

**MODEL
TRIBAL
RESEARCH
CODE**

***With Materials for
Tribal Regulation for Research
and
Checklist for Indian Health Boards***

***Third Edition
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MATERIALS FOR TRIBAL REGULATION OF RESEARCH

THE MODEL TRIBAL RESEARCH CODE

I. INTRODUCTION

Over the years, research has produced many good things for society in general and for Indian people in particular. Many, if not most, researchers are sincere and dedicated professionals who want to help Indian communities solve their health and social problems and preserve their cultural heritage, and in the process to be sensitive to the legitimate needs of the individuals and communities with which they work. But governments, unfortunately, cannot assume that everyone will act according to the highest standards. Legislation is necessary where there are, or might be, problems affecting society in an important way. In order to look at tribal legislation regulating research on Indian reservations, then, we must look at the worst-case situations resulting from research and determine whether the tribal government should act.

Research has caused problems for some Indian tribes. Among the complaints have been:

- individual Indian people have been persuaded to participate in research in which they did not fully understand the risk to their health and safety;
- individuals may have felt that they were required to participate in research in order to maintain their right to health services;
- research was conducted which did not respect the basic human dignity of the individual participants or their religious and cultural beliefs;
- researchers have not respected the confidentiality of Indian people to the same degree that they would have those of non-Indian individuals or communities;
- researchers have been interested in Indian people as an "isolated" or "pure" gene pool to be used for laboratory purposes, demeaning the dignity of Indian individuals and communities;
- researchers have profited economically and professionally from research in Indian communities, but many of them make no effort to employ local people in any capacity regardless of their abilities and make no effort to compensate the individual subjects of research, regardless of the risks or burdens associated with the research;
- researchers have treated Indian researchers as "informants" rather than as colleagues, allowing themselves to appropriate the work of Indian researchers as their own;
- researchers have pursued issues of importance to the larger society but of marginal interest to Indian people, and have been uninterested in problems of more urgent concern to the Indian community;
- researchers have sought and published sensitive religious and cultural information, in some cases destroying its efficacy by publication;
- researchers have violated promises of secrecy regarding sensitive religious or cultural materials and information;
- researchers have taken cultural information out of context and, as a result, have published conclusions that were factually incorrect;

- researchers have collected, published and profited from information about Indian tribes that are part of the heritage of the tribe and -- in the sense understood and valued by the dominant society -- "owned" by the tribe;
- researchers have failed to respect the cultural beliefs and practices of the Indian community in their research methods;
- researchers have sensationalized Indian tribal, community, family and individual problems and released publications heedless of their impact on legitimate Indian social or political interests;
- despite promises at the outset that research would benefit the Indian community, researchers have failed or refused to follow through on promised benefits, to share preliminary results with the Indian community or to give the community an opportunity to participate in the formulation of recommendations or of a final report.

Some of these issues are matters of professional ethics among the various research professions and, at the very least, matters of common courtesy and basic respect for human dignity. But the federal and many state governments have determined that self-regulation by the professions is not sufficient for the society at large. For the purposes of this project, the first question is whether tribes should rely on federal and state regulation or whether there is a need for tribal regulation as well. In fairness to researchers, the expectations of the Indian community may not always be clear to them, and a published set of tribal standards embodied in a regulatory process may be helpful. These materials are intended to help Indian tribes provide both a framework within which the tribe's expectations will be clearly articulated to would-be researchers, governments, and other funding agencies, and a clear process for compliance.

II. THE FEDERAL REGULATORY PROCESS

The federal government has adopted laws and procedures regulating federally-funded and federally-sponsored research affecting human subjects. Two parallel sets of regulations govern such research. One set applies to all federally funded or conducted projects which involve human subjects and the other applies to drug studies that will be submitted for marketing approval to the federal Food and Drug Administration. Some states also have laws setting ethical standards for research.

Institutional Review Boards (IRBs) are the vehicles used to ensure that federally funded or sponsored projects comply with the regulations. The primary mission of an IRB is to protect the rights and welfare of people who will be subjects of research. IRBs, generally, are set up by institutions performing research on a large scale, such as universities and medical facilities. A few IRBs are company-based or independent. Membership is supposed to include laypersons or proposed consumers as well as scientists, and reflect the cultural and ethnic mix of study populations.

The Indian Health Service (IHS) has a national IRB as well as one in each Area. A few tribes have established their own IRBs, and a number are investigating the feasibility of doing so. Chapter Seven of the IHS *Indian Health Manual* governs research activity that is undertaken in or uses IHS facilities or personnel. The policy statement in Chapter Seven clearly states that

the research must have the full understanding, documented approval, and support of the Indian tribes or Alaska Native villages involved, and that the tribes and villages will be kept informed of IHS research needs, activities, and results. In addition, IHS will respond to tribal requests for technical review, assistance, and advice for any research activity in which the tribe is involved.

"Research" as defined by IHS is:

[t]he use of systematic methods to evaluate concepts or practices to discover new knowledge. It usually means an organized scientific investigation. For the purpose of this chapter, the term . . . includes (1) basic and clinical research, (2) behavioral studies, (3) anthropological studies, (4) the development of clinical and public health methods and techniques for practical application to the Indian Health program, and (5) studies to determine the extent of special health problems, or solutions thereof. (at p. TN 87.3)

Chapter Seven of the IHS *Indian Health Manual* provides a regulatory **process** as well as a structure. It is important to note that the mission of IHS IRBs is not clearly limited to commonly understood scientific or medical projects, but includes all federally-supported research involving human subjects. The information contained in this discussion is applicable to non-medical research as well, including research which does not involve individual human subjects.

Where research affects Indian tribes, the federal IRB process seeks to include tribal and community representation. Tribes should participate fully in the IRB available to them to ensure that their interests are fully reflected in the federal regulatory process. But the federal process was designed to deal with research in general in a complex urban society, not specifically with Indian tribes. Like many federal regulatory systems, it cannot be expected to address all of the specialized issues presented by research on Indian reservations. These materials represent an attempt to identify those special issues, both to enable tribes to develop their own approach to the regulation of research and to provide federal regulators with additional insight into the special circumstances of Indian communities.

Research presents challenges to Indian tribes that are both more specific and more general than those covered in the IRB process. They are more specific in the sense that the economic and cultural circumstances of Indian tribes give rise to unique issues for researchers which may require attention to considerations not evident where the researchers and the subject individuals and communities are part of the same culture. They are more general in the sense that the IRB process is limited to research which:

- 1) requires the participation of individual human subjects; and,
- 2) includes federal involvement, either through federal funding or the use of federal facilities, programs or resources.

Tribes are concerned about research which seeks to utilize individual Indian people or the Indian community itself as subjects regardless of funding source or the involvement of the

federal government. Unlike the mainstream society, which because of its size can more easily absorb the impact of research, Indian tribes must consider the impact of research on the life of the community itself, and in particular the impact of social science research, which often may view Indian communities as examples of social pathologies interesting to the mainstream society, but may have little respect for the interests of the community.

The fundamental responsibility to govern Indian tribes and to protect their members lies in the tribes themselves. Tribal regulations should be seen by the tribes as establishing the fundamental tribal policies in this area. The tribal and IRB processes should be seen as complementary to each other: the IRB may be able to provide technical support to the tribal process, and a clear statement of tribal policy will guide the deliberations of the IRB. Indeed, it is difficult to imagine an IRB approving a project in defiance of clear tribal policies.

Some tribes have expressed an interest in having their own IRB recognized by the Office for Protection from Research Risks (OPRR), Department of Health and Human Services (DHHS). Such a step is worth consideration, if only because it might give the tribe control over the resources devoted to supporting the IHS IRB. But tribes should be aware that an IRB in the minds of the OPRR and DHHS is a specific body organized under federal regulations (45 CFR 46) and exercising delegated federal power in accordance with those regulations, as compared with a tribal regulatory process utilizing inherent tribal sovereignty in accordance with tribal law. An IRB, for example, is not empowered by the regulations to consider the long-term social impact of research in deciding whether to grant approval, while tribally-based regulation would likely take the long-range impact on the tribe heavily into account. In approaching the question of the regulation of research, as in any governmental activity, tribes would be well advised to keep in mind the distinction between tribal and federal power, and be sure they are relying on the appropriate source of power to accomplish a certain purpose. In the final analysis, tribes with a strong interest in the regulation of research would probably decide in the end to establish a tribal IRB in conformance with DHHS regulations **and** to enact tribal legislation and create a parallel tribal regulatory process, with the one tribal IRB exercising dual authority and functions under both regulations.

III. POSSIBLE RESISTANCE

As Indian tribes undertake to regulate research, their professional competence and their motives may be attacked. Studies of intergovernmental relations on Indian reservations in the past 20 years, for example, show that in the unhealthy and unproductive stages of these relationships, state and local government tend to object to the very idea of tribal government itself, the notion often being that Indian people should not have the right to and lack the capacity for self-government in any circumstances. As the intergovernmental relationship matures, state and municipal governments accept the fact of tribal government and concern themselves with how the tribe governs, disagreeing with some actions and agreeing with others just as they would in any intergovernmental relationship. It is to be hoped that, in the same way, researchers faced with the prospect of a tribal regulatory process will accept the tribe's rights and powers, and seek to persuade the tribe of the merits of a particular research proposal.

The responsibility of researchers to the Indian community as defined by the tribe may be different from that as defined by the researchers themselves. The fundamental policy question underlying tribal regulation of research involves the relationship between the community and the research world. The question might be put in this way:

Is the burden on the researchers to show why tribes should participate in a particular research project, or do Indian tribes have a social obligation to participate and, therefore, the burden to show why they should decline to participate in a particular project?

Indian societies are struggling to survive the pressures of a much larger modern culture with overwhelming technological impact. Researchers in their professional capacity approach Indian communities from an academic and theoretical perspective. Indeed, in some cases, it may violate academic and intellectual principles for a researcher to consider the impact on the community of his or her findings. From an objective viewpoint, one might agree on the merits with a tribe on one research issue and with a researcher on another.

Indian tribes, in addressing the question of regulating research in the Indian community, are in fact defining for themselves the degree to which they wish to make themselves available as subjects. While they may and probably should feel a responsibility as members of the human community to participate in some kinds of research and assume a fair share of the risks inherent in research which will benefit society as a whole, they must define this responsibility for themselves, and they should not feel that the value systems of research professions are of universal validity, binding on them for all purposes.

Indian tribes share with other governments the problem of defining the degree of self-regulation which will be allowed any group in society. Within the large and complex mainstream American society, specialized social and professional institutions have formed which are subcultures in themselves, with their own rules of ethics and expectations of the behaviors of others. These subgroups tend to resist the intrusion of outsiders and feel somewhat self-contained, confident that their internal structure and rules are sufficient to enable them to regulate themselves. While these internal rules may be adequate for most purposes, insofar as the activities of these groups affect other people or groups, their self-regulating systems may be seen as incomplete or even self-serving. Intellectual freedom is one of the most important values in society, but it is not the only value. It is difficult enough to balance it with other social values in the larger society, and much more so in the heightened pressures of an Indian tribal society trying to survive in the modern world.

IV. USING A MODEL

A model code is a tool to assist a tribe in developing law which meets the particular needs of the tribe. Two inappropriate reactions to a model code are:

1. we liked it and we adopted it at our last meeting; or
2. we didn't like it because several provisions didn't meet our needs exactly.

A model is not intended to meet exactly the needs of any single government or to save that government the job of deciding what is right for the community. A model is intended:

1. to guide discussion of a problem; and
2. to call attention to the issues which must be addressed and the decisions which must be made in the process of developing legislation on a particular topic.

It does that by providing examples which can then be discussed as part of the community discussion and the legislative deliberation process. A model code is successful if it has helped the tribe ask the right questions in the right way. Even if the tribe decides not to adopt a formal code on this subject, working through these materials may help the tribe to use the IRB process more effectively or to develop less formal tribal procedures for regulating research.

The best way to use these materials is for the tribal council, or a committee of the council, to work through them step by step, clarifying its own thoughts and preparing itself for future factfinding by identifying questions as to which the council or committee would like to hear the views of others, whether they be community members, cultural and religious leaders, tribal staff, BIA/IHS personnel, or researchers. The council or committee might then want to schedule hearings on the legislation and ask these people to testify, giving them an indication in advance of the questions they should address and even, perhaps, asking them to prepare for the consideration of the council draft language for certain provisions.

More specifically, the council or committee drafting legislation should seek the views of the executive branch of tribal government and in particular the tribal department which will likely be responsible for implementing the legislation. The tribal executive will have an important perspective as to how the legislation could be administered and how detailed the legislation should be to balance the need for clarity with the need for flexibility.

V. THE STRUCTURE OF A CODE

A code is simply a systematic collection of laws. A code commonly deals with a specific issue or one area of concentration. The U.S. Code (USC), for example, contains the laws of the United States, arranged by subject matter. A subject-related code such as a criminal code contains the body of law related to crimes. A code also may be a collection of rules or regulations. For example, the Code of Federal Regulations (CFR) consists of the accumulated regulations issued by the federal executive departments and agencies, arranged into broad subject areas. Volume 25 of CFR contains regulations for the Bureau of Indian Affairs, Indian Arts and Crafts Board, and the Navajo and Hopi Indian Relocation Commission.

A code can be organized in a variety of ways, but it will ordinarily include some basic information set up in sections that are titled so that readers will have an idea what is covered in a particular section. The following is only one example of how a code could be organized.

- A. Title - describes the formal title of the code which will be used or cited in legal documents.

- B. Policy Statement - describes the policy or the philosophical underpinnings for the code. For example, the Indian Child Welfare Act, 25 *U.S.C.* §1901 *et. seq.*, contains a statement of Congressional policy and intent by which courts should be guided in interpreting the Act.
- C. Purpose Statement - describes the intent of the legislation, what it should accomplish, *e.g.*, "The purpose of this code is to protect elders within the jurisdiction from abuse and neglect as defined in this Code."
- D. Jurisdiction Statement - describes the persons and the geographic area covered.
- E. Definitions - define important terms so that courts deal with the code in a uniform and consistent basis and from a common understanding.
- F. Procedural Sections - set out the process of how matters are handled under the code. This fosters uniform processing of cases. These sections might designate which governmental office is responsible for implementing the code, including issuing regulations, and prescribe elements of the procedures which the council wants to ensure are included. This section might specify the scope of judicial review by the tribal court of actions taken under the code, which would be subject to the regular procedures of the tribal judicial system.
- G. Substantive Provisions - set out the substance of the code creating duties, rights, and obligations as opposed to procedure.
- H. Remedies Sections - set out what happens if the law is broken. If this is a criminal code, it covers sentencing provisions. In a civil code, remedies might include money damages or injunctive relief.

VI. THE DEVELOPMENT PROCESS

The tribal council or a committee, in using these materials, should begin with an overall view of the policies which underlie the legislation. In the following section, materials are intended to facilitate this stage of the development process. If language is drafted before the council or committee has defined the policies and goals of the legislation, the risk is that the legislative language will not be appropriate to accomplish these goals. Specific language will come more easily if there is a clear agreement on the broad outlines of the legislation.

A. POLICY STATEMENT

Broad-based, significant or possibly controversial legislation commonly begins with an opening section articulating legislative findings and the underlying policies. Including such an opening policy statement is advisable as a general rule for several reasons. It clarifies the intention of the council and explains to the public the rationale for the legislation and the public policy goals it pursues. It informs those whose activities might come under the legislation about its overall purpose so that they can decide their future course of action accordingly. And it gives guidance to the courts in their interpretation of the legislation.

Tribal legislation providing for the regulation of research should have such an opening statement because the policies underlying the tribe's attitude toward research reflect the

most profound tribal views regarding the tribe's policy toward cultural and social integrity and survival and the tribe's relationship with the outside world. A clear statement of policy in this legislation will help the tribe itself and will serve as a clear message of policy to all who are interested in the legislation.

Another consideration may be important to Indian tribes. While they have sovereign immunity from suit, it is not uncommon for tribal actions to be challenged in federal court by various procedural devices, for example, in the course of the tribe's efforts to enforce its laws. Because of the approach often taken by federal courts to these cases, the court may not merely review the particular tribal action, but it may undertake to decide whether tribes in general have the kind of power being exercised at all. For this reason, it may be important that the legislative history of a tribal code lay a clear foundation for this type of tribal power in a way that any federal judge can grasp and, one might hope, uphold. Federal courts are most clearly supportive of tribal government actions which seem to them to be actions of internal self-government, as distinguished from actions regulating the activities of others. This legislation could make clear the sense in which important self-government interests of the tribe are seen to be at stake.

The majority society places a great value on intellectual freedom and is suspicious of government attempts to regulate it. Federal, state and municipal governments, subject to the First Amendment of the U.S. Constitution and various state constitutional protections, are limited in their power to regulate or prohibit certain kinds of research, particularly research not funded by the government and not posing a threat to the safety and well-being of human subjects. Indian tribal governments are subject to the Indian Bill of Rights in the 1968 Civil Rights Act, which has a version of the First Amendment protecting free expression. These rights are often enforced in tribal court, and it is important that tribal governments, both in their legislative and judicial functions, be able to show how they are balancing the values of the community with those of individual free expression.

An action by any government, including tribal government, which seeks to regulate research raises questions concerning sensitive issues of intellectual freedom. An opening policy statement, then, could clearly articulate the interests the tribe is seeking to protect and explain why these interests might be different for tribal societies than for the majority (cultural survival, for example). It could also reassure the general public and researchers that the tribe is weighing the values of intellectual freedom and the relationship of tribe to society as well. Following are some ideas on an approach to drafting a policy statement.

A policy statement could begin with a brief set of findings describing the types of problems caused by research in the community, that is, the problems which led to the adoption of this legislation.

Next, the policy statement could outline the overall tribal interests to be pursued in the legislation: the safety and well-being of human subjects of research and the interest of the tribe in cultural self-determination and preservation.

In addressing these issues, an important distinction should be made which is often overlooked. The **purpose** of tribal governments is to govern Indian societies, which have an inherent right to self-government. A tribe may rate preservation of the tribal culture as a high priority, which most tribes do, as a **policy** of the tribe. Tribes should not declare that cultural preservation is the purpose of the tribal government. To do so, in some sense, sets themselves up for their actions to be judged by outsiders according to the criterion of whether a particular action is consistent with historical tribal culture, thereby limiting the tribe's right to adapt its culture to new circumstances. Tribes should always remember the efforts of their adversaries in fishing and water rights cases to limit tribal use of the resource to the technologies available at the time the treaty was signed or the reservation established on the ground that tribes in the treaties were only securing their right to a traditional way of life.

Next, the policy statement could indicate the tribe's recognition of the value of research to the tribe itself, to the Indian people in general, and to society in general. This section would make it clear that the tribe is not unthinkingly embarking on the regulatory process without carefully weighing competing valid interests and without being willing to assume a fair share of the risks inherent in all research.

B. DEFINE SCOPE

The scope, or reach, of the legislation must be defined in terms of geography, persons and subject matter. In the broadest sense, the scope of all possible tribal legislation is defined by federal law (primarily in terms of limitations on the powers of tribes that will be recognized within the American legal and governmental systems) and by the tribal constitution, other organic document or the tribe's traditional form of government. It must be remembered that some tribal constitutions limit the jurisdiction of a particular tribal government to a scope narrower than that permitted by federal law (such as when a tribal constitution limits the power of the tribe to tribal members, or when the constitution requires that tribal actions be reviewed or approved by the Interior Department when federal law makes no such requirement). A particular tribal legislative act can also be applied to a range of territory, persons or subject matter narrower than the full range of tribal powers. Prior to legislative drafting, the tribe should discuss the scope of the legislation in broad terms in order to see the legislation in the broadest possible context of tribal policy and to gain an overview of where certain issues will be handled in the legislation.

The **geographical** scope is, basically, the territorial jurisdiction of the tribal government, which is usually prescribed in the tribal constitution, other organic document, the treaty or statute establishing the reservation, or fundamental tradition. The constitutional language may limit tribal jurisdiction to the external boundaries of the reservation or may be more complex depending on the nature of the power being exercised. There may also be complexities concerning the exact territorial jurisdiction of a particular tribe because of cessions after the establishment of the reservation, later acquisitions and other legal uncertainties.

Extraterritorial jurisdiction presents different issues. The above questions involved only questions as to the physical boundaries of tribal territory because of historical anomalies. Extraterritorial jurisdiction, for any government, involves the attempt of a government to exercise its powers outside its territory, whatever the definition of boundaries might be. Asserting extraterritorial jurisdiction presents complex problems for any government, and tribes would probably be on shaky ground trying to exert extraterritorial jurisdiction over non-Indians (which many researchers would be). These materials adopt strategies for tribal governments to establish rights which could be enforced off the reservation by a different approach than asserting full tribal jurisdiction over universities throughout the world, for example.

Personal jurisdiction defines the classes of persons who are subject to the legislation. Current federal law permits tribes civil jurisdiction over Indians and non-Indians, tribal members and non-members. Tribal criminal jurisdiction is limited by case law and statute to Indian persons. The tribal constitution, however, may define a more restricted class of persons over whom the tribal government has jurisdiction. In the recent *Duro* case¹, the Supreme Court held that Congress had recognized tribal criminal jurisdiction over only Indians who were members of the local tribe, but Congress corrected that misreading of its intent and restored tribal power over non-member Indians, defined as the same class of persons subject to federal criminal jurisdiction². Federal statutory law does not specifically define "Indian" for purposes of federal criminal jurisdiction, but generally, case law requires that to be subject to federal criminal jurisdiction a person possess some Indian blood and be recognized as an Indian, a somewhat circular definition.

Subject matter jurisdiction describes the types of activities covered by the legislation. "Research" must be defined in a way that is as clear and understandable as possible, enabling those who might be affected to know from reading the legislation whether their activities fall within it or not. At some point in the discussion, the drafters should decide whether the legislation should be addressed exclusively to researchers or whether the tribe should attempt to regulate **participants** in research, that is, human subjects of medical research or informants in social science research. Regulation of researchers may raise fewer issues of personal freedom than a regulation which purports to tell individuals on the reservation whether they can participate in research of their own free will. Regulations addressed to the right of researchers to ply their trade on the reservation is much easier to enforce than those which might try to control the activities of all reservation residents who might wish to participate in research as subjects.

The discussion of the definition of research should address whether research sponsored by the tribe or conducted by tribal members should be treated differently in the regulatory process. Generally, fairness should indicate that as to substantive matters (especially those promoting safety and the dignity of human subjects) the tribe should

* *Duro v. Reina*, 110 S. Ct. 2053 (1990).

@ 25 USC § 1301 (2), as amended by P.L. 101-511, Sec. 8077 (b) (1990).

abide by its own standards, as should researchers who happen to be tribal members. The tribe may want to include some form of Indian preference or some form of waiver of a fee for researchers of limited means.

The discussion should also address whether any other research should be treated differently because of the funding or sponsoring organization, *e.g.*, IHS, BIA, any other federal agency (although it should be remembered that federally-funded or sponsored research or research involving federal resources is subject to IRB regulation). Federal law limits the tribe's power to exclude from the reservation federal officials acting in their official capacity, and it is not clear whether this limitation would be applied only to those federal officials administering the federal trust responsibility as narrowly defined or whether it might be applied to federal researchers. While it is most unlikely that the federal government would force unwanted research on an Indian tribe, it is also in the tribe's political and legal interest not to test its powers against those of the federal government where the test is likely to end up in a federal court. This is an additional reason for the tribal process to be coordinated with the IRB process, to extend tribal influence over the federal regulatory process and avoid a confrontation between tribal and federal governments.

C. DEFINE THE PROCESS

At this point, the discussion should move to the process itself. Legislation, to be most effective, must balance generality and specificity. Although many tribes do not have Separation of Powers as a constitutional matter, virtually all tribes have an executive branch of government established to administer tribal programs, often under the direction of the tribal chairman, president or governor. Legislation guiding the administration of these procedures should be general in nature, leaving to the executive branch the discretion to organize and adopt procedures which can then be shaped and revised to meet the particular needs of the situation. Legislation which is too specific can be confining, requiring an amendment as the tribe implements the legislation and encounters unforeseen contingencies. At the same time, the tribe should give specific consideration to exactly how the regulatory process might work, in order to shape the legislation accordingly. It should give clear enough directions so that the goals of the legislation can be implemented properly by the executive branch of the tribal government. Among the considerations to be discussed are the following.

1. Administration

What agency of the tribal government will administer the regulatory process?
What kind of expertise will be required of those making the decisions for the tribe?
How much documentation will be required of the applicant?
Will the decision makers be tribal civil servants, or will a committee of the council be the decision maker (in which case the role of the executive branch should be defined: just paperwork; factfinding)?

Should there be a committee of experts or specialists to review applications? If so, who should be on the committee, and how should they be selected?
Will there be a role for the local IRB, if there is one?

There may be a need for provisions for obtaining assistance from outside the tribal government in situations where the technical requirements of evaluating a particular research proposal involve expertise which tribal council members or employees do not possess.

2. The Review Process

The reviewing process to determine whether to allow a research project to proceed is particularly sensitive. A number of issues must be decided. Will there be a distinction between those who process the forms and those who make the decision? Will there be timelines and deadlines within which the tribe must make its decision? Can there be approval timelines for some kinds of research and not others? Approval by default of the process, *i.e.*, failing to process the documents in a timely manner, could be dangerous to the community or to human subjects. Should the tribe be required to give reasons for an unfavorable decision? This is a critical decision since one of the elements of due process of law is that reasons need to be given for decisions which affect an applicant.

What are other procedural rights of applicants? Will there be an administrative appeal from an unfavorable decision and to which body will it be appealed: tribal council, tribal court, administrative court?

3. The Application Process

The application process is the formal procedure for a research request. What issues should be addressed in the application process?

- the nature of the research
 - Research in medical, general social, archaeological, anthropological, psychological, or physical sciences?
 - Research using animals?
 - Research possibly exposing humans to animal diseases?
- goals and objectives of the research
 - What are they looking for?
 - What kind of specific information are they seeking?
- benefits of research
 - Will there be specific and immediate benefits to the tribe?
 - Will there be specific benefits to the individuals participating?
 - Will there be more general benefits to society as a whole?
- risks associated with the research
 - What are the risks to the community?
 - What are the long-range risks, as distinguished from immediate risks?

- Is there a risk of a deleterious impact on community cultural, social or political interests?
- What are the risks to individual human subjects?
- Are the risks "greater than minimal risks" (see IRB regulations, 45 CFR 46)?
- Does the research include greater than minimal risk, including that of stigmatization of individuals, tribe, or community?
- Does the research include procedures or substances that are experimental?
- steps taken to minimize the risks
- duration of the proposed research
- use of human subjects
 - What is the nature of their participation?
 - What are the possible risks to them?
 - What precautions will be taken?
 - Do they have a right to treatment associated with the research?
 - Do they have a right to treatment if something goes wrong with the research?
 - Do they have a right to subsequent treatment?
 - What is the liability of researchers?
 - What is the role of IRB regulations?
- confidentiality of data
 - [AS TO THE TRIBE OR COMMUNITY] Will the tribe or community be identified in the final report or elsewhere in the research materials?
 - [AS TO INDIVIDUALS] Will human subjects be promised confidentiality as to data associated with them?
 - What assurances are there that this promise will be honored?
 - What are conditions in which this promise might be impossible to fulfill [federal regulations, court order, etc.]?
- ownership and control of data from the research
 - Will the tribe's interest in its cultural and community heritage for the tribe's future generations be protected?
- ownership and control of human biological material from the research
 - Will the tribe's interest in its cultural and community heritage for the tribe's future generations be protected?
- post-research protection
 - Who will answer future questions regarding the research?
 - Who will be responsible for future concerns of and effects on individuals, tribe, and community?
- tribal participation
 - Will the tribe, the community, or its designees be able to review and comment on the research goals and objectives?
 - Will a preliminary report be made to the tribe for comment?

- What will be the responsibility of the researcher to address and satisfy tribal concerns in drafts and final report?
- tribal rights
 - Is tribal control over sensitive personal, community, cultural and religious information recognized?
 - Are the researcher and the funding and sponsoring organizations willing to be bound by the tribal regulations and bound contractually if necessary to ensure that tribal and individual rights are honored throughout the process?
 - Are they willing to agree to the tribe's right to prevent publication?
 - employment
 - Is the researcher willing to give Indian preference or local preference in employment throughout the project?
 - tribal institutions
 - Is the researcher willing to cooperate with and involve a tribal college or other institution specified by the tribe?
 - data storage
 - Is the researcher willing to deposit the raw data in a tribal or tribally-designated repository?
 - Is the researcher willing to deposit other working papers from the project (*e.g.*, copies of the project materials)? NOTE: the confidentiality of individual information must be protected in a tribal depository as well.

4. Licenses and Fees

The issue of licenses and fees needs to be discussed since the cost of processing requests will not be inexpensive. Again, a series of associated issues must be considered. What should be the form of the tribal approval process? Will a would-be researcher be required to obtain a permit or license, to register with a tribal office, to pay a fee? Will the fee be based on an estimate of the administrative cost to the tribe? Will there be a profit motive for the tribe? Would the answer to this question depend on the nature of the research? Are there circumstances in which a bond should be posted, *i.e.*, to ensure compliance with terms of the permit or contract?

D. ENFORCEMENT

The simple act of passing legislation will have an important impact on research in at least two respects. First, it will have what is called a normative impact. That is, the behavior of researchers will tend to conform to tribal standards merely by the fact that they have been published. Second, the existence of a tribal regulatory scheme will drive away those researchers who do not want to subject themselves to the requirements of the tribe.

A tribe with regulations that are too strict, fees that are too high, unreasonable employment requirements, or unreasonable claims to control over data or results, risks driving away good research along with the bad and may lose the opportunity to benefit from research. A tribe may want to build into the legislation a clear statement that research is not necessarily unwelcome, unless it is, and that researchers are encouraged to enter into discussions with the tribe.

Despite the effects of the very existence of the legislative scheme, enforcement provisions are necessary in the event a researcher fails to comply with the tribal legislation. In deciding on enforcement mechanisms, the drafters should consider the various phases in the total regulatory process and determine which enforcement mechanisms will be most effective at each stage. As with any government, tribal governments should not adopt approaches to enforcement which will be difficult to accomplish, which will create divisiveness and dissension on and off the reservation, and which will hold the government up to ridicule.

In the **pre-application, application, and initial decision stage** and at the most general level, the code should define research, declare that the code applies to the defined activities, establish the actions that should be taken by all who would undertake such activities within the prescribed jurisdiction of the tribal government, and describe the consequences of violation, that is, the enforcement mechanism or the sanctions to be applied to anyone who would undertake research activities in violation of the code. The code will probably require a tribal license or permit, and prescribe as a civil matter that anyone conducting research on the reservation without a tribal permit would be subject to a civil fine or be excluded from the reservation or both, and the research data confiscated.

The IRB process provides an excellent framework for the definition of the rights of human subjects and the power of governments to enforce these rights. Governments in recent years have also made great strides in defining and protecting interests in intellectual property, which is a close analogy to tribe's interest in protecting cultural and religious information.

The United States and many other countries have important principles protecting intellectual freedom and the right of free inquiry. Broad government regulations which enable governments to suppress intellectual activity after the fact, if, for example, officials don't like its content, would be difficult for many people to support. Tribal regulations focused on procedures, that is, how the research is conducted, will be least controversial. If a researcher refuses to agree to tribal procedural requirements, permission to work on the reservation can be denied. If a researcher agrees to the procedural requirements and then fails to comply during the period when he/she is working on the reservation, the regulations may provide that the tribe can:

- cancel the license or permit;

- stop work on the project;
- expel the researcher from the reservation permanently or for a defined period;
- fine the researcher;
- require the researcher to forfeit a required bond;
- notify (or file a formal complaint with) the researcher's sponsoring institution, funding agency, IRB, professional association and peer researchers.

As in any community, policies may change with the change of government on an Indian reservation. For the sake of stability and reputation of the tribe, it may be advisable for the tribe to include some sort of protection for the researcher in the event that a subsequent administration seeks to cancel the research even though the researcher has complied with all provisions of his/her original license to conduct research. Sufficient protection may be provided if sanctions must be enforced in tribal court, where due process of law should ensure fair treatment of the researcher from political interference. But the tribe may also want to include a contractual provision protecting the researcher who in good faith has complied with all requirements.

When the project has reached the **post-research** stage and after the on-reservation research has been completed, researchers commonly return to their offices or universities to analyze the data and write their conclusions and, if appropriate, recommendations. At this stage, tribal enforcement is most difficult because the researcher is outside the territorial jurisdiction of the tribe. A tribal government order, such as an enforcement order in tribal court to seize documents or prevent publication, would have to be enforced through an off-reservation court, probably a state court where the researcher is located. Enforcement of tribal court orders by state courts is increasing slowly and should increase even more so in the future. But in any situation where a court is being asked to enforce the orders or actions of another jurisdiction, it is most comfortable enforcing those actions that are familiar and more or less consistent with those of the enforcing court. On the other hand, if the order being enforced involves policy issues that are unfamiliar, unusual, controversial or inconsistent with the public policy of the enforcing jurisdiction, the court may decline to enforce the order.

Where a tribal government is asking a state (or federal) court to enforce a tribal court order seizing data or preventing publication, the tribe must take great pains to convince the court that its order should be given effect, especially in light of the strongly-expressed public policy in federal and state governments in favor of publication.

The federal Central Intelligence Agency has long had the practice of requiring its employees to sign a contract agreeing that any publications they write during or after their employment with the Agency will be reviewed by the Agency and

amended as required or, if necessary, permission to publish will be withheld if the Agency insists. Although this contract has been upheld and enforced by federal courts, it can be expected that non-Indian courts will be more sympathetic with the national security interests of the United States, however broadly defined, than with the interests of an Indian tribe.

Nevertheless, as part of the application and approval stage, tribal regulations may require in some cases that researchers sign a contract agreeing to certain tribal rights and prerogatives which will protect tribal interests at stages of the process where the researcher is not within the physical jurisdiction or control of the tribal government. The tribe might also want to consider having the contract joined by the researcher's sponsoring organization (the university for which she/he works, for example) and the funding source. Such a contract will make it clear in the course of subsequent enforcement proceedings that all concerned knew and agreed in advance as to the scope of tribal and individual rights that were to be protected.

VII. THE MODEL TRIBAL RESEARCH CODE

001. TITLE.

This code shall be known and cited as the "Tribal Research Code".

002. LEGISLATIVE FINDINGS AND POLICY.

The _____ Tribal Council recognizes the value of medical, social and physical science research to the _____ Tribe, to the Indian people, and to society generally. The _____ Tribal Council, accepting the Tribe's responsibility to bear a fair share of the burdens and risks of research along with other communities, must also act to protect the safety and well-being of the individuals subject to the Tribe's jurisdiction. The _____ Tribe also has a fundamental policy to protect and preserve the culture of the _____ Tribe and to ensure that activities permitted on the _____ Reservation are conducted in a way that does no harm to the culture of the _____ Tribe. The _____ Tribal Council has found that research has been conducted in ways that do not respect the safety and human dignity of human subjects and that do not recognize the legitimate interests of the _____ Tribe in the integrity and preservation of its culture and religion.

003. PURPOSE.

The purpose of this code is to define tribal research policies, and to establish a means by which tribal research policies will be administered by the tribe and to provide for procedures by which the _____ Tribe will grant permission to researchers to conduct research on the _____ Reservation. The Code provides:

- A. An application and permitting procedure with which applicant researchers must comply in order to obtain permission to conduct research of any kind on the _____ Reservation;
- B. Standards of conduct designed to protect individuals, communities and the tribe itself from improper research procedures;
- C. Provisions to protect the rights of individuals and the Tribe in data;
- D. Provisions to ensure appropriate Tribal and community participation in the design and evaluation of research, and appropriate local opportunities in employment in all research projects permitted on the _____ Reservation.

004. SCOPE AND NATURE OF CODE.

- A. This code is civil in nature and hereby amends all existing tribal legislation inconsistent with it.
- B. This code shall apply within the exterior boundaries of the _____ Reservation. It shall also be enforceable outside the boundaries of the Reservation as applicable law permits with respect to research conducted on the _____ Reservation or research using materials as to which the tribe has a claim of ownership.
- C. This code shall apply to all persons subject to the civil jurisdiction of the _____ Tribe, including members and non-members, Indians and non-Indians and other corporate and institutional persons who or which might undertake to conduct research on the _____ Reservation.
- D. This code is adopted pursuant to the Constitution and Bylaws of the _____ Tribe, in the exercise of Article __. Powers. Specifically, this code asserts the Tribe's power to provide for the welfare and safety of the _____ Tribe (Article __, Section/Clause __), the Tribe's power to tax and regulate business conducted on the _____ Reservation (Article __, Section/Clause __), and the Tribe's power to exclude non-members from the Reservation (Article __, Section/Clause __).
- E. This code shall apply to all research (as defined elsewhere in this code) conducted on the _____ Reservation, whether involving human subjects or not, and all research regarding materials wherever located as to which the _____ Tribe has a claim of intellectual, cultural or other ownership, legal or equitable.

005. DEFINITIONS.

- A. RESEARCH is the use of systematic methods to gather and analyze information for the purpose of proving or disproving a hypothesis, evaluating concepts or practices or otherwise adding to knowledge and insight in a particular discipline or field of knowledge or to demonstrate or investigate theories, techniques or practices. For the purpose of this code, research includes:
 - 1) Basic and clinical research;
 - 2) Behavioral studies;
 - 3) Anthropological and archaeological studies;
 - 4) Feasibility and other studies designed to evaluate or test programmatic techniques or to develop basic data in all phases of public administration.

[Commentary - In this section, the tribe should define any other terms whose meaning might not be obvious to the community, to individual tribal members, or to researchers.]

006. UNLAWFUL ACTS.

It shall be unlawful for any person to conduct research on the _____ Reservation (whether involving human subjects or not) or with respect to materials wherever located as to which the _____ Tribe has a legal or equitable claim of intellectual or cultural ownership unless the researcher has obtained a permit as specified in this code. Failure to obtain a permit or to abide by its terms shall result in the penalties and sanctions specified in this code.

007. ADMINISTRATION.

The _____ Department of the _____ Tribe is hereby designated as the administrator of the Tribal Research Code.

OR

{The _____ Committee of the _____ Tribal Council is hereby designated as the decisionmaking body under the Tribal Research Code. The Committee shall perform its functions with staff and administrative support from the _____ Department of the _____ Tribe.}

OR

{There is hereby established a Tribal Research Review Committee to approve research submitted pursuant to this code. The Committee shall be composed of ***** MEMBERS BY ORGANIZATION, OFFICE, ETC. ***** The Committee shall receive staff support from the _____ Department of the _____ Tribe.}

008. INFORMATION TO BE PROVIDED.

The code administrator shall prepare the appropriate application forms and shall develop a review process which adequately implements the intent of this code and which provides fundamental fairness to each applicant for a permit. At a minimum, the following information shall be provided by an applicant researcher in support of an application for a permit.

- A. Description of the nature of the research being proposed, including the goals and objectives and the type of information that will be sought from individuals or other participation involving individuals (including the donation of samples), the type of information concerning the culture, religion and customs and practices of the _____ Tribe, either historical or contemporary.

- B. Description of other related research and justification why the research should be done on this reservation at this time.
- C. Expected benefits of the proposed research, including immediate and long range benefits to: the science or discipline represented in the research; the sum total of human and scientific knowledge; human subjects or participants; the _____ Tribe; the Indian people generally; and society generally.
- D. Risks associated with or inherent in the research, including risks to the physical or psychological well-being of individual human subjects or participants and risks of deleterious impact on the cultural, social, economic or political well-being of the community. The assessment of risk will also address the steps that are being taken to minimize the risks and the ameliorative and curative steps that will be taken in the event the research causes actual harm to participants or others.
- E. Assurances of confidentiality of data as appropriately applied to individuals and, where necessary, to families, communities and the tribe itself. The applicant shall: provide assurances of confidentiality for the life of the project; indicate how confidentiality will be protected after the project and for how long; indicate where raw data and other materials will be deposited and stored at the completion of the project; and indicate the circumstances in which confidentiality may be breached by legal or contractual obligations of the researcher.
- F. Who will own the data from the research? What control will the individual research participants have over the use of their own data? What control will the tribe have over the current and future use of the data, and how will the control be exercised? What control will the tribe have over publication and other dissemination of results?
- G. Who will own specimens -- human biological material -- from the research? What control will the individual research participants have over the use of their own specimens? What control will the tribe have over the current and future use of the human biological material, and how will the control be exercised?
- H. Opportunities for the tribe, individual subject communities and individuals to have the research project fully explained to them and opportunity to comment on the research; opportunities for the tribe, communities, and individuals, as appropriate, to receive periodic reports on the progress of the research and to comment on periodic and draft final reports, the burden under this code being on the researcher to show that tribal, community, or individual input would be inappropriate.
- I. Provisions for Indian and local preference in employment in all phases of the project, including both on and off-reservation phases. The priorities in Indian preference shall be: 1) tribal members; 2) Indians generally; 3) local residents.

- J. Willingness of the researcher to involve the tribal community college in the research and specific steps that will be taken, including using the tribal college library as a depository for data (with specific safeguards to preserve confidentiality).

009. ENFORCEMENT.

This code shall be enforced in the following manner.

- A. No research shall be done on the _____ Reservation or otherwise subject to this code unless the researcher has first received a permit from the tribe according to the procedures specified herein. Any violation of this provision shall be subject to the sanctions provided in this section. Where circumstances indicate, particularly where off-reservation enforcement of tribal rights and interests may be of special importance, the researcher, his/her sponsoring institution, her/his funding source, may be required to sign a contract with the _____ Tribe specifying contractual tribal rights in data or materials or with respect to ultimate publication. When such a contract is required, applicant researchers will have the burden to show that it is not necessary or that alternate acceptable mechanisms exist and are adequate for tribal purposes.
- B. Any researcher conducting research on the _____ Reservation without a permit or otherwise in violation of this code shall be subject to permanent expulsion from the _____ Reservation or expulsion for a term as determined by the Tribal Court of the _____ Tribe in accordance with the _____ Tribe's general exclusion ordinance [citation to ordinance].
- C. Whenever it appears that a person has violated, or is violating, or is threatening to violate any provision of this act, the (administrator) (prosecutor) (attorney general) or (an aggrieved person) may file a civil suit in tribal court to enforce this act.
- D. In any action brought for violation of this act, the court may grant injunctive relief, including a temporary restraining order, temporary injunction, and permanent injunction, to restrain the person from continuing the violation or threat of violation. The court may order restitution, civil penalties not to exceed \$ _____, and such other relief that may be necessary to redress any injury suffered by any person, family, organization, or community resulting from the violation. (The prevailing party in such a legal action shall be awarded court costs.)

[Commentary - The Tribal rules of civil procedure should include provisions setting out the procedure for deciding petitions of injunctions, including restraining orders, temporary injunctions, and permanent injunctions. Provisions also should set out how the court is to proceed if the petitionary party seeks the court's temporary order and does not wish to give

notice of the petition to the defending party until the property is seized and safeguarded. For example, the following or similar language may be used in a court rule:

(No writ may be issued directing the immediate seizure, sequestration, or attachment of personal property, ... without written or oral notice to the adverse party or the party's attorney unless:

- (1) it clearly appears from specific facts shown by affidavit or verified petition that immediate and irreparable injury, loss, or damage will result to the tribe or applicant before the adverse party or the party's attorney can be heard in opposition; and*
- (2) the applicant's attorney certifies to the court in writing the efforts, if any, which have been made to give notice and the reasons supporting his claim that notice should not be required. Further, no order allowing seizure will be issued unless security, in an amount and form satisfactory to the court, is given for the payment of such costs and damages that may be suffered by the adverse party; provided, however, that for good cause shown and stated in the (petition), the court may waive security unless it is required by law.)]*

010. NOTICE TO OTHER PERSONS OR INSTITUTIONS.

If a petition is filed pursuant to this act, notice shall be given to the research project's sponsoring organization and/or funding source. If a judgment is entered against the persons conducting the research project subject to this act, notice of the judgment shall be given to the project's sponsoring organization and/or funding source as well as to the professional organization or licensing agency of the person conducting the research.

CHECKLIST FOR INDIAN HEALTH BOARDS

SUPPORT OR APPROVAL OF RESEARCH PROPOSALS

The governmental power to regulate activities on Indian reservations lies primarily in the tribal governments, secondarily in the federal government. Many tribes have Indian Health Boards, but few if any of these boards have been formally chartered as public agencies (similar to Housing Authorities, for example) and delegated governmental power. By common understanding, they have often been understood as speaking for the tribe on health-related matters and they often serve as the principal channel of consultation between the Indian Health Service and the tribe. Thus the approval or support of Indian Health Boards (IHS) for proposed research projects is often sought by researchers, both within and outside IHS, as a means of demonstrating community support to funding agencies and strengthening a research proposal when Institutional Review Board (IRB) approval is sought.

This Checklist is adapted from the MODEL TRIBAL RESEARCH CODE, developed by the American Indian Law Center, Inc. Health Boards are often concerned about the impact of their approval or support of proposed research, particularly where the tribal council has not provided standards or guidelines by which the Health Boards can act. This concern is increased in the case of a multi-tribe Health Board where the interests of several or sometimes many tribes must be balanced. The checklist provides a set of questions that may be asked of the research proponents by the Health Board and a set of considerations which the Health Board may want to address during its deliberations.

We recommend that the MODEL TRIBAL RESEARCH CODE and attached materials be studied by the Health Board, so that a more detailed checklist can be developed which meets the needs of the tribes to be served.

CHECKLIST

- ___ What is the nature of the research (medical, social science, psychological, etc.)?
- ___ What are the goals and objectives of the research?
 - ___ What do they want to prove or disprove?
 - ___ Is it or can it be stated in terms that are understandable?
- ___ What specific kind of information are they seeking?
- ___ How will the information be obtained (interviews, access to individual records, blood or tissue samples, periodic tests while the research subjects are in the process of taking medication or in the course of some other process - exercise, etc.)?
- ___ What are the expected benefits of the research:
 - ___ To the tribe and the local community?
 - ___ To the individual research subjects?
 - ___ To society as a whole (including the totality of knowledge and understanding)?
- ___ What are the risks associated with the research:
 - ___ To the tribe and community (including the possible impact on cultural and community integrity)?
 - ___ To the individual human subjects?
 - ___ To society as a whole?
- ___ What steps will be taken to minimize the risks?
 - ___ Are human subjects fully informed of the risks?
 - ___ Are human subjects fully informed of their rights in case of harmful effects of the research; their right to treatment, compensation, etc.?
- ___ What steps will be taken in case something goes wrong with the research?

- ___ Who is liable in case something goes wrong with the research that is harmful to the research subjects or others, including families and the community?
 - ___ Are the funding and sponsoring agencies liable along with the individual researcher?
- ___ What are the assurances regarding the confidentiality of data?
 - ___ Regarding individual subjects:
 - ___ Subsequent use of data by other researchers?
 - ___ Conditions under which individual data might be released (court order, etc.)?
 - ___ Range of protections (*e.g.*, at which stage of the research will names of individuals be separated from data; will there be research involving individual data after that stage, which will be anonymous)?
 - ___ What are the assurances of enforcement of these promises of confidentiality?
 - ___ Regarding the tribe or community:
 - ___ Will the tribe or community be identified in the research report?
 - ___ Are there areas of possible research which might, because of their cultural sensitivity, require special consideration or permission by the tribe?
 - ___ Are there research techniques that might create special problems with the tribe or community because of cultural considerations?
- ___ Ownership and control of data from the research:
 - ___ How will the tribe's interest in its cultural and community heritage for its future generations be protected?
- ___ Ownership and control of human biological material from the research:
 - ___ How will the tribe's interest in its cultural and community heritage for its future generations be protected?
- ___ Tribal Participation:

- _____ Has the tribe or community had the opportunity to review and comment on the research proposal prior to its being presented to the Health Board?

- _____ Will the Health Board, the tribe, or the community have the opportunity to review and comment on preliminary results and draft reports of the research?

- _____ Will the researcher agree to attempt to satisfy tribal, Health Board, and community concerns in final drafts and the final report?

- _____ Where does the proposed research fall along the following spectrum?
 - (1) "Safari" or helicopter research, in which the researcher drops into the community, gathers the data, then leaves with the data for good;
 - (2) "Show and Tell" research, in which the researcher comes back to report the research results to the community;
 - (3) The tribe and the researcher agree that in exchange for the tribe's approval of and consent to research in the community (in addition to the essential consent of individual research subjects), certain additional services or benefits will be accorded to the tribe or community by the researcher;
 - (4) As part of the project, the research increases the capacity of the tribe or individuals, *i.e.*, improves the capabilities of the tribe to deliver services or do its own research, trains individuals to work in research projects or conduct their own research;
 - (5) The researcher and the tribe are partners in the design, execution, analysis and reporting of the research; with its own capacity the tribe contributes resources and ideas that contribute significantly to the research.
 - (6) The tribe determines its research priorities, and initiates the research. It calls in researchers as needed to be partners or consultants in the design, execution, analysis, and reporting of the research.

_____ Tribal Rights:

- _____ Is tribal control over sensitive personal, community, cultural and religious information recognized?

- _____ Are the research, sponsoring and funding organizations willing to be bound contractually to ensure the protection of tribal and individual rights and interests?

- ___ Is the researcher willing to attempt to employ local people in the research?
 - ___ Is the researcher willing to attempt to find means of using local people and resources rather than import all resources?
- ___ Is there a tribal college or other tribal institution that might be interested in this research?
 - ___ Is the researcher willing to work with them?
- ___ Is the researcher willing to deposit the raw data in a tribal or tribally-designated repository or otherwise share the data with the tribe?

The Health Board is urged to add questions to the checklist as more is learned about research proposals and about tribal and community concerns about and reactions to research conducted on reservations. Health Boards are also urged to make clear to researchers, tribal councils, and IRBs the nature of their deliberations and the limits which the Health Board may want to place on their roles. That is, Health Boards have expressed a concern about their support for a project being used to convince tribal councils or communities to support a project, or to convince IRBs that research proponents have done more community consultation than they in fact have.