	S	Y	Y	S	S		Y
Access		Y	OL	Y	Y			Y			Y	Y	Y	Y	Y	Y	Y	Y	Y	S	S	Y

Note. Y – Yes; N – No; Blank – Unaddressed; S – Inferred Support; D – Discussion; LH – Living humans only; H – Humans and nonliving humans; B – All biologicals; K – Knowledge; P – Participant; C – Community; EC – Ethics Committee; G – Guardian; OL – On loan; R – Return; DiB – Disposal with blessing