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Community
Participatory
Research:

Enhancing
Partnerships with
the Native American
Community



This guidebook is a product of the Arizona Biomedical Research Commission

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PREFACE

Underserved populations in the U.S. including members of minority populations and the elderly have not benefited from the investments made in the nation's healthcare system. As a result, it has become a national initiative to engage underserved populations more effectively in translational research and clinical trials as one component of improving the health and well being of underserved populations.

In the fall of 2004, the Arizona Biomedical Research Commission and the Flinn Foundation convened a working group of representatives of leading healthcare and research organizations in Arizona to identify key issues that hinder or discourage members of underserved populations from engaging in translational research programs.

This working group identified Community-Based Participatory Research as the foundation for developing collaborative, team based engagements among their organizations and communities in Arizona. Native Americans communities were chosen as the initial focus for this initiative. This document is the culmination of one of the goals of this initiative—the creation of a handbook to familiarize and guide investigators in the principles and applications of Community-Based Participatory Research.

The handbook is the product of the efforts of many individuals, both local and national. One on one interviews, conferences, focus groups engaging community leaders and examination of publicly available information were used to inform the development of the handbook. Appendices present templates developed by other organizations that can serve as the basis for discussion by Arizona investigators and community leaders. The information presented in this handbook is intended to provide guidance for productive dialogue(s) among parties and should not be construed as the “final word.”

The handbook is, and will continue to be, a living document—flexible and dynamic in its organization and content in response to the evolution of partnerships and activities.

The existing document is a working draft developed as the initial best effort. We recognize that input from tribal and community leaders is essential prior to distribution in order to ensure that the document reflects the views and needs of the community. For this reason, we request your assistance as reviewers by providing your comments and suggestions for improving the current version.

SUMMARY OF RECOMMENDATIONS FOR ENHANCING COMMUNITY-BASED TRANSLATIONAL RESEARCH IN ARIZONA

BEST PRACTICES

- Establish a long-term commitment by all partners.
- Recognize and acknowledge the community as a valuable and contributing partner, and create the means for the community to participate in the research activities, and work to build capacity within the community for the mutual benefit of all partners.
- Facilitate collaborative, equitable involvement of all partners in all phases of the research and in decision-making regarding the activities.
- Integrate knowledge and intervention for the mutual benefit of all partners.

KEY LESSONS FOR ARIZONA FOR THE ENHANCEMENT OF COMMUNITY-BASED PARTNERSHIPS THE NATIVE AMERICAN COMMUNITY

- Develop structures and processes that facilitate the trust and the sharing of influence and control among partners.
- Build the capacity of all partners.
- Plan ahead for sustainability.
- Be inclusive on all decisions regarding the communication of project results.

INTRODUCTION

There is a health crisis facing the Native American community. The disparities in health status are staggering.

Native Americans suffer disproportionately from diabetes, alcohol-related deaths, injuries, and suicide.¹ Native Americans have the highest prevalence of Type 2 diabetes in the world and rates are rapidly increasing². Native Americans are 770 percent more likely to die from alcoholism, 650 percent more likely to die from tuberculosis, 420 percent more likely to die from diabetes, 280 percent more likely to die from accidents, and 52 percent more likely to die from pneumonia or influenza than the rest of the United States, including white and minority populations.³

A key component of these high levels of health disparities reflects differences in lifestyle as well as a lack of access to quality and timely healthcare services for Native Americans. In March 2002, The Institute of Medicine (IOM) published a report on healthcare disparities that made suggestions for reducing and eliminating these disparities.^{4 5} Based on this report, the U.S. Department of Health and Human Services (HHS) issued its report on

National Healthcare Disparities in 2003 that, while minimizing some of the conclusions of the IOM report, does discuss the complexity involved in solving the problem of health care disparity. “There are differences in the care-seeking behavior of patients, which vary due to differing cultural beliefs, linguistic barriers, degree of trust of health care providers, or variations in the predisposition to seek timely care. In addition, the availability of care is dependent upon such factors as the ability to pay for care (directly or through insurance coverage), the location, management and delivery of health care services, clinical uncertainty, and health care practitioner beliefs, among others.”⁵

But addressing health care access alone will not fully address the problem of health disparities for underserved populations. As the HHS report further explains, there are “different underlying rates of illness due to genetic predisposition, local environmental conditions, or lifestyle choices.” In fact, there is a growing body of research on the complex interplay of environmental and genetic factors contributing to the health disparities for Native Americans. For example, there is evidence of a genetic basis for the susceptibility to Type 2 diabetes for both Pima Indians. The existing evidence raises the

possibility of finding populations-specific molecular targets (enzymes, receptors, substrates for new drug development).⁶

Even more revealing on the challenges to treating diseases found among Native Americans is the different responses to standard drug treatments than whites.⁷

This growing body of evidence linking environmental and genetic factors to differences in health outcomes suggests the significant value that translational research targeted to these underserved population groups can have in improving the detection, prevention and treatment of specific diseases that disproportionately affect Native Americans. Translational research links the discoveries of the research bench to the development of better diagnostic methods, therapeutic products and preventive processes that improve healthcare outcomes. More specifically, translational research programs can help in understanding the contributions of the various factors to health disparities by addressing the following issues:

- Identification of genetic vs. environmental effects on disease etiology;
- Use of genetic and metabolic profiles to better the design and delivery of

drugs and other treatment modalities for specific population groups; and

- Development of preventive medicine procedures to help minimize healthcare disparities.

But translational research targeted to Native Americans can only be effective if performed within a framework that considers the real world differences in culture, broader community needs, socioeconomic status, and structure of health care delivery for these communities. Defining this framework and putting it into practice is at the heart of developing a “community-based participatory research model” for Arizona.

DEVELOPMENT OF HANDBOOK

This handbook is a first step in helping to develop guidelines to inform the advancement of translational research within the framework of a community-based participatory research model in Arizona for Native American Tribes.

The handbook is organized in five sections:

- **Section One** considers the Arizona situation in collaborations with the Native American community and the state of preparedness of the research community.

- **Section Two** provides an overview into the concept of Community-Based Participatory Research
- **Section Three** examines several of the best practices models and key lessons relevant to the Arizona situation.
- **Section Four** advances a framework for implementing Community-Based Participatory Research with model research codes and templates developed by other organizations included in the appendices to provide guides for further discussions and development of Arizona specific approaches.
- **Section Five** sets out recommendations for statewide activities to support the development of CBPR in Arizona.
- Link the knowledge gained from research on environmental and genetic contributions to the development of more effective treatments for diseases based on gender, ethnicity and/or age.
- Be culturally sensitive and responsive to the needs of special populations that can be addressed by research as opposed to those projects that provide value only to the investigator.
- Create mechanisms that will enable researchers to develop and work in true partnership with special populations. Key mechanisms will include cultural sensitivity training, academic tenure policies, capacity building and revenue sharing policies.
- Increase both federal (and state) funding that is more responsive to specific goals of Community-Based Participatory Research.

The development of this handbook is an outgrowth of the Arizona Translational Research Pathway project sponsored by the Arizona Biomedical Research Commission and Flinn Foundation. A Work Group of translational research leaders engaged with underserved populations was organized to determine how Arizona could go about building a stronger foundation for collaborating with underserved population groups.

The Work Group began with a focus on determining the best ways to:

The Work Group agreed that these goals were best accomplished within the framework of advancing “community-based participatory research” (CBPR) in Arizona on a statewide basis. This, in turn, requires that community representatives be actively involved in shaping the requirements and implementation of a tailored approach to community-based participatory research

for Arizona. Although many institutions have made efforts to engage in CBPR, there has not yet been an initiative to engage community leaders in a coordinated, ongoing statewide program that would build a sustainable process for CBPR in Arizona. This handbook is one part of that process.

Valuable guidance in the shaping and development of this handbook has been provided by the Native American community, the Inter-Tribal Council of Arizona (ITCA).

**SECTION ONE:
THE ARIZONA SITUATION**

To help set the stage for tailoring an approach to community-based participatory research for Arizona, it is critical to be guided by an understanding of the situation on-the-ground facing the research community and the Native American community. On the positive side, there is experience in researchers working with the Native American

community to advance together disease-focused research that will develop more effective healthcare for members of the community. But the unique challenges for all parties involved of conducting translational research emphasizes the need for a new compact to make community-based participatory research a reality in Arizona.

Below is a summary of the challenges and views of each of the major participants involved.

Figure 1: Representative Efforts of Arizona Institutions to Engage in Translational Research with the Native American Community (Developed in 2006)

As of 2006, many institutions in Arizona have ongoing programs with the Native American community.		
Institution	Selected Initiatives/Projects Underway*	Approach to Improving Engagement
Sun Health Research Institute	Member of Alzheimer's Consortium, Work with elderly of Native American Tribes in Alzheimer's	Designated liaison for community interactions Development of educational materials to assist community in providing healthcare for elderly members
TGen	Member of Alzheimer's Consortium, work with Salt River-Pima Tribe on diabetes, member of Southwest Indian Cancer Network.	Leadership, financial commitment, on-the-ground community commitment, educational programs for community
Mayo Clinic Cancer Center	Provides research training for Navajo Community College.	Leadership, financial commitment, dedicated liaison to link community with appropriate investigator
Barrow's Neurological Institute	Works with Alzheimer's Consortium,	Leadership, financial commitment, bilingual staff, works with caregivers, gives talks in community
Southern Arizona VA Healthcare System	Arthritis Centers in Phoenix and Tucson for Native Americans, Home Buddies for home based primary care, Alzheimer's and Diabetes programs	Strong community involvement and volunteerism; home-based care intervention
Northern Arizona University	Numerous educational and training programs, economic development programs, environmentally linked research, member Southwest American Indian Cancer Network	Institutional commitment; coordinating center for ease of access
University of Arizona	Lead on Southwest American Indian Cancer Network Grant (Arizona Health Sciences Cancer Center), Center for Health Disparities, Diabetes Prevention and Control,	Coalition building; established community health workers organization; centralized assistance to faculty; shared services across projects; bilingual staff.

RESEARCH COMMUNITY SITUATION

Many Arizona biomedical research institutions are actively involved in translational research programs with Native Americans. Figure 1 summarizes many of the activities ongoing in Arizona today, with greater detail presented in Appendix I. Many of these initiatives are promoting exciting innovations to improve the ways of engaging researchers and the underserved communities.

Problems and Barriers to Address

Researchers and their institutions continue to face significant barriers to working with the Native American community.

From the perspective of the individual researcher, community-based participatory research is a time-intensive effort fraught with delays. In many cases, each researcher needs to establish their own relationship with the community. This often means learning as they go what it means to be culturally sensitive and responsive to the needs of the community. Typically it can be more than 18 to 24 months to project launch.

From the perspective of the research institution, Arizona's efforts in collaborating with underserved Native

American community are currently highly fragmented. No mechanism(s) exists to support the scale up of efforts or to learn from best practices. Newer entities trying to establish programs find that they are often less than successful due in part to a lack of understanding of the complex issues involved.

Currently, Arizona institutions need to overcome:

- Disjointed efforts both among and within institutions. There is no system or infrastructure to help researchers and institutions in Arizona work together.
- A level of distrust in among Native Americans due in part to a lack of cultural sensitivity and true partnership on the part of investigators.
- Poor communication and dissemination of knowledge gained as a result of the research to the community.

The missing spark is a predictable, community-led effort to engage with the research community.

TRANSLATIONAL RESEARCH WITH THE NATIVE AMERICAN TRIBES OF ARIZONA

Native American tribes are becoming more aware of the possibilities of translational research as a key complement to the provision of health care to their Native American communities.

Many of the existing activities in translational research with Native American communities in Arizona have occurred not with the partnership of Native Americans, but with their permission. Examples include:

- **Cornell** – the Many Farms project that investigated tuberculosis in the Navajo tribes.
- **NIH** – a twenty five year project with the PIMA Indians examining diabetes.
- **Johns Hopkins University** – an investigation of pediatric gastroenteritis and dehydration in White Mountain Apache.

New, more participatory approaches are being developed in Arizona. Leading efforts in advancing participatory research include:

- Native American Research Centers for Health (NARCH) led by the Inter

Tribal Council of Arizona. This cooperative program uses funds from research agencies such as the National Institutes of Health and the Agency for Health Research and Quality to support developmental and pilot research activities and research training at Tribes, Tribal Organizations, and Indian Health Boards. Goals include developing community-based capacity such as Native American health professionals and scientists, enhancing partnership activities and encouraging research linked to the health priorities of the community and to reduce health disparities.

- The Southwest American Indian Cancer Network which includes the University of Arizona, Arizona State University, the Phoenix Indian Medical Center, TGen and ITCA in a inter-institutional program. The goal of the network is to promote the development of Community-Based Participatory Research in Indian country including working with communities and researchers to develop fundable pilot projects for the cancer network project (funded by NIH).
- TGen-Salt River Pima Maricopa Indian Community Collaborative Agreement. The partners are working

together to identify and design research projects that will address the genetic basis of disease and develop educational programs.

- Northern Arizona University is working with Indian tribes to investigate observations made by the Native American community related to the environmental effects on the health of community members both directly and indirectly through effects on their livestock.

Understanding of Structure of Native American Tribes Is Critical to Advancing Translational Research

It is essential to remember that Native Americans are members of sovereign nations. Approval of the tribal government is central to any research project.

In addition to their ability to protect the rights of individual members, tribal governments also serve to protect the collectively-held rights of the tribe as a whole. The notion of group rights, particularly those that may be paramount to individual rights, is sometimes very foreign to those living in the mainstream culture, which usually assumes that rights and property are to be held by individuals and that all property can be alienable. However, American Indians, and many cultures

worldwide, continue to recognize certain areas in which the concerns of the group are paramount to those of any individual.⁸

National authorities acknowledge the complications involved in working closely with members of the Native American tribes.

There are many different American Indian cultures in the United States, and these cultures can differ from those of the mainstream culture in many, sometimes unexpected, ways. It would be virtually impossible for any researcher to anticipate all the factors that an individual American Indian would deem important in deciding whether to participate in a particular study. That is why it is important that American Indians be educated as much as possible about a study before they are asked to participate. In the field of genetics, the necessary education includes information about how samples are handled before, during, and after the research, and what the final product of the research is likely to be, in addition to education about the particular study.⁹

Native Americans are not a homogenous population—a key point to remember when developing community participation and analyzing project data.

“It is important to recognize that there is no single ‘American Indian Culture’.

Over one thousand tribal groups exist in North American, each with a unique culture and system of beliefs...The application of research findings, or effectiveness of future health-care interventions, will involve cultural issues related to treatment, recovery, and healing¹⁰ as well as the distinctiveness of individual American Indian communities.¹¹

There are 24 sovereign tribes in Arizona —each with its own cultural heritage.

Problems and Barriers to Address with Native Americans

Various concerns regarding previous interactions and research projects have been expressed by community liaisons, caregivers, community leaders and investigators via one on one interviews and feedback provided at various conferences. These concerns have resulted in a level of distrust that threatens to hinder future initiatives. Arizona institutions need to confront this distrust.

At conference convened by the ITCA in October 2005, Native American leaders came together to voice their concerns with translational research initiatives. Several issues were enumerated that need to be acknowledged and resolved

by the Arizona research community, including:

The need for greater involvement of tribal representatives in the study design, implementation, data collection, analysis and evaluation.

Researchers often fail from the outset to engage with the Native American communities in order to understand their needs and obtain their input on topics of relevance to the communities. Other key issues arise in experimental design; and the collection and analysis of data; and the dissemination of results obtained from the project. Native Americans are often suspicious that confidentiality and anonymity will not be sufficiently honored. In addition, researchers often bring naïve understandings to the interpretation of results, especially when seeking to account for cultural impacts. In pursuing research discoveries, it is often inappropriate to assume that the westernized, individual-focused model of self-interest is a primary motivator of Native American participation.

The need for more well-documented approaches for sharing findings with the communities, involving communities in the analysis of the results and ensuring community approvals before publication of study results. Ownership of the data, rights to publication and intellectual property are

also issues that require upfront engagement with the Native American communities.

By fostering greater involvement, researchers can overcome the traditional distrust that so often surrounds translational research activities with Native American communities.

The need for more comprehensive approaches that recognize the larger healthcare picture and issues confronting Native American Indians when developing collaborations with these communities.

Native American Tribes have limited resources for supporting health care and are plagued by high poverty rates. The access to health care among Native Americans is low. There are also significant differences in the incidence of disease and death rates in the Native American community compared to the other communities in the U.S. Still, many healthcare problems in the Native American community can be addressed on a behavioral, preventative level, such as alcoholism, diabetes, and suicides. If not addressed, these persistent health care problems threaten efforts to engage on a greater number of longer term research questions.

Translational research projects can and should be a key source of new health

care resources for Native American communities. Creation of sustainable programs that address the community's health care needs must be a component of translational research activities. In addition, there needs to be better coordination by many partners to develop a body of knowledge on how best to integrate the results of research studies into the community to improve health care.

The need for capacity building to conduct translational research. Native Americans are not simply study subjects. Native American communities are seeking to improve the life of tribal members through translational research. This involves not only employing members of the community as staff engaged in the research studies (data collection, analysis and data communication/dissemination) but also developing the skills of the community to undertake their own translational research.

A major concern among Native American leaders in translational research is how to increase national and state funding for important research projects, while at the same time increasing the number of Native American researchers.

The need for communications. At the heart of translational research with Native Americans must be an active effort to foster respect and open communications. Lack of communication often means that critical information on the health implications of research studies tends to stay in research silos and is not adequately shared with healthcare providers and the community. Poor communication also results in unproductive utilization of resources such as the advancement of competing research programs without adequate discussion.

Many tribes in Arizona are currently developing codes and protocols for conducting research. These will be guidelines for discussion and negotiations. Templates developed by other organizations are included in Appendices III, IV, and V of this handbook. It is important to remember that these templates can be used as the basis and first step in development and discussion of project plans—their use is not a guarantee of approval.

SECTION TWO: OVERVIEW OF COMMUNITY- BASED PARTICIPATORY RESEARCH (CBPR)

The ABRC/Flinn Foundation Special Populations Work Group on Translational Research and Special Populations recognizes Community-based Participatory Research (CBPR) as the foundation for enhancing partnerships with Native Americans. This approach is used by several institutions in the U.S. to support programs with underserved, minority groups. Information about selected CBPR programs is presented in Appendix II.

WHAT ARE THE GUIDING PRINCIPLES OF CBPR?

From discussions with and publications by national leaders in the field of CBPR, four key principles emerge as providing the basis of successful CBPR:^{12,13}

- **Long term commitment** to developing and maintaining trusting relationships of value to the communities. Ongoing communication and support for capacity building within the community is essential.
- **Cultural sensitivity** ensuring that the beliefs, customs, laws and other

aspects unique to special populations and communities are respected and incorporated into any project on an ongoing basis.

- **A true partnership** involving the community in all phases of the project with an active, ongoing dialogue as the project is implemented. Community input into project design, implementation, data analysis and communication of results is essential to successful research projects.
- **Sufficient funding** for completion of the project and with focus appropriate to the needs of the community.

Ultimately, the litmus test of CBPR is ensuring that the rights of community participants are respected and effectively embedded in the process. These rights include:

- Certain rights that are determined by law (for example—privacy rights through HIPPA; human subject protection; federal laws on the sovereignty of Native American Tribes; and state laws on healthcare guardianship, safeguards on personal/medical information).
- Projects/programs that provide benefit to the community.

- Institutional Review Boards that include community members and evaluate human subjects research in light of cultural issues.
- Respect as full partners in the research including input into design, evaluation and information prior to dissemination to external sources.
- Data collection and evaluation processes that accurately reflect the unique characteristics of the community.
- Agreement as to and acceptance of said agreements related to ownership of data and disposal of data and other contributions such as tissue and DNA. Some communities will not allow publication under certain circumstances and any research must be performed as a service to this community.
- Allocation of financial resources that recognize community contributions including indirect cost funds, Intellectual Property royalties, workforce/training funds.
- Hiring policies that support community participation in programs.
- Commitment to and sustainability of programs in order to provide benefit to community.

DEFINING CBPR FOR ARIZONA?

While there is a national movement towards Community-Based Participatory Research, there is no single definition that fits all situations. National leaders in the field of CBPR have found that it is important to understand the historical context and barriers facing a community in order to set out an appropriate definition for that particular situation.

To define CBPR for Arizona, the concept was discussed with Arizona research and community leaders using published definitions as a starting point.

For Arizona stakeholders, an effective working definition of CBPR is:

A collaborative partnership approach to research that involves community members, organizational representatives, academic institutions, state and local public health agencies, health care institutions, funding agencies and researchers in all aspects of the research process. The partners contribute their expertise and share responsibilities and ownership to enhance understanding of a given problem, “foster community and institutional capacity for participatory research at national and local levels” and “facilitate approaches for effectively translating community-based interventions in public health and prevention into widespread practice at the community level.”¹⁴

**SECTION THREE:
BEST PRACTICES: EXAMPLES
AND LESSONS LEARNED**

There is a number of examples of leading CBPR programs from across the nation. The focus of these efforts range from disease oriented programs, preventive care programs, and more comprehensive research to health care programs.

Given the focus on translational research, the involvement of university partners is a central attribute, along with the many different funding partners involved.

Table 1 (below) sets out an overview of several of the leading programs found across the nation.

Table 1: Examples of Leading CBPR Programs Across the U.S.

	Partnership Characteristics	Project Orientation	Best Practices
Mature Programs	Extensive integration of research and community		
The Healthy African American Families Project, Los Angeles, CA	Integrates funding agency, community, university participants into a strong partnership with joint decisions and commitment on part of funding agency to be closely involved	Holistic approach to health care needs of community— prevention, intervention, extended care and social support	Hired from community Project was housed in community
Community Action Against Asthma, Detroit, MI	University and community united in addressing asthma in community	Project focused on positive interventions	Community members involved in leadership positions and hired as staff; community hired researcher
Johns Hopkins University, Baltimore, MD	In Native American tribal communities since 1970's, operates community health stations on reservations	Began by addressing healthcare problems/needs of the community (ex., newborn diarrhea)	Summer training program for youths from community. Hires and trains staff from community as outreach workers
Emerging Programs	Early development invested significant time and effort in establishing relationships		
University of New Mexico, NM	Community involved in all stages of planning including initiated contact with university in order to solve community-based problem of dental care	Expanded programs with specific support groups (ex., breast cancer)	University made commitment by convening partnership conference with Native American tribes, IHS and the university to extend interactions
University of Washington, WA	University wide initiatives rather than a focus on any specific population		University commitment to CBPR signaled with published guidelines for CBPR that have been endorsed by Dean and University president. University has centralized advisory committee to interact with community and coordinate communications. Have some funds flow through community organizations to signal partnership relationship

BEST PRACTICE LESSONS

Among the best practice lessons that emerge from these successful examples of CBPR are:

- **Establish a long-term commitment by all partners.** This is seen in the ongoing programs by Johns Hopkins University which began in the 1970's and continue to address specific healthcare problems that result in healthcare disparities among Native American Tribes. Active demonstration of an interest in the needs and concerns of the community over a period of time is merely the first step in establishing a partnership. Developing a community-institutional partnership is inevitably a non-linear process involving many "starts" and "restarts." Interaction with and participation in the life of the community must occur on an ongoing basis.

Community-based partnerships can not be rushed. Time plays a significant role in developing community partnerships and success will be defined differently for each stage of the process. Providing benefits to the community on multiple levels on an ongoing basis should be the prime definition of success. Early stages will be

successful if the community begins to trust researchers and has the opportunity to communicate their needs and concerns. Later stage successes will include research projects that address the healthcare needs of the community and involve the community in the process of solving these needs.

Long term commitments must include funding resources sufficient to support initiatives and projects. It is highly important therefore to maintain close involvement of funding institutions/agency. Funding agencies need ongoing participation in order to understand the progress and alterations that may be requested. Inclusion of the funding agency as a member of the team permits timely and necessary revision of protocols, timelines, and funding needs. This is shown in the Healthy African American Families Project that integrated the funding agency with other participants to ensure alignment of goals and expectations and in the work of Johns Hopkins University which provides institutional support in addition to external funding agencies.

- **Recognize and acknowledge the community as a valuable and**

contributing partner, create the means for the community to participate in the activities, and work to build capacity within the community for the mutual benefit of all partners. This is demonstrated in the Healthy African American Families project which identified key healthcare issues and possible causes, designed preventive measures and provided ongoing support to enhance the overall health of the community. Social and cultural contributions are essential to the successful identification of health issues and implementation of preventive behaviors as well as therapeutic interventions. Without community participation and feedback, long term benefits will diminish over time. Hiring and training community members is found in all best practice institutions and embeds knowledge gained from the project into the fabric of the community to ensure ongoing application and interpretation of research findings.

- **Facilitate collaborative, equitable involvement of all partners in all phases of the research and in decision-making regarding the activities.** Recognizing the strengths and resources within the community enhances the caliber of the research

project by incorporating community knowledge and expertise. This is shown in the emerging programs at the University of New Mexico that are based upon initial outreach from the community. Partnerships have been developed that jointly identify key issues and actions. Equitable involvement is also demonstrated by the Michigan project in which community members are an important part of the information dissemination process-often appearing as co-speakers at conferences and as co-authors on publications.

- **Integrate knowledge and intervention for the mutual benefit of all partners.** This is shown in the work by Michigan university researchers and community leaders in Detroit, Michigan to enhance mechanisms for asthma intervention and ongoing support for patients. Dissemination of key findings and knowledge to all partners provides a positive impact on the health of the community as seen in the prevention of newborn diarrhea in Native Americans resulting from a partnership between the tribal community and Johns Hopkins University.

WHAT IT TAKES TO ESTABLISH AND MAINTAIN COMMUNITY-BASED PARTICIPATORY RESEARCH EFFORTS

Existing CBPR programs can also provide guidance on what it takes to establish and maintain such programs. Based on a two year benchmarking project by The Centers for Disease Control (CDC),¹⁵ it was found that CBPR institutional partnerships differ by:

- Age and history.
- Type of research focus and mission.
- Levels and mechanisms of community participation.
- Staffing structures.
- Geography.
- Funding sources.
- Types of partners involved.

There is no one right way to address who should be invited to form or join a research partnership but it is very important that members have a prior history of positive working relationships. Newer members must be willing to abide by the rules and procedures of the ongoing partnership.

The CDC has recently produced a list of recommendations developed from surveying national leaders in the field of CBPR. These recommendations can

serve as an outline for discussions by investigators and other participants to identify issues that could become barriers and potential methods of resolving them.

There are four key lessons of particular relevance for Arizona:

1. Develop Structures and Processes that Facilitate the Development of Trust and the Sharing of Influence and Control among Partners

Jointly create the mission, vision and priorities for the partnership and jointly develop partnership principles and operating procedures. As with any joint effort, there will be the inevitable conflict and tensions. Procedures and mechanisms based on mutual respect should be included in the initial plan to identify and resolve conflicts before they become barriers to a successful community-institutional partnership.

Community involvement is critical, including participation in: the process of building a shared conceptual model of health and disease; the development of data collection instruments that are relevant, valid and culturally appropriate; data collection processes that enhance response rates and data quality; data analysis; the dissemination of findings and follow-up actions for

incorporation of findings into community action.

These processes require researchers and community partners who are willing to approach problems from each other's perspective.

No one set of principles and procedures are applicable for all partnerships. While partnerships can build upon previous examples, all partnerships must engage in the process of developing, adopting and putting into practice their own principles and procedures that are tailored to the local culture and community context. Such principles and procedures should be reviewed periodically, changed as needed and "codified" for dissemination to new potential collaborators to ensure that any new projects affiliated with the partnership are in compliance.

2. Build the Capacity of All Partners

Develop and implement strategies for capacity building of all partners involved. Strategies should include striving to achieve and invest an equitable distribution of costs, benefits and resources among the partners. This can include the establishment and maintenance of on-site facilities; hiring of community members as staff; purchasing supplies; partnering with

local businesses; and providing training, technical assistance, and continuing education to partners.

In addition, "capacity building and structural changes must occur at the institutional and funding levels so that funding agencies, ethics review boards, and university promotion and tenure committees are informed of and responsive to the necessity of the time needed for trust building, community entry, and the building of sustainable research relationships within an OCAP (ownership, control, access, and possession) era."¹⁶

3. Plan Ahead for Sustainability

Issues of sustainability need to be addressed at all phases of a partnership. Sustainability will require dedication and commitment on the part of both partners in terms of dedicated personnel, time and resources. A key contributing element of sustainability is the engagement of funding agencies to ensure ongoing financial resources. This can be approached by working with funding agencies to increase their understanding of and support for the benefits gained and the resources required by this work. The partnership should routinely send partnership reports, papers, news clippings and other

products to funding agency project officers and key organizational leaders.

4. Be Inclusive on All Decisions Regarding the Communication of Project Results.

Establish policies at the inception of the project concerning the communication of project results. The community must have significant input as to the use and communication of information resulting from the research project. A consensus among investigators and community must be established on many aspects of the communication process prior to any dissemination of results. Key decision points include: the interpretation and implication of project results, determination of which results are to be communicated to third parties, the identity of the third parties, the extent of community participation in the communication of results and the choice of preferred medium of communication.

Successful community-institutional partnerships recognize the contributions of all members often including community members as authors and presenters of the information.

Long term benefits of the partnership can result from the dissemination and translation of research findings that lead to policy change(s). Education of policy

makers requires developing ongoing relationships with policy makers and their staff, developing a policy agenda for the partnership, and creating and disseminating policy briefs that reflect the key issues, findings and recommendations for action.

SECTION FOUR: FRAMEWORK FOR IMPLEMENTING CBPR IN ARIZONA

The objective of this handbook is to advance a framework in which Arizona can go forward in establishing statewide approaches to community-based participatory research, especially with Native Americans. As emphasized previously, the research agenda must be established with community involvement. Participatory research to fulfill this agenda requires attention to the procedural specifics that underpin translational research.

The key elements of the framework include how to address:

- Coordination
- Institutional Review Boards
- Patient Consent
- Data Ownership and Dissemination
- Biological Samples
- Intellectual Property
- Funds Flow

Below is a presentation of each of these specific elements based on discussions with Arizona-based organizations, a review of literature, and an assessment

of best practice models. As mentioned previously model codes and templates related to the key elements of this framework have been included in Appendices III–V.

We also set out key principles for the research community to embrace as they seek to work with special underserved communities.

A. COORDINATION

Why it is critical to implementation:

Coordination of research activities among institutions and with the communities involved is a critical differentiator in the success or failure of CBPR programs. Coordination in the CBPR is a cross-cutting need at all stages.

Key Issues Involved:

Members of the community are not interested in inter-institutional political battles.

A lack of coordination among institutions hinders 1) the development of more effective trusting community-based partnerships due to inconsistencies in the application of the principles of CBPR by various institutions and 2) the development of strategic long range planning efforts by research

organizations and key state and community organizations.

Ongoing community outreach programs, on the other hand, do lead to a positive positioning of the institution within the community—a pre-requisite for successful CBPR projects.

Best Practice Guidelines:

Establish advisory committees both at the institutional and statewide level to formulate long term goals and plans for attaining them.

Hire a dedicated community liaison to facilitate interactions between institutions and the community.

Define (on a preliminary basis at minimum) roles, responsibilities, funds flow and communication plans among institutions prior to initiating dialogue with the community.

Coordinate, communicate and educate all parties of the partnership via community outreach programs including attendance at healthcare fairs, presentations at schools, and use of community-based media.

Further Information on Coordination can be found in:

Appendix I (Model Tribal Research Code), pp 1–24. This document was developed by the American Indian Law Center, Inc. and the first section provides an introduction into problems, regulatory issues, and a discussion of development process and issues involved in developing a research code. Pages 25–29 provide a checklist of key principles for evaluating a project in relation to the issues discussed in the document.

Appendix II (Model Academic Research Agreement) was developed by the Indigenous Peoples Council on Biocolonialism. (www.ipcb.org) The document contains model templates for composing a research contract between Tribal Communities and Academic institutions including definitions of key terms, identification of major issues and cultural, policy needs.

B. INSTITUTIONAL REVIEW BOARD

Why it is critical to implementation:

Any research involving human subjects must ensure the safety of the individual. The federal government has adopted laws and procedures regulating federally-funded and federally-sponsored research to ensure that human subjects are protected. The trust necessary for successful CBPR projects is dependent upon an Institutional Review Board process that acknowledges the involvement of both the community and the individual in the research project.

Key Issues Involved:

IRB policies need to respect culture, language and other restrictions of the community. The Native American community has strong beliefs in community ties and benefits. When research affects Indian tribes, the federal IRB process seeks to include tribal and community representation. IRB applications will need to discuss the benefit(s) of the research to the communities as well as to individual

subjects. Data collection (biological and surveys) must respect the sensitivities of the community. As a result, guidelines related to storage, secondary use and disposal of biological samples are likely to be more complex than many investigators are used to.

Best Practice Guidelines:

- Invest the time up-front to confer with community representatives in the preparation of an IRB application prior to submission.
- Include community/tribal members as reviewing and voting members of IRB committees.

Further Information on IRBs can be found in:

Appendix I [The Indian Health Service Multiple Project Assurance (MSA) for Compliance with DHHS Regulations for the Protection of Human Subjects (45 CFR 46)]. Part 2 of this document, pp 8–16, discusses IHS Institutional Review Boards, their duties and requirements. Part 5 of the document, pp 32–29, provides an IHS Institutional Review Board Checklist with questions to guide the review process. Part 5, p 35, identifies those categories of research that may be reviewed by the IRB through an Expedited Review Procedure.

C. PATIENT CONSENT

Why it is critical to implementation:

Inadequate attention to obtaining truly informed patient consent is a major cause of distrust. In the case of research with tribal members, individual consent is only one step—tribal consent may also be needed. Attendant issues that are not discussed (time commitment, financial costs and compensation) may result in volunteers withdrawing from the study at a later date.

Key Issues Involved:

Language barriers can cause significant confusion—many concepts or disease conditions will not have a corresponding term in Native American culture rendering the process of informed patient consent a difficult process. In addition, condescending behavior/attitudes on the part of the investigator can lead to reluctance on the part of the participant to ask questions resulting in a lack of or an uninformed consent.

Best Practice Guidelines:

- It is essential that this be a bi-lingual process that recognizes the difficulty of appropriate translation.
- Patient Consent materials must be developed with language appropriate to the target audience.
- Inclusion of family/community/tribal members in the process is important.
- Allow sufficient time for examination of the form and questions in order to increase the level of comprehension.

Further Information on Patient Consent can be found in:

Appendix III [The Indian Health Service Multiple Project Assurance (MSA) for Compliance with DHHS Regulations For The Protection of Human Subjects (45 CFR 46)], Part 5, pp 20–31, presents two model templates of Model Volunteer Consent Forms for the Indian Health Service.

D. DATA OWNERSHIP AND DISSEMINATION

Why it is important to implementation:

The lack of inclusion of the community in data acquisition processes, analysis and communication is a major source of dissatisfaction with research projects and a violation of one of the key principles of CBPR.

Key issues involved:

Project design without involvement of the community often results in inappropriate instruments and incorrect data. Data evaluated out of cultural context has resulted in incorrect and damaging conclusions that have not been communicated to the community prior to publication. In addition, project data has often been used for secondary, unapproved projects without permission of the community. Native American Tribes have full ownership of data and there will be occasions when the results of a project can not be published.

Best Practice Guidelines:

Every case is different but it is *essential* to agree up front on issues related to data ownership, confidentiality and dissemination.

Investigators need to take the time to obtain and include community feedback and revisions to ensure data interpretation includes cultural issues and subtleties.

Investigators should also insure that the community understands the results of the research and its implications for their benefit. Provision of links to university, organization libraries will help knowledge transfer independent of specific individuals.

Further Information on Data Ownership and Dissemination can be found in:

Appendix II (Indigenous Research Protection Act, Model Academic Research Agreement)

pp 7, 8, sections L and M, provide possible wording related to these issues.

E. BIOLOGICAL SAMPLES— OWNERSHIP AND DISPOSAL

Why it is important to implementation:

Collection, use, and disposal of biological samples as dictated by the cultural beliefs of special populations is an area that is rarely addressed properly by investigators resulting in serious dissatisfaction (and worse) by research participants.

Key issues involved:

To members of many cultures, biological samples are not mere research reagents.

Many Native Americans believe that an individual must leave the world as whole as when they were born. Storage and disposal of biological samples must respect the cultural beliefs of the community. In addition, secondary use of biological samples is viewed as a separate project and must be approved by the community in order to ensure cultural sensitivity.

Best Practice Guidelines:

Biological samples include tissue samples, DNA, and other materials.

The investigator needs to determine and negotiate ownership of these samples and the limitations and utilization in repositories, and secondary use and development of cell lines.

The investigator also needs to understand cultural beliefs in the disposal of such samples. Native American tribes will require that these samples be returned to the tribe.

Further Information on Biological Samples can be found in:

Appendix I (Model Tribal Research Code), pp 29–34, provides IHS Guidelines for Implementing and Complying with IHS Policy on Specimens.

Appendix II (Indigenous Research Protection Act, Model Academic Research Agreement), p 6, section E, discusses Disposition of Data and Samples; p 8, section M, discusses Data Ownership/Archive; p 9, section 10.2, discusses modifications in data collection; and pp 9–10, section 11, discusses Regulation of Biological samples.

F. INTELLECTUAL PROPERTY

Why it is important to implementation:

The creation of intellectual property (IP) from research activities is often considered a significant success of the project. While not all discoveries have commercial value, there is a significant level of effort required to identify, protect, manage and license intellectual property generated through research activities. In the context of translational research collaborations, the basic issues relating to intellectual property (disclosure, patenting, marketing/commercializing) are compounded by questions concerning the rights to share in IP generated among the collaborating parties. These rights to IP are closely linked with rights to data ownership and publication rights. The community has an ownership share in IP generated as a result of the CBPR research project.

Key issues involved:

Communities are interested in benefiting from research discoveries made through study of their populations. That interest is now extending to the commercialization of research discoveries. Many tribal organizations are just beginning to develop IP policies.

Community interests in controlling the release of information and the right to publish may at times conflict with the need to protect intellectual property. Policies dictated by funding source and the partner organization may result in barriers to some community-based research projects.

There is no short cut to negotiations related to intellectual property—an issue that is likely to become more and more complicated with increasing collaborative research projects. IP generated by research projects is usually owned or controlled by the funding agency. Research investigators and institutions may negotiate allocation of their shares (and their shares only) of the IP. The portion of Community-Based ownership of IP is retained by the community.

While a coordinated effort among Arizona organizations to establish basic policies would be useful it is more reasonable to realize that negotiations will be needed on a case by case basis.

Best practice Guidelines:

Key issues for negotiation include:

- Inventor and institutional designation (a legal determination),

- Ownership and control of research data,

- The decision process for:

Utilization of intellectual property: assigning rights to third, not-for-profit entity, direct licensing to industry, and use as the basis for establishment of company.

Involvement in licensing negotiations, for example: distribution of royalties.

Institutions may need to revise existing intellectual property policies in order to support CBPR projects.

Further Information on Intellectual Property can be found in:

Appendix II (Indigenous Research Protection Act, Model Academic Research Agreement)

pp 7–8, sections L, M discusses Intellectual Property Rights; p 10, section 11.7, discusses intellectual property issues related to biological materials.

G. FUNDS FLOW

Why it is important to implementation:

True CBPR partnerships are more likely to be successful with “open book” sharing of financial resources leading to some level of capacity building for the community.

Key issues involved:

Projects will not be successful if the community believes that the research project has been developed only to acquire funding for and advance the career of the investigator.

Resentment from the community has resulted from projects where “the riches” were not shared. Control of funds by the research organization contributes to a perception of control and superiority by failing to communicate the use of research funds.

Best practice guidelines:

Return of some funds to the community is an important component of CBPR as a sign of true partnership and a road to capacity building. Administration of some awards through a community/tribal

organization is one method of “sharing the wealth.”

Indirect Cost Determination and Distribution: any negotiation about the allocation of funds among partners may require alteration/revision of university policies.

Intellectual Property, Royalties and Other Revenues: allocation of revenues from intellectual property needs to be negotiated at the beginning of the project design; utilization of Intellectual Property may provide the opportunity to enhance business development by community members.

Procurement/Staffing: increased use of local business and employees may be a means of offsetting university-directed Indirect Costs.

Further Information on Funds Flow can be found in:

Appendix II (Indigenous Research Protection Act, Model Academic Research Agreement), p 8, section G, presents wording related to funding and budget issues.

SECTION FIVE: RECOMMENDATIONS FOR AN ARIZONA STATEWIDE APPROACH TO COMMUNITY- BASED PARTICIPATORY RESEARCH

Arizona can best advance a statewide approach to community-based participatory research by:

- Recognizing the rights of community members
- Addressing, statewide, the issues of coordination, funding, intellectual property, IRBs and patient consent, data ownership and distribution and biological samples.

RIGHTS OF COMMUNITY MEMBERS IN CBPR

Research investigators and participants in CBPR need to ensure that the community/participant is entitled to:

- Upfront negotiations and understanding by all partners on key issues related to the specific project;
- A valid project conducted by qualified investigators;
- Respectful treatment of samples and information;

- Periodic updates (if desired) on successes, failures and implications;
- Community involvement including the hiring of local members to be part of process when possible; and
- Inclusion of community participants in presentations and meetings with funding agencies when possible.

It is important for the investigator to remember that one of the returns for their investment in establishing true CBPR partnerships is the increased quality of their research as a result of community input into data acquisition and interpretation.

RECOMMENDATIONS FOR ARIZONA RESEARCH ORGANIZATIONS

In order to establish trust with the Native American community, Arizona research institutions would benefit from coordinated, standardized policies and procedures for a more reliable implementation of CBPR. With consistent base line procedures and policies, time and effort could be invested in more value added negotiations related to project specific issues. The following recommendations would contribute to the goal of statewide implementation of CBPR initiatives.

Coordination of statewide efforts

Establish a Statewide Advisory Committee to facilitate research/community partnerships

Each institution should consider designating a point person/office to facilitate team building and community interactions. When multiple departments/programs are involved with their own representatives—ongoing coordination and communication is essential to support community interactions.

Funding

Establish a pool of funding dedicated to CBPR projects for special populations

Research priorities are often set by funding agencies rather than community needs. Additionally, little funding is available for early stage projects in Community-Based Participatory Research yet it is the early stages that provide the basis for success or failure. A dedicated, ongoing statewide pool of funds that would require application of CBPR principles would provide the incentive and support and time to align research projects with community needs.

Institutional Review Board (IRB)

Develop a pool of Tribal representatives that are available for consultations prior to submission of the IRB application.

The added complexity of IRB applications for projects involving Native American community members demonstrates the need to have a pool of committee members trained in both the technology and the cultural aspects of projects.

Development of a pool of representatives from the Native American community that would advise and serve on a statewide basis would be a valuable coordinating and communication resource. Overlapping terms for these representatives would provide consistency, aid knowledge transfer and accelerate the application process.

Intellectual Property

Historically, research subjects have not experienced immediate benefits from successful research projects. Therapies developed commercially from research projects may be inaccessible to members of special populations due to cost; the financial return on resulting intellectual property in the form of royalties does not find its way downstream. Consequently,

members of special populations are revising their approach to ownership of intellectual property to more actively participate and benefit from commercialization.

Training for Research Community Working with Special Populations

Require that all researchers working with members of special populations utilizing state funding support or conducting research at public universities take a training course.

Training of researchers in CBPR concepts is critical to achieve the required cultural mind set on the part of the research community. Training is an important element for building capacity and ensuring quality control. It may be useful to have such training provided by a third party, which can serve as a more neutral and honest broker of needs from both the researcher's and community's point of view. Identification of key qualifications for participation in CBPR projects would help identify those investigators best qualified to participate and lead sensitive research programs. In addition, a *dedicated residency program and/or qualified mentors* could provide relevant training to physicians and other primary care providers to better engage in research with special population groups.

Key elements of the training program are as follows:

1. Acquire a more holistic mind set

The investigator needs to recognize that communities are dealing with complex issues—many of which will not be solved by the investigator's research agenda. Within the broader social/healthcare context, the research project may not provide value to the community within the time frame expected (or at all). The investigator's funding/career is not the primary concern of the community and a research interest does not automatically translate into value to the community. The balance between intellectual freedom and social responsibility with links between the research and healthcare policy is an important component of CBPR.

2. Gather the right team

Traditional research projects, not involving special populations, typically require only that the investigator research team be competitive for funding from federal and state agencies or foundations. This is not the case in working with special populations, where the community needs to be integrated into the research activity. As a result, investigators are not used to building

teams with members from widely diverse areas of expertise. To participate successfully in CBPR, investigators will need to be more inclusive in their approach.

In order to understand the cultural, legal, social and regulatory issues, it will be necessary to perform a significant amount of due diligence prior to approaching the community. In addition, the complete institutional team is needed early in the process to a) facilitate this due diligence and b) assist in developing and negotiating the project plan. Team members could include research administrators, anthropologists, other social scientists, legal experts, and primary caregivers. Community representatives should also need to be included in early stages of project design and negotiations to ensure a successful project.

In all of this, investigators will need to recognize that *sharing of control and authority is a given*. Be prepared for iterative consent procedures for many aspects of the project—including such issues as manipulation of materials and secondary use of samples (viewed by many communities as a new study). Ongoing communication and management will also be significant time commitments in CBPR. When dealing with tribal governments, it may be

necessary to renegotiate many issues when new members join the tribal council.

3. Use complete and clear language, not jargon

Experts in any area communicate with others in the field by jargon and technical terminology. Other team members and members of the community are not likely to be fluent in what is essentially another language. For example, “Standard procedures” does not provide sufficient information for the research participant to truly understand what is involved in the project. Use plain language and explain fully the concepts involved in the project.

4. Exercise cultural sensitivity

The beliefs and customs of each community must be respected in all aspects of the research project. Commit time to learn about the culture of the community and participate in community events in order to build a trusting, long term relationship.

Many indigenous peoples regard their bodies, hair, and blood as sacred elements, and consider scientific research on these materials a violation of their cultural and ethical mandates. Immortalization, cloning, or the

*introduction of genetic materials taken from a human being into another living being is also counter to many indigenous peoples cultural and ethical principles. Indigenous peoples have frequently expressed criticism of Western science for failing to consider the inter-relatedness of holistic life systems, and for seeking to manipulate life forms using genetic technologies.*¹⁷

Investigators need to take the time to obtain community feedback and revisions to ensure the project design and interpretation of results includes cultural issues and subtleties. One person's "myth" is another's deeply held belief. It is also important that the community understands the procedures and results of research and implications for their benefit. For example, significant educational efforts may be needed for some tests or procedures such as an autopsy.

Probe and clarify your assumptions. Members of the community are receiving their information from many sources. What you assume is common knowledge may not be so. For example, the Indigenous Peoples Committee on Biocolonialism (IPCB) and World Health have issued opinions regarding genetics research and indigenous populations. Not everyone feels positively regarding the human genome

project and other genetics research projects. Be willing to respect diverse opinions and question your own assumptions regarding the value of research to communities and healthcare.

IN SUMMARY

Translational research is the process by which basic science discoveries are advanced into new clinical operations leading to improved health care outcomes. It is increasingly recognized, however, that translational research is not a "one size fits all" endeavor and that certain populations are significantly underserved in the current approach to linking research and healthcare.

As an extension of the current Arizona initiative that seeks to enhance the contributions of translational research to healthcare, the Arizona Biomedical Research Commission and The Flinn Foundation convened a broadly representative group of major academic and research institutions and healthcare providers in Arizona to better understand how translational research can serve the needs of Arizona's Special Populations by improving and expanding the partnerships between their organizations and members of Arizona's special populations.

The group chose as their initial focus the advancement of collaboration mechanisms that establish community-based participatory research (CBPR) with initial concentrations on working with the Native American community.

The accomplishment of a key goal—development of this handbook to guide investigators in CBPR—is the result of work by and information from many individuals. The contents were informed by an investigation of national best practices as well as discussions with the Inter-Tribal Council of Arizona.

This handbook is meant to serve as a living document and guide for developing a collaborative and productive dialogue with community members that will lead to interactions of benefit to both investigator and community.

ENDNOTES

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Community
Participatory
Research:

Enhancing
Partnerships with
the Native American
Community

APPENDIX

I

MODEL TRIBAL RESEARCH CODE

**WITH MATERIALS FOR TRIBAL REGULATION FOR RESEARCH
AND CHECKLIST FOR INDIAN HEALTH BOARDS**

American Indian Law Center, Inc.

P.O. Box 4456 – Station A

Albuquerque, New Mexico

**MODEL
TRIBAL
RESEARCH
CODE**

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

***Third Edition
September, 1999***

***American Indian Law Center, Inc.
P.O. Box 4456 - Station A
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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.

APPENDIX



**INDIGENOUS PEOPLES COUNCIL ON
BIOCOLONIALISM**

INDIGENOUS RESEARCH PROTECTION ACT
MODEL ACADEMIC RESEARCH AGREEMENT

Indigenous Research Protection Act

Introduction

The **Indigenous Research Protection Act** is offered to assist tribal leaders and attorneys when a Tribe desires to protect itself and its people by taking control of research conducted on its Reservation. It may be copied, adapted, and adopted freely. The appendices can also serve as stand-alone documents in the case of tribes that have not adopted legislation like this Act. Following are some points that we think are important to discuss about the Act as written.

1. While a Tribe concerned about research on its members could decide to ban research altogether, the Act as written assumes that a Tribe might want to allow some research on its Reservation, and it allows for this possibility to occur under the Tribe's own terms. The Act is intended to foster cooperation and set the stage for research that the Tribe sees as beneficial. See Sections 1 & 2 for more explanation of the purpose of the Act as it is written.
2. The Act as written should be seen more as a cookbook than as a model to be adopted outright. Each Tribe will know best which individual provisions it wants to include, and which to cut out, when drafting its own legislation.
3. The Act includes provisions setting out two fees: an administrative fee, to cover costs of administration of an application, and a refundable security bond, to ensure that the researcher(s) comply with the terms under which they are allowed to do their research. Each Tribe will want to set its own fee rates, and may even choose not to charge fees.
4. Permits are a part of the Act as written. The provisions for permits may be easily removed, but a permitting procedure will usually make enforcement easier, because a researcher being required to carry a permit provides immediate verification whether their research has been approved by the Tribe, and should the researcher violate any Act provisions the Tribe may revoke the permit.
5. A penalties section is included, but appropriate penalty provisions may vary depending on each Tribe's situation. Factors that may come into play include ownership of land on the Reservation and make-up (members, non-member Indians, and non-Indians) of the Reservation community.
6. Appendix. In addition to the regulatory requirements, the Act provides for the entering into of research agreements. The Tribe may choose not to require such agreements, but such agreements may serve as protection should certain data or samples be removed from the Reservation and the Tribe seeks recognition of its terms and conditions in another jurisdiction. A model **Academic Research Agreement** is included as Appendix 1.

Dated: September 30, 2000

Indigenous Research Protection Act **Appendix 1: Model Academic Research Agreement**

or

WORD

For more information contact:

Indigenous Peoples Council on Biocolonialism
P.O. Box 818
Wadsworth, NV 89442
Tel: (775) 835-6932
Fax: (775) 835-6934
Email: ipcb@ipcb.org
www.ipcb.org

Indigenous Research Protection Act

WHEREAS, pursuant to the _____ Treaty, [or Executive Order or Agreement] the _____ Tribe reserved the _____ Reservation (hereinafter "Reservation") for present and future generations of the _____ people, and the _____ Tribal Council (or Executive Committee) has a duty and responsibility to protect the Reservation and traditional aboriginal homelands of the _____ people; and

WHEREAS the Reservation forms a sizeable geographic area for the exercise of Tribal jurisdiction, supports a residing population, is the basis for the Tribal economy, and provides an irreplaceable forum for cultural vitality based on religious and cultural traditions premised on the sacredness of land; and

WHEREAS the original territory of the Tribe, including land off-Reservation, contain significant cultural and religious sites which continue to be utilized by Tribal members; and

WHEREAS the _____ Tribe, by and through the _____ Council, has the inherent sovereign authority to regulate the conduct and activities on all lands within the jurisdiction of the Tribe, and as expressly established in the Constitution of the _____ Tribe, to promulgate, adopt, and enact laws for the control and regulation on all lands within the jurisdiction of the Tribe, and to protect the health, economic security, and general welfare of the Tribe and its members

NOW THEREFORE BE IT ENACTED BY THE COUNCIL OF THE _____ TRIBE an Ordinance to be known as the "Indigenous Research Protection Act."

SECTION 1. FINDINGS AND POLICY.

1.1 The natural and cultural landscapes, including wildlife, flora, fauna, waters, and biogenetics, among others, located on aboriginal and present day Tribal lands are owned by the Tribe and the disposition, development, and utilization thereof are under the Tribe's full control and supervision.

1.2 The integrity and orientation of past, present, and future generations of the _____ people is founded upon a unique and invaluable cultural, historical and environmental ethic. This Tribal ethic defines and perpetuates a communal identity, language, history, and value system which involves an irrevocable cultural attachment to the native landscape ecology, and the human inseparability and interdependence with species and biological diversity.

1.3 The Tribe has the right of self-determination and in exercising that right must be recognized as the exclusive owner of indigenous traditional knowledge.

1.4 Indigenous knowledge, cultural and biogenetic resources, and intellectual property rights have been, and continue to be, damaged, destroyed, stolen, misappropriated, both on and off the Reservation and Tribal members have been the subjects of research for decades, with virtually no benefits returning back to the community from the research.

1.5 The Tribe finds that it is in the best interest of the Tribal community to establish a research review mechanism to prevent the continued abuses, to protect the people's traditional knowledge and properties, and thereby to ensure our rights to continue to practice traditional lifeways and long term survival thereof.

1.6 The established research review process is developed as a mechanism to improve relations between the Tribe and scientists/researchers, and to promote collaboration within the framework of mutual respect, equity, and empowerment, and to identify benefits and risks to the Tribal community.

SECTION 2. PURPOSE.

2.1 The purposes of this Ordinance are to:

- a. protect the people, culture and natural resources of the Tribe and the Tribe's future generations from unauthorized scientific research; and
- b. to reduce the adverse effects of research and related activities on the Tribal community; and

c. to ensure that researchers recognize Tribal control of research activities and that the Tribe owns all data and information generated or produced by such research; and

d. to establish and provide a statutory basis for a process to review and govern any research, collection, database, or publication undertaken on the Reservation.

2.2 All research activities conducted on the Reservation must comply with this ordinance.

2.3 The Tribe reserves its right, through its inherent sovereign authority and its police power, to exclude individuals from the Reservation and to deny permission and access for any research activities whatsoever.

SECTION 3. DEFINITIONS.

For purposes of this Act:

3.1 "_____ Tribal Community" includes Tribal members, their descendants and ancestors, and other individuals, families, clans, governments and people residing within the exterior boundaries of the Reservation.

3.2 "Academic Research" means research carried out to obtain educational qualifications or as part of their academic career at a university or affiliated institutions.

3.3 "Biodiversity" means the total variety of life in all its forms. It includes many levels that range from the level of alleles to the biosphere. The major elements of biodiversity include alleles, genes, populations, species, ecosystems, landscapes, and the ecological processes of which they are a part.

3.4 "Biogenetic Resources" means biological and genetic resources, including plant material, animals, microorganisms, cells, and genes.

3.5 "Biological Samples" means, but is not limited to: bacteria and other 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 these samples.

3.6 "Commercial Purposes" means to sell, purchase, barter, trade, delayed compensation for profit, exchange, transport, or offer to sell, purchase, barter, trade, delay compensation for profit, exchange, or transport.

3.7 "Cultural Research" means any endeavor, by means of critical investigation and study of a subject, to discover new or collate old facts or hypotheses on a cultural subject, the latter being defined as any ethnographic or anthropological study, including basic data collection, studies of or incorporating traditional knowledge or classifications systems (e.g. studies of medicinal properties of plants), documentary films, archaeology, linguistics and ethno-historical accounts.

3.8 "Indigenous" means native, originating or growing naturally in a specific landscape. Also refers to people descending from the original inhabitants of the Western Hemisphere who have maintained distinct languages, culture, or religion from time immemorial.

3.9 "Products of Research" means publications (including but not limited to reports, studies, articles, theses, books, manuscripts, sound recordings, film and video, media interviews, computer databases), field notes, illustrations, photographs, sound recordings, collected material artifacts, replicas, and specimens, including any derivative forms they may take such as translations, and communications through the electronic media, including the internet and world wide web.

3.10 "Research" includes identification, description, classification, collection, database, recordation, analysis, and publication in fields including, but not limited to: agronomy, archaeology, astronomy, biology, ethnobotany, ecology, ethnography, history, linguistics, paleontology, medicine, photography, psychology, remote sensing, sociology, theology, videography, and other investigative disciplines or approaches as identified by the Tribe.

3.11 "Reservation" means all lands outside or inside the exterior boundaries of the _____ Reservation

which are under the jurisdiction of the Tribe, and such lands as may hereafter be obtained or added to the jurisdiction of the Tribe.

3.12 "RRC" means the five member Research Review Committee established under this Act.

3.13 "Taboo/Sacred" means subject to which access is restricted to any degree. Such subjects can include places, names, knowledge, oral traditions, objects, and practices.

3.14 "Traditional Indigenous Intellectual Property" means the indigenous cultural information, knowledge, uses, and practices unique to the Tribe's ways of life maintained and established over tribal homelands and aboriginal areas since time immemorial. This knowledge is based upon millennia of observation, habitation, and experience, and is a communal right held by the Tribe, and in some instances by individuals. This property includes, but is not limited to, the following:

- a. knowledge of remembered histories and traditions;
- b. details of cultural landscapes and particularly sites of cultural significance;
- c. records of contemporary events of historical and cultural significance;
- d. sacred property (images, sounds, knowledge, material, culture or anything that is deemed sacred by the community);
- e. knowledge of current use, previous use, and/or potential use of plant and animal species, soils, minerals, objects;
- f. knowledge of preparation, processing, or storage of useful species;
- g. knowledge of formulations involving more than one ingredient;
- h. knowledge of individual species (planting methods, care for, selection criteria, etc.);
- i. knowledge of ecosystem conservation (methods of protecting or preserving a resource);
- j. biogenetic resources that originate (or originated) on indigenous lands and territories;
- k. 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;
- l. cultural property (images, sounds, crafts, art, symbols, motifs, names, performances); and
- m. knowledge of systems of taxonomy of plants, animals, and insects.

3.12 "Traditional Knowledge Right" means the traditional right of individuals to control the ways the information they provide is used and accessed. The issue of traditional knowledge rights arises when individuals either own or are the custodians of specialized (or usually taboo/sacred) knowledge and its communication. This knowledge can include names, ceremonies, designs or forms, oral traditions, practices and skills.

3.13 "Tribal Member" means an individual Indian who is enrolled in the _____ Tribe.

3.14 "Tribe" means the _____ Tribe.

SECTION 4. RESEARCH REVIEW COMMITTEE ESTABLISHED.

4.1 There is hereby established a Research Review Committee, which shall be comprised of five (5) Tribal members who shall be appointed to serve on this committee by the Tribal governing body.

4.2 The RRC shall have the following duties and responsibilities:

- a. to examine and comment on all proposals for research to be conducted within the Reservation.
- b. to develop and propose to the Tribal governing body rules under which the RRC shall operate.
- c. to coordinate and insure that affected Tribal programs', departments', and members' interests are protected and represented.
- d. submit recommendations regarding proposals to the Tribal governing body for final approval.
- e. coordinate and interact with the researcher(s) in order to ensure Tribal control of the research process and Tribal ownership of data and information generated by such research.
- f. negotiate the terms and conditions of a research agreement, and submit such agreement for execution by the Tribal Council.

SECTION 5. GUIDING PRINCIPLES FOR RRC.

5.1 The RRC, in examining proposals, shall be guided by the following principles:

- a. Principle of Fully Informed Consent After Full Disclosure and Consultation

Research should not be conducted until there has been full consultation with all potentially affected Tribal communities and individuals, and each such community and individual has approved the research after full disclosure. Full disclosure is of: the full range of potential benefits and harms of the research, all relevant affiliations of the person(s) or organization(s) seeking to undertake the research, and all sponsors of the researcher(s).

b. Principle of Immediate Risks and Benefits to the Tribal Community

The research should be of immediate benefit to the Tribal community, and the risks associated with the research should be less significant than the benefits to be gained.

c. Principle of Confidentiality

This principle recognizes that the Tribe and local communities, at their sole discretion, have the right to exclude from publication and/or to have kept confidential any information concerning their culture, traditions, mythologies, or spiritual beliefs. Furthermore, researchers and other potential users shall guarantee such confidentiality.

d. Principle of Respect

This principle recognizes the necessity for researchers to respect the integrity, morality, and spirituality of the culture, traditions, and relationships of Tribal members with the world, and to avoid the imposition of external conceptions and standards.

e. Principle of Communication

This principle recognizes that communications should be carried out in the local language, using translators as necessary.

f. Principle of Empowerment

This principle recognizes that empowerment is the sharing of power and is premised on mutual respect. Empowerment means that each affected party feels that their needs are being met through a fair and equitable manner. Empowerment also means that research authorship must be shared between the Tribal community and the researcher.

g. Principle of Equity

This principle recognizes that equity is a sharing of resources. Both the researchers and the Tribe must bring equity to any research contract, agreement or understanding. Each of the participants in a good research agreement must evaluate such equity in relation to the research. Finance or money is only one form of equity. Community knowledge, networks, personnel and political or social power are other forms of equity useful to the project. Each of these commodities has value and must be shared between the researchers and the Tribe if a good agreement is to be formulated. The parties must continuously review equity over the duration of a research agreement.

h. Principle of Mutual Respect

This principle recognizes that in order to develop a good research agreement, the researchers and the Tribe must generate respect for each other. Respect is generated by understanding the social, political and cultural structures of the other party. The researchers and the Tribes can not assume that they believe in the same things or share the same goals and expectations. Good communication is required if a proper research agreement is to be generated. Cultural sensitivity training for the researchers and Tribal awareness presentations will help develop a mutual understanding in conducting the research project. Definitions and assumptions must be clarified and questioned by each side and set forth in an agreement. The Tribes and the researchers must listen to each other with open minds.

i. Principle of Prior Rights

This principle recognizes that indigenous peoples, traditional societies, and local communities have prior, proprietary rights and interests over all air, land, and waterways, and the natural resources within them that these peoples have traditionally inhabited or used, together with all knowledge and intellectual property and traditional resource rights associated with such resources and their use.

j. Principle of Self-Determination

This principle recognizes that indigenous peoples, traditional societies and local communities have a right to self determination and that researchers and associated organizations will acknowledge and respect such rights in their dealings with these peoples and their communities.

k. Principle of Inalienability

This principle recognizes the inalienable rights of indigenous peoples in relation to their traditional territories and the natural resources within them and associated traditional knowledge. These rights are collective by nature but can include individual rights. It shall be for indigenous peoples to determine for themselves the nature and scope of their resource rights regimes.

I. Principle of Traditional Guardianship

This principle recognizes the holistic interconnectedness of humanity with the ecosystems of our Sacred Earth and the obligation and responsibility of indigenous peoples to preserve and maintain their role as traditional guardians of these ecosystems through the maintenance of their cultures, mythologies, spiritual beliefs and customary practices.

SECTION 6. RESEARCH PROPOSAL REQUIREMENTS.

6.1 Time Frame:

As a cooperative venture, research requires an appropriate time frame for Tribal review and approval. Researchers must begin working with the RRC in the earliest stages of planning their proposals. Depending on the nature of the proposed project, researchers are advised to allow sufficient time for the RRC to thoroughly review and understand all aspects of the study, ask questions and resolve differences. Even the simplest of proposals must be submitted at least three months prior to the anticipated project start date. The RRC reserves the right to reject last minute proposals.

6.2 Format:

A short (a maximum five (5) pages, single sided) synopsis of the project shall be submitted to the RRC. A full length proposal should be submitted as a supplement, but the requested summary must contain sufficient information to allow the RRC to make an informed decision. The following information must be included in any request for approval of a research project:

a) Statement of the Issue/Problem/Research Question:

The research applicant shall briefly describe the issue/problem the applicant is addressing by the proposed research. Specific questions related to this issue/problem and the theoretical rationale behind the questions shall be set forth. If the applicant has a specific hypothesis, the applicant shall briefly set forth such hypotheses.

b) Intent/Benefit to the Tribe:

The research applicant must clearly outline and discuss the intent of the research project and the benefit(s) that the project, research or activity will have to the Tribal community. Some questions to be answered are: 1) what are the anticipated consequences or results/outcomes of the project; 2) what groups will be affected and what groups will benefit; and 3) in what ways will these groups and the Tribe's benefit?

c) Method:

As a part of the application process, the applicant shall briefly describe the procedure for the collection of all data to be used in your study. Included shall be a description of subjects, settings, proposed procedure and the nature of the data to be collected.

d) Confidentiality:

A very important part of the application process is a description on how confidentiality will be protected. The applicant shall identify the circumstances under which the obligations of the researcher may constitute a breach of confidentiality. A description shall be given on how individual participants will be informed of the degree of confidentiality that will be maintained throughout the study. The Tribe maintains that unless otherwise specified, only aggregate data, not individual data, shall be published or released to the general public. All individual identifiers such as names, addresses and phone numbers must be kept confidential and no sale or transfer of databases outside the specific research project shall be allowed. The applicant must state in their application summary whether the Tribal community will be identified in any data released to the general public.

e) Disposition of Data and Samples

A portion of the application process shall describe how individual participants will be informed of how data and samples will be used. Both the Tribal community and the participants must clearly understand what the researcher plans to do with the information and samples that are collected. A description of the plans to provide individual participants with their own personal results must be provided. In addition, the research applicant shall describe how the community at large will be educated or empowered by this study. A description of the frequency and manner by which the aggregate data and progress reports will be shared with the RRC must be set forth. Furthermore, communication strategies to present aggregate data to the community at large shall be described.

f) Risks:

The applicant must describe any potential legal, financial, social, physical or psychological risks that are anticipated in the research. Any risks of deleterious impact on the cultural, social, economic or political well-being of the Tribe or Tribal members shall be assessed. The assessment of risk will also address the steps that will be taken to minimize, ameliorate or repair any actual harm caused to the Tribal community by the research. Explanation shall also be given on how potential risks will be explained to participants and how the risks are justified by the potential benefits of the research.

g) Funding/Budget:

If the study is funded by any public or private sources, the applicant shall provide a full reference of this funding source and explanation of any limits on the confidentiality of research results. If the researcher is currently seeking funding, the researcher shall list all funding agencies for which proposals are being sought. Researchers shall budget funding to cover cultural sensitivity training, to provide adequate resources to cover community education and outreach efforts as a part of the research, and finally, to rectify any harm to, or exploitation of, Tribal property resulting from the research.

h) Cultural Sensitivity Training:

All principal investigators, researchers, graduate students and any other people involved in the research will be required to undergo cultural sensitivity training to be provided at the researcher's expense. Costs will be determined based on the scope of the project. The training shall be provided by _____.

i) Equity:

The proposal must demonstrate how the participants and the Tribe will be given a fair and appropriate return for cooperation in the research. Just compensation or fair return includes but is not limited to: obtaining copies of the research findings, authorship, co-authorship or acknowledgment, royalties, fair monetary compensation, copyright, patent, trademark, compensation for expenses incurred in reviewing/advising researchers, coverage of training/education or outreach expenses or other forms of compensation.

j) Consent:

The proposal must address mechanisms for informed consent, which may be required from individual participants, families, clans or the Tribal Government. The applicant shall list all the agencies, professionals, government representatives or individuals within the Tribal community with which the applicant has previously discussed the proposed research and whether or not these people have given their informed consent, or other support, to the research.

k) Empowerment:

The applicant shall describe how individuals and Tribal members will be empowered by the research process through employment, training or outreach efforts. Native American preference must be given in employment and training in all phases of the project or activity, especially where the research is occurring on the Reservation. The Tribal preference laws shall govern the order of priorities in hiring.

l) Intellectual Property Rights:

The application shall address the plans (pre, during and post-project) for publication or commercialization of

the research findings. If such publication or commercialization is contemplated, the applicant shall address how the Tribal community shall share in the authorship of publications or commercialization of the research findings. The Tribe also needs to know how the Tribal community will have access to the project, research data or findings for the Tribe's own use. Researchers must inform the RRC of journals, publishing houses or conferences that they plan to print or present the results of their studies before papers are submitted or presented. The proposal must demonstrate a process whereby the RRC and the Tribe will have an opportunity to review, critique and approve the results of all studies before any publication, presentation, news conferences or release of data to the general public occurs. Researchers shall be responsible for addressing, correcting and satisfying the concerns of the Tribe in both drafts and final reports, papers or data summaries before they are released to the general public.

m) Data Ownership/Archive:

The Tribe reserves the right to require the deposit of raw materials or data, working papers or product in a tribally designated repository, with specific safeguards to preserve confidentiality. Duplicates of data or split samples may be required to be stored in such a local archive.

6.3 Administrative Fee:

The researcher shall remit with the research proposal an administrative fee in the amount of \$_____ to cover administrative costs associated with review of the proposal and permitting.

SECTION 7. REVIEW OF RESEARCH PROPOSALS AND REVIEW PROCESS.

7.1 All research proposals must be complete before the RRC is required to consider the proposal. A proposal is complete when it contains the fee and all of the information required in Section 6 that is necessary for the RRC to decide whether or not the proposal should be considered.

7.2 Any research summaries and support documents requested by the RRC pursuant to the proposal process should be sent to:

[Insert Address]

7.3 The RRC shall review the application materials that are submitted and either:

- a) Return the proposal to the researcher with requests for additional information or with suggestions for clarification or change; or
- b) Forward the proposal and request to the Tribal governing body with a recommendation for approval or disapproval; or
- c) Consult with other Tribal members, Tribal elders, professionals, technical experts or specialists for a second evaluation before sending recommendations to the Tribal governing body.

7.4 The review process and approval of the research is complete when the researcher receives a letter of notification from the RRC and enters into a binding Research Agreement (see Appendix) that contains the obligations and responsibilities of the parties. Upon approval, principal investigators, researchers, graduate students and any others involved in the research shall undergo cultural sensitivity training at the researcher's expense before any project begins within the Reservation. The RRC expects periodic progress reports and will use these reports to update the Tribal governing body on the status of the project.

7.5 The RRC may specify a Compliance Fee in an amount appropriate to ensure the researcher's compliance with the conditions of the research. Upon completion of the research, the compliance deposit may be refundable.

7.6 Following approval of the research, the researcher shall secure all permits and licenses that may be required by Tribal law, including but not limited to a permit as provided under Section 9.

SECTION 8. RESEARCH AGREEMENTS.

8.1 An agreement specific to the research shall be developed so that studies proceed in a manner that is both culturally sensitive and relevant to the participants and the Tribal community.

8.2 Where any of the products of the research are to be used for commercial purposes, a separate agreement will be made specifying the bases on which sales are to be made and the proceeds of sales are to be distributed. Where research is engaged in for commercial purposes, it is the responsibility of the researcher to make all informants and suppliers of information aware of this fact, and to come to an agreement with them on the amount of compensation to be paid. There must be a limit on samples that the researcher may obtain and take off the Reservation, and the approved list and amount of samples to be taken must be followed strictly.

8.3 A sworn notarized declaration of noncommercial use of research products and/or traditional and indigenous knowledge is required in conjunction with an Academic Research Agreement. This declaration may be included in the body of the Research Agreement.

8.4 If a research project receives approval by the Tribe, the approval remains in effect for the period of time specified in the research agreement unless substantial changes are made in the research protocol. At the end of the period approved for the research project, the researcher must submit a letter in writing which summarizes the status of the project (complete, incomplete, discontinued), any unanticipated problems that occurred during the data collection phase of the project, and a time schedule for completion of all work, including community education/outreach, related to the project. If the project is incomplete, the researcher must also request in writing an additional period for the data collection phase of the project.

SECTION 9. PERMITS.

9.1 The RRC shall develop standard application forms for Research Permit applicants and set forth the type of information that must be submitted.

9.2 The RRC shall develop a standard permit form, which at a minimum shall include the name(s) of the researcher(s) covered, name and/or brief description of the study approved, location(s) of research to be conducted, and effective start and ending dates of the permit.

9.3 Upon execution of a Research Agreement, all persons conducting research on the Reservation shall obtain from the Office of the Tribal Secretary a Research Permit in accordance with the terms of this Section.

9.4 An application form for a Research Permit may be obtained from the RRC or from the Office of the Tribal Secretary.

9.5 All persons covered by a Research Permit shall have such Permit in their possession at all times while conducting research. The Research Permit must be produced for inspection or surrendered upon demand by authorized Tribal authorities.

9.6 A Research Permit issued under this Section may be suspended or revoked at any time by the Tribal Chairperson, Tribal Council, or the RRC, if a permit holder is engaged in activities not allowed by the permit, fails to abide by a permit term or condition, has committed fraud or misrepresentation or provided incorrect statements in the application or permitting process, or is engaged in or has engaged in activities prohibited by this Act or any other Tribal law or resolution.

9.7 A revocation or suspension of a permit issued pursuant to this Section is final and not subject to appeal.

SECTION 10. MODIFICATIONS OF AN APPROVED PROJECT.

10.1 If the researcher wishes to make substantial changes in his or her research project after receiving approval from the Tribe, he or she must submit a summary of the proposed modifications to the RRC.

10.2 Modifications in the data collection procedures must be reviewed by the RRC and approved by the Tribal governing body. Modifications to the research project shall not be implemented until the researcher and the RRC have amended the research agreement and permits, and the researcher receives written approval from the RRC.

SECTION 11. REGULATION OF BIOLOGICAL SAMPLES

11.1 Any researcher who seeks to collect, acquire, or analyze any biological samples must agree and abide by the following conditions with regard to research with biological materials.

11.2 The Tribe may, at any time, decide to withdraw from the research project or any portion thereof, and request the return of all biological samples. The researcher, and any other parties, must comply.

11.3 Upon completion of the research project, or termination or cancellation of the project at any time prior to completion, the biological samples must be completely and fully returned to the possession of the Tribe.

11.4 No biological samples from this study may be released to, or used by, any other researcher(s), research institution, or any other entity, whether public or private, without the prior and fully-informed written approval of the Tribe.

11.5 If the Tribe permits any biological samples to be stored in any other locations, the researcher shall maintain at all times a complete list thereof. The list shall include a description of the sample or data, source, specific use or purpose of each item, responsible person(s) at the location, and where the item is housed (e.g., in a "gene bank" or on a specific computer), and any relevant time lines with regard to use of, disposition, return, or destruction of the samples or data. The researcher shall provide an updated copy of the list to the Tribe whenever changes are made. The updated list shall include identification of changes made since the last copy of the list was provided to the Tribe.

11.6 Any situation where biological samples will leave the possession or control of the researcher will require a separate agreement between the Tribe and the external party in accordance with this Act.

11.7 No entity may seek to patent or commercialize any biological materials obtained from the Tribe, from the Tribe's jurisdiction, or under the authority of the Tribe. This includes genetic samples, any copies of the original genetic samples, any cell lines containing copies of the original genetic samples, and data derived from these samples.

SECTION 12. RESERVATIONS AND TERMINATION.

12.1 The Tribe reserves the right to:

a) Withdraw consent to use or release information and/or prevent the publication of data which is unauthorized, insensitive, misrepresents or stereotypes Tribal people or will harm the health, safety or welfare of the Tribe or the Tribal environment.

b) Deny researchers the opportunity to conduct research in any Tribal community within Tribal jurisdiction. In addition, other researchers or scientists from the same research institution may be denied any future access to the Reservation.

c) Withdraw approval for projects. Should this occur, the Tribe will explain the rationale for withdrawing approval and explain why this project or the release of data is deemed to be harmful to individuals or the Tribal community at large. In the case of withdrawal of approval by the Tribe, all information and copies of data must be returned to the Tribe.

d) Exclude individuals from the Reservation

e) Seek injunctive relief, including an order restraining a person from continuing to enter onto the Reservation.

12.2 If a project is terminated, the research entity or individual must provide just compensation to any field staff or member of the Tribe for their time and efforts spent related to the research project.

12.3 This ordinance does not apply to Tribal members or communities conducting research within their own community for their own use, provided, however, that this ordinance shall apply if a Tribal member is conducting research for, or is affiliated with, an outside institution.

SECTION 13. PROHIBITED CONDUCT.

13.1 No person shall conduct any academic research or cultural research without first obtaining approval by the RRC pursuant to Section 7 of this ordinance;

13.2 No person shall conduct any academic research or cultural research without obtaining a fully executed research agreement pursuant to Section 8 of this ordinance;

13.3 No person shall conduct any academic research or cultural research without maintaining in their possession a permit issued pursuant to Section 9 of this ordinance;

13.4 No person shall collect, acquire, or analyze any biological samples without abiding by the provisions of Section 11 of this Ordinance;

13.5 No person shall alter, damage, disturb, excavate, removed, or desecrate and biodiversity related resources, biogenetic resources, or traditional indigenous intellectual property on or of the Reservation or Tribe;

13.6 No person shall, while on the Reservation, conduct any visitation, inventory, collection, research, or filming related to any biodiversity related resources, biogenetic resources, or traditional indigenous intellectual property, or disturb any animals, vegetation, or landscapes of the Reservation or Tribe;

13.7 No person shall sell, purchase, exchange, transport, receive, or offer to sell, purchase, exchange, transport, or possess any biodiversity related resources, biogenetic resources, biological samples, or traditional indigenous intellectual property if such resource or property was obtained in violation of this Ordinance or any permits.

SECTION 14. PENALTIES.

14.1 CRIMINAL PENALTIES

Any person over whom the Tribe may assert criminal jurisdiction, who knowingly violates or counsels, solicits, or employs any other person to violate any section of this ordinance, or any condition of limitation of a permit issued under this ordinance, shall be guilty of a criminal offense. Each criminal offense shall be punishable by restitution, community service, a fine not to exceed \$10,000, imprisonment in the tribal jail for not more than one year, or any combination of these penalties. Criminal offenders may also be subject to civil penalties and damages set forth in this ordinance.

14.2 CIVIL PENALTIES

a) Any person who violates any section of this ordinance, or any permit issued under this ordinance, shall be assessed a civil penalty not to exceed \$10,000 per violation, or if applicable, any civil penalty provided for under Federal laws.

b) No civil penalty shall be assessed unless such person is given notice and an opportunity for a hearing with respect to such violation. Each violation shall be a separate offense. The trial of any such violation shall be by the Tribal Court and the prosecution shall have the burden of proving the alleged violation by a preponderance of the evidence.

c) Any person who violates this ordinance, or any permit issued under this ordinance, may lose the privilege of doing business or conducting research on the _____ Reservation.

d) Any nonmember of the Tribe who violates this ordinance or any permit issued under this ordinance may be excluded from the Reservation.

14.3 CIVIL DAMAGES

a) Assessment of Actual Damages: Any person who violates any section of this Ordinance or any permit issue under this Ordinance shall be liable to the Tribe for civil damages to be assessed by the _____ Tribal Court after a hearing. "Civil Damages" shall be interpreted liberally by the _____ Tribal Court to include, but not be limited to, the following:

1. Cost of restoration and repair; and
2. Enforcement costs associated with the enforcement of this Ordinance; and
3. Costs associated with the culturally appropriate disposition of resources, including conservation, curation, and/or reburial.

b) Assessment of Treble Damages: In addition to actual damages, the _____ Tribal Court, in its discretion, may assess damages of up to three times the amount of actual damages.

14.4 FORFEITURE

a) All objects or property in the possession of any person, and obtained in violation of this Ordinance or in violation of a term or condition of a permit obtained thereunder, shall be seized by law enforcement agents and forfeited to the Tribe for disposition.

b) A person may recover all such property incapacitated by paying to the Tribe the costs incurred by the Tribe in carrying out legal proceedings, and by paying all fines due for violations of Tribal law.

14.5 SEIZURE OF SECURITY

The citing law enforcement agent shall:

a) Seize such property in the possession of the alleged perpetrator, including vehicles, or equipment involved in the violation, as the enforcement program or agent deems reasonably necessary to secure payment of any fine or civil damages which may be levied upon the defendant upon conviction of the infraction or crime.

b) The property seized shall be released to the owner upon timely payment of any related civil assessments.

c) Any seized property shall be forfeited to the _____ Tribe if the assessment has not been paid within 15 days of the hearing at which the civil assessment was levied or 15 days from the final determination of any appeal taken pursuant to this Ordinance, whichever is later.

SECTION 15. PERSONAL JURISDICTION.

15.1 As to a cause of action arising under this ordinance, a court may exercise jurisdiction over a non-domiciliary on any basis consistent with and on the broadest basis permissible under the Constitutions of the United States and the _____ Tribe.

SECTION 16. SEVERABILITY.

16.1 If any provision of this ordinance or the application thereof to any person, court, or circumstance is held invalid by a Tribal Court or another court having competent jurisdiction, the invalidity shall not affect other provisions of this ordinance which can be given effect without the invalid provision or application and to this end, the provisions of this ordinance are severable.

SECTION 17. REPEAL OF CONFLICTING LAWS OR REGULATIONS

17.1 Any ordinance, resolution, act, or rules and regulations in conflict with the provisions of this Ordinance shall be superceded and repealed to the extent of such conflict.

SECTION 18. WAIVER

18.1 No individual person, Tribal official, or Tribal employee is authorized to waive any part of this Ordinance.

SECTION 19. SOVEREIGN IMMUNITY

19.1 The Tribe and all its constituent parts, subordinate organizations, boards, committees, including the RRC, are immune from suit in any jurisdiction except to the extent that such immunity has been expressly and unequivocally waived by the Tribe.

SECTION 20. AMENDMENTS

20.1 This Ordinance may be amended following public hearings by Resolution by the _____ Tribal Council in accordance with the _____ Constitution.

SECTION 21. EFFECTIVE DATE.

21.1 This Act is effective upon the date of passage by the _____ Tribal Council.

APPENDIX 1- ACADEMIC RESEARCH AGREEMENT

Research Agreement

THIS AGREEMENT is entered into by and between the _____ Tribe, located at _____ (hereinafter referred to as "Tribe"), and _____, located at _____ (hereinafter referred to as "the Researcher").

WHEREAS, the Researcher has applied to the Tribe to do research, and agrees to the conditions placed upon the Researcher in this agreement and to comply with the intent of the Indigenous Research Protection Act and the principles set forth therein; and

WHEREAS, the Tribe agrees to permit the Researcher to do such research;

NOW THEREFORE, in consideration of the mutual covenants and conditions contained herein, the parties hereto understand and agree as follows:

Section 1. Parties Bound.

The provisions of this Agreement shall apply to and be binding upon the Tribe and the Researcher and the Researcher's officers, agents, successors, assigns and all persons acting on the Researcher's behalf. Each party certifies that its undersigned representative is fully authorized by the party he or she represents to enter into the terms and conditions of this Agreement, to execute it on behalf of that party, and to legally bind the party on whose behalf he or she executes this Agreement.

Section 2. Tribe's Authorization

The Tribe hereby authorizes the Researcher to undertake research work in _____ (location) _____ on the subject of:

with the communities of:

in the capacity of (if more than one researcher is involved):

for the period up until (specify if research will involve more than one visit):

Section 3. Responsibilities of the Researcher.

3.1 The Researcher shall pay an administrative fee of \$_____ to cover all administrative fees and costs incurred in the setting up and implementation of the research venture, unless, in the discretion of the RRC, the fee has been waived.

3.2 The Researcher shall provide copies of non-artifact products or research to the RRC and, where feasible, to the local community. Two copies of films, videos, or other audio or visual media are to be provided, one for public screening and the other for deposit in the Tribal archives, library, or repository. Any artifacts collected become the property of the Tribe unless traditional ownership has been established in a Traditional Copyright Agreement. The removal of any artifacts or specimens outside of the Reservation is prohibited, unless agreed upon by the parties to this Agreement. The conditions for return of the materials shall include:

(a) a letter from the institution with which they are affiliated guaranteeing the researcher's compliance with the conditions below; and/or

(b) a deposit in the amount of \$_____ to ensure compliance with the conditions.

(c) Identify specimens, materials, artifacts, and conditions for return in addition to (a) and/or (b) above:

3.3 The Researcher agrees to involve Tribal scholars, students, and members of the community in research, to provide full recognition of their collaboration, and to provide training to enable future contribution to the community.

3.4 The Researcher guarantees a product of immediate benefit and use to the Tribal community and the Researcher shall provide such product no later than six months after termination of the research period. This product is:

3.5 The Researcher, in addition to the research work and as a service to the Tribal community, shall undertake to:

3.6 The Researcher, in undertaking research, shall:

(a) recognize the rights of people being studied, including the rights not to be studied, to privacy, to anonymity, to confidentiality, and to fully informed consent;

(b) recognize the primary right of informants and suppliers of data and materials to the knowledge and use of that information and material;

(c) respect traditional copyrights;

(d) respect local customs and values, and carry out research in a manner consistent with this Agreement and the Indigenous Research Protection Act;

(e) assume a responsibility to make the subjects in the research fully aware of their rights and the nature of the research and their involvement in it;

(f) contribute to the interests of the community in whatever ways possible so as to maximize the return to the community for their cooperation in the research work; and

(g) recognize their continuing obligations to the local community after the completion of the fieldwork, including returning materials and providing support and continuing concern for the well-being of the local community;

3.7 The Researcher shall enter into a Traditional Copyright Agreement where the Researcher obtains information or material data. The Traditional Copyright Agreement shall be completed by the Researcher, the supplier of data or information, and the RRC. The Researcher has the responsibility to make such consultants fully aware of their rights and obligations, and those of the Researcher, in the signing of the Traditional Copyright Agreement

3.8 The Researcher shall maintain all information and data gathered in his/her research and shall make such information and data available to the RRC upon request for inspection and review.

3.9 The Researcher shall provide the RRC with monthly status reports of the research conducted on the Reservation.

3.10 The Researcher, and the Researcher's employees, students, and agents, shall maintain confidentiality of any and all records, data, and information gathered relating to the Tribe which is in the Researcher's possession and control. Such information shall only be released or disseminated pursuant to the strictest policies of confidentiality and privacy with the consent of the Tribe.

3.11 The Researcher is an independent contractor and nothing contained in this Agreement shall be deemed, construed, or interpreted to constitute the Researcher as a partner, agent, or employee of the Tribe, nor shall the Researcher have any authority to bind the Tribe.

3.12 A breach of any part of this Agreement by the Researcher or a decision by the affected community that it no longer desires to be involved in the research will result in the termination of the research project.

Section 4. Responsibilities of the Tribe.

4.1 The Tribe is the owner of the communal cultural, natural, and biogenetic resources, and retains ultimate discretionary authority and final authority and responsibility for the approved research.

Section 5. Noncommercial Purpose

5.1 The Researcher hereby warrants that no research performed under this Agreement, no research products, and no traditional or indigenous knowledge will be used for commercial purposes, unless otherwise provided for in this Agreement.

Section 6. Termination of Agreement.

6.1 This Agreement may be terminated by:

- (a) the mutual agreement of both parties in writing; or
- (b) either party giving the other party not less than sixty (60) days advance notice of termination; or
- (c) the non-breaching party in the event the breaching party fails to correct a material breach within fifteen (15) days of receiving written notification from the non-breaching party;

Section 7. Miscellaneous Provisions.

7.1 The Tribe does not assume any liability by entering into this Agreement.

7.2 The failure of the Tribe to require the strict performance of any provisions of this Agreement in any one or more instances, or to exercise rights hereunder or seek enforcement of such provisions or rights at law or equity, shall not be construed as and shall not constitute a waiver or relinquishment of such provision or rights, and such provisions and rights shall continue in full force and effect.

7.3 This Agreement, including all matters relating to the validity, construction, performance, and enforcement thereof, shall be governed by the applicable laws of the _____ Tribe and federal law. The _____ Tribal Court shall have jurisdiction to hear disputes under this Agreement, and the Researcher and the Tribe shall be subject to the personal jurisdiction of the _____ Tribal Court and all court rules thereof, and shall accept venue in the _____ Tribal Court. The Researcher agrees that any process served for any action or proceeding shall be valid if mailed by Certified Mail, return receipt requested, with delivery restricted to addressee, its registered agent, or any agent appointed in writing to accept service.

7.4 All notice required to be given under this Agreement shall be in writing and shall be either (1) personally delivered to the party to whom addressed, or (2) sent by United States mail, postage prepaid, registered or certified mail, return receipt requested, addressed to the party at the address which follows or to such other address as the parties may hereafter designate in writing. Any such notice shall be deemed to have been given, if mailed as provided herein, as of the date mail stamped.

Tribe's Address:

Researcher's Address:

7.5 If any provision of this Agreement is found unlawful, void, or unenforceable by a court of competent jurisdiction, that provision shall be deemed severed from this Agreement, and in no way shall affect the validity or enforceability of the remaining provisions of this Agreement.

7.6 Neither party shall assign, pledge, or transfer, in whole or in part, their rights, duties, responsibilities, or interests under this Agreement without the prior written consent of the other party. No assignment of this Agreement shall be made to an individual, organization, firm, or business entity that has been convicted of a criminal offense related to or involved in any research concerning research of an Indian tribe or indigenous community. The provisions of this Agreement shall be binding upon and inure to the benefit of the parties hereto and each of their respective successors and permitted assigns.

7.7 This Agreement constitutes the entire agreement between the parties and no agreements or representations have been made or shall be binding upon either party unless set forth herein. This Agreement supersedes any prior oral or written statements made by either party, its employees, representatives or agents.

IN WITNESS WHEREOF, the Tribe and the Researcher have executed this Agreement, in triplicate, individually or by signature of this duly authorized representative as of the date and year written below.

_____ Tribe The Researcher

Date: _____ Date: _____

Consent and Consultation in Genetic Research on American Indians and Alaska Natives

by Brett Lee Shelton, J.D.

There are many reasons why a person might choose not to participate in as a subject in scientific research. It may take too much time, make the person uncomfortable, or infringe on privacy in a way that makes it undesirable to participate. There may be other reasons, as well, such as religious qualms with the research or certain aspects of it, or a dislike for the researcher. Whatever the reason, most civil societies deem it important that a person generally not be required to participate in any research in which they do not want to take part. There are many laws and ethical canons that address this requirement that subjects "consent" to being studied before research is allowable.

Moreover, it is not enough to merely get consent from a potential study participant, the person must be informed of what their participation will entail in order for their consent to be considered valid. While there is some debate about just how much information a potential subject must be given in order for consent to be considered "informed consent," it is generally agreed that the participant must be fairly well-informed in order for their consent to be valid. Otherwise, the potential subjects are not aware of that to which they are consenting. The consent is not real.

In the United States, the only real legal protection for informed consent is in the Federal Policy for the Protection of Human Subjects ("Federal Policy"). The Federal Policy covers only research funded or conducted by the federal government, and it requires consent by requiring that research be approved by Institutional Review Boards (IRBs). The IRBs in turn, must require that informed consent be a part of the design of all research that they approve. See 45 C.F.R. Part 46.

Consent Among Individual American Indians in Genetic Research

Among American Indians, there may be many culturally-based reasons why an individual might choose not to participate in genetic studies. In addition to the reasons any person might decline to participate in genetic research, an American Indian might have other reasons. Their particular tribal background, and the degree to which that particular tribal culture affects their values and beliefs, will determine on whether they have such objections.

There are many different American Indian cultures in the United States, and these cultures can differ from those of the mainstream culture in many, sometimes unexpected, ways. It would be virtually impossible for any researcher to anticipate all the factors that an individual American Indian would deem important in deciding whether to participate in a particular study. That is why it is important that American Indians be educated as much as possible about a study before they are asked to participate. In the field of genetics, the necessary education includes information about how samples are handled before, during, and after the research, and what the final product of the research is likely to be, in addition to education about the particular study.

This education does not take place very often before consent for genetic research is sought from American Indians. American Indian people are frequently shocked and disappointed to hear that they may have been the source of biological samples being used in ways they never understood to be a possibility. Further, many of the scientific journal reports on genetic research show evidence of a lack of any consent to the use of samples. By using biological samples from American Indian people without their fully informed consent, researchers are violating the human rights of those individuals. By supporting the research through funding, the agencies involved are complicit in the human rights violations.

The federal agencies funding genetic research need to make at least two changes in order to correct the current systemic flaws that violate the human rights of American Indians. First, education of American Indian people about genetics and its procedures is necessary on a large scale, so that potential study participants are informed about what they might participate in, and so that they may bring their own cultural values to

bear on the decision of whether to participate or not. Second, a system requiring specific consent for each secondary use of biological samples must be implemented and enforced. Each secondary use is a new study, and neither consent for the primary use nor blanket consent by an under-informed sample source legitimately establishes the informed consent necessary for the protection of the subject American Indian's human rights.

Consultation Protects Individuals and Group Rights

American Indians, if they are members of tribes that have been officially recognized by the United States government, have another potential governmental safeguard for their interests—in the form of their tribal governments. In theory, tribal governments can help protect the rights of their members.

Through all the years since the first contact with non-Indians, tribes have retained their sovereign authority to act for the benefit of their members. This sovereign authority is frequently recognized by the United States and thereby made a part of federal law as well. Further, sometimes the federal government grants additional authority to tribal governments that it would have otherwise claimed itself. However, tribal governments must have sufficient power to make their protective actions effective.

In addition to their ability to protect the rights of individual members, tribal governments also serve to protect the collectively-held rights of the tribe as a whole. The notion of group rights, particularly those that may be paramount to individual rights, is sometimes very foreign to those living in the mainstream culture, which usually assumes that rights and property are to be held by individuals and that all property can be alienable. However, American Indians, and many cultures worldwide, continue to recognize certain areas in which the concerns of the group are paramount to those of any individual.

Tribal governments must frequently act in the interest of the tribe as a whole, and thereby protect group rights. In cases where group rights of the tribe and individual rights of tribal members are in potential conflict, the people of the tribe are uniquely able to strike the culturally appropriate balance. Most frequently, the people of the tribe are able to strike this balance most effectively by acting through the governing body of the tribe, the tribal government.

Recognizing (1) the often inherent imbalance in power between itself and tribal governments, (2) the important function that tribal governments play in protecting the rights of tribal members and the tribe as a whole, and (3) the appropriateness of tribal determination of issues involving tribal values, the federal government has chosen a policy that encourages the development of tribal governments and vests as much authority as possible in tribal governments whenever possible. In terms of policy development and administration of the executive branch, this policy is manifest in a mandate that that agencies consult with Indian tribal governments whenever a federal action will affect Indian people.

Executive Policy Requires Tribal Consultation on Research

Executive Orders and Executive Memoranda are two official documents that the President of the United States uses to direct internal management of the agencies in the executive branch of the federal government. At least twice, the President has directed all federal agencies to consult with Indian tribes whenever they take actions that will affect tribes. In the Executive Memorandum on Government-to-Government Relations with Native American Tribal Governments (April 29, 1994), the President directed that:

[e]ach executive department and agency shall consult, to the greatest extent practicable and the extent permitted by law, with tribal governments prior to taking actions that affect federally recognized tribal governments. All such consultations are to be open and candid so that all interested parties evaluate for themselves the potential impact of relevant proposals.

Four years later, the President augmented this sentiment in the Executive Order on Consultation and Coordination with Indian Tribal Governments (May 14, 1998). The Executive Order states that:

[e]ach agency shall have an effective process to permit elected officials and other representatives of Indian tribal governments to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.

Research projects that focus on Native American tribes and their members “significantly or uniquely affect” tribes by their very nature—without the targeted tribe(s), the study would not exist in the same form. Therefore, according to the executive documents on consultation, federal agencies have an obligation to consult with targeted tribes prior to funding research that targets the tribes or their members.

The Trust Responsibility Requires Consultation

The United States has unique power in Indian affairs, stemming from the power to make treaties and the reservation to the federal government of the Constitutional power to “regulate commerce with the Indian tribes,” (or the “Indian Commerce Clause” of the U.S. Constitution). Along with this authority, courts have routinely held, comes a special responsibility, the trust responsibility of the United States towards American Indian people and tribes.

The trust responsibility applies to all agencies with programs concerning Indians, and it may not be subordinated to other public interests unless specifically authorized by Congress (see Nevada v. United States, U.S. Sup. Ct. 1983). Because research involving American Indian people as subjects, particularly involving them because they are American Indians, concerns Indian people and tribes, participation in the research by the federal government creates a trust responsibility on the part of the governmental agencies involved. Is this trust relationship not being violated if the human rights of the subjects of the research are violated? The current processes whereby federal funding decisions are made repeatedly result in such violations.

WHAT MUST BE DONE

In order to protect the rights of individual American Indians whose participation might be sought in genetic (and other) research, several steps must be taken at the federal level. Without better education on the basics of genetic research at the grassroots community level, the possibility of truly informed consent is negligible. Therefore, if the federal government desires to spend money on research involving American Indians, it must first make sure that the potential subjects are sufficiently informed to be able to validly consent to participating. **Spending for education is a necessary precursor to valid spending for actual research.**

Tribal consultation, as a method for obtaining tribal consent, is also necessary for every proposed research project involving a tribe. The federal mandate to consult with tribal governments must be honored, in order to ensure good policy and decisions, and to help protect against human rights violations of individuals and violations of tribal group rights.

Finally, **effective controls must be put in place to prevent secondary uses of biological samples and information when specific informed consent for those uses has not been obtained.** Each new study is a new use, and informed consent should be required. Each participant’s right to decide whether they will participate should be honored. This right should not be compromised by a lack of information, or by empty general “blanket” consent, as is the current norm.

All of these changes will be best implemented at the federal level, by the agencies controlling and supporting the research. The agencies need to develop and implement policies restricting secondary sample use. The agencies also need to consult with tribes prior to funding research that targets tribes, or at least require that research proposals show valid evidence of tribal approval prior to funding.

Tribes can **advocate for these changes at the federal level.** In the meantime, it will also be useful for tribes to **pass tribal legislation that will protect them and their members** locally, relying on their own sovereign authorities.

Only when such protective measures are enacted will American Indian participation in genetic research be able to proceed, if at all, on valid grounds. Until such measures are enacted, the long list of human rights

and tribal rights violations that is being stacked up by the actions of federal agencies funding research on American Indians will only continue to get longer. And the possibility for embarrassing human rights violations and concomitant lawsuits will only continue to grow as well.

Information About Intellectual Property Rights No.6, January 1995

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APPENDIX



IHS

**DIVISION OF HUMAN SUBJECT PROTECTIONS
OFFICE FOR PROTECTION FROM RESEARCH RISKS
NATIONAL INSTITUTES OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

The INDIAN HEALTH SERVICE

MULTIPLE PROJECT ASSURANCE (MPA)

FOR COMPLIANCE WITH DHHS REGULATIONS

FOR THE PROTECTION OF HUMAN SUBJECTS

(45 CFR 46)

AS AMENDED

GLOSSARY

- Affiliate Institution** - an institution which is legally separate from the signatory institution(s) to an Assurance but has a formal affiliation with the signatory institution(s) through an OPRR-approved Inter-Institutional Amendment or Assurance
- Assurance** - a document negotiated with and approved by OPRR which assures institutional compliance with 45 CFR 46
- Component** - any institution which is legally inseparable from the signatory institution(s)
- Cooperative Project Assurance (CPA)** - an Assurance designed to accommodate CPRP multi-protocol, multi-site research specifically recognized by OPRR
- Cooperative Protocol Research Programs (CPRP)** - DHHS multi-site, multi-protocol clinical trials in differing subject areas where data are pooled across institutions and which are explicitly recognized by OPRR as suited for CPAs (e.g., cooperative oncology trials of the National Cancer Institute)
- Federal** - departments and agencies of the Federal government that are a party to the Federal Policy (see 56FR28003)
- Federal Policy (56FR28003)** - minimum Federal standards for the protection of human research subjects, effective August 19, 1991 (see FR Volume 56, No. 117, Tuesday, June 18, 1991), and contained in 45 CFR 46 as Subpart A - also known as the Common Rule
- 45 CFR 46 (DHHS Regulations)** - Title 45 of the Code of Federal Regulations, Part 46, which consists of Subpart A (the Federal Policy for the Protection of Human Subjects) and Subparts B, C, and D which apply to fetuses, pregnant women and in-vitro fertilization of human ova; prisoners; and children respectively
- Inter-Institutional Amendment (IIA)** - a limited form of assurance to comply with 45 CFR 46 which is prepared by certain MPA affiliates (see Affiliate Institution). IIAs apply only when the affiliate regularly serves as a performance site for research conducted by a signatory institution(s)
- Multiple Project Assurance (MPA)** - a DHHS Assurance which applies during fixed and renewable periods to a broad spectrum of unrelated research activities
- Noninstitutional Investigator Agreement (NIA)** - an OPRR-authorized document entered into between a signatory institution and a non-institutional affiliate investigator (e.g., private practitioner) which assures compliance with 45 CFR 46 for a specified activity (e.g., cooperative oncology group trials)

- Headquarters Division of Medical Systems Research & Development (DMSRD), and Area Research & Publication Committee (ARPC) - the IHS offices whose functions include those of an "office of research administration," that is: providing a central focus for researchers, IRB, and administrators in processing protocols; arranging IRB reviews; keeping records; doing internal audits; and reporting and communicating pertinent information about human subject research--the Director, DMSRD providing research administration for the Headquarters IHS, the ARPC Chair for its Area
- Performance Site - any location where human subjects are involved in research for which an MPA, NIA, IIA, SPA, or CPA Assurance is required
- Primary Signatory Institution - where applicable, the signatory institution of two or more which is chosen to assume the function of the "office of research administration" for all signatory institutions
- Signatory Institution - an institution which OPRR finds eligible to enter into an Assurance and which has signed the Assurance
- Single Project Assurance- (SPA) - an Assurance document which is submitted to OPRR, upon request, for a specific DHHS research activity at a performance site where an MPA, IIA, NIA or CPA does not apply

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The INDIAN HEALTH SERVICE

Multiple Project Assurance of Compliance with DHHS Regulations for Protection of Human Research Subjects

The Indian Health Service (IHS), hereby gives assurance, as specified below, that it will comply with the Department of Health and Human Services (DHHS) regulations for the protection of human research subjects, 45 CFR Part 46, as amended to include provisions of the Federal Policy for the Protection of Human Subjects (56FR28003) as Subpart A, and as may be further amended during the approval period for this Assurance.

PART 1 - PRINCIPLES, POLICIES, AND APPLICABILITY

I. Ethical Principles

- A. The IHS is guided by the ethical principles regarding all research involving humans as subjects, as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (entitled: Ethical Principles and Guidelines for the Protection of Human Subjects of Research [the "Belmont Report"]), regardless of whether the research is subject to Federal regulation or with whom conducted or source of support (i.e., sponsorship).
- B. All institutional and non-institutional performance sites for the IHS, domestic or foreign, will be obligated by the IHS to conform to ethical principles which are at least equivalent to those of the IHS, as cited in the previous paragraph or as may be determined by the DHHS Secretary.

II. IHS Policy

- A. All requirements of Title 45, Part 46, of the Code of Federal Regulations (45 CFR 46) will be met for all applicable DHHS-supported research, and all other human subject research regardless of sponsorship, except as otherwise noted in this Assurance. Federal (all departments and agencies bound by the Federal Policy) funds for which this Assurance applies may not be expended for research involving human subjects unless the requirements of this Assurance have been satisfied.
- B. Except for those categories specifically exempted or waived under 45 CFR 46 § 101(b)(1-6) or 101(i), all research covered by this Assurance will be reviewed and approved by an Institutional Review Board (IRB) which has been established under a Multiple Project Assurance (MPA) with the Office for Protection from Research

Risks (OPRR) (see this MPA, Section 1.II.G). The involvement of human subjects in research covered by this Assurance will not be permitted until an appropriate IRB has reviewed and approved the research protocol and informed consent has been obtained from the subject or the subject's legal representative (see § 46.111, 46.116, and 46.117).

- C. The IHS assures that before human subjects are involved in nonexempt research covered by this Assurance, the IHS IRBs will give proper consideration to:
 - 1. the risks to the subjects; and
 - 2. the anticipated benefits to the subjects and others; and
 - 3. the importance of the knowledge that may reasonably be expected to result; and
 - 4. the informed consent process to be employed.

- D. Certification of IRB review and approval for all Federally-sponsored research involving human subjects will be submitted to the Division of Medical Systems Research Development (DMSRD) or the Area Research and Publication Committee (ARPC) for forwarding to the appropriate Federal department or agency. Compliance will occur within the time and in the manner prescribed for forwarding certifications of IRB review to DHHS or other Federal departments or agencies for which this Assurance applies. As required under § 46.119, the IRB will review and recommend approval for involvement of human subjects in Federal research activities for which there was no prior intent for such involvement, but will not permit such involvement until certification of the IRB's review and approval is received by the appropriate Federal department or agency.

- E. Institutions that are not direct signatories to this Assurance are not authorized to cite this Assurance. The IHS will ensure that such other institutions and investigators not bound by the provisions of this Assurance for DHHS-sponsored research will satisfactorily assure compliance with 45 CFR 46, as required (see this MPA, Sections 2.I.D. and 2.II.N.), as a prior condition for involvement in human subject research which is under the auspices of the IHS (see this MPA, Section 1.III.A.). Institutions that have entered into an Inter-Institutional Amendment (IIA) to this Assurance must submit a Single Project Assurance (SPA) to OPRR of DHHS for DHHS-sponsored research, on request, when that research is not conducted under the auspices of a signatory institution to this Assurance.

- F. The IHS will comply with the requirements set forth in § 46.114 regarding cooperative research projects. When research covered by this Assurance is conducted at or in cooperation with another entity, all provisions of this Assurance remain in effect for that research. The IHS may accept, for the purpose of meeting the IRB review requirements, the review by an IRB established under another DHHS MPA. Such acceptance must be (a) in writing, (b) approved and signed by Director of DMSRD, and (c) approved and signed by correlative officials of each of the other cooperating institutions. A copy of the signed understanding will serve as an addendum to this Assurance and will be forwarded to the OPRR of DHHS by the DMSRD for approval.

- G. The IHS will exercise appropriate administrative overview to ensure that the IHS's policies and procedures to protect the rights and welfare of human subjects are being effectively applied in compliance with this Assurance.

III. Applicability

- A. This Assurance applies to all research involving human subjects, and all other activities which even in part involve such research, regardless of sponsorship, if one or more of the following apply:
1. the research is sponsored by the IHS; or
 2. the research is conducted by or under the direction or co-direction of any employee or agent of the IHS in connection with his or her institutional responsibilities; or
 3. the research uses any property or facility of the IHS; or
 4. the research involves the use of the IHS's non-public information to identify or contact human research subjects or prospective subjects.
- B. All human subject research which is exempt from IRB review under § 46.101(b)(1-6) or 46.101(i) will be conducted in accordance with:
1. the Belmont Report; and
 2. the IHS's administrative procedures to ensure valid claims of exemption; and
 3. orderly accounting for such activities.
- C. Components of the IHS are bound by the provisions of this Assurance. Those components which can be expected to participate in human subject research sponsored by DHHS or other Federal departments or agencies for which this Assurance will apply are identified in Appendix A. Appendix A will be revised as changes occur and revisions forwarded to OPRR.
- D. This Assurance must be accepted by other Federal departments or agencies that are bound by the Federal Policy for the Protection of Human Subjects when appropriate for the research in question and therefore applies to all human subject research so sponsored. Research that is neither conducted nor supported by a Federal department or agency but is subject to regulation as defined in § 46.102(e) must be reviewed and approved, in compliance with §§ 46.101, 46.102, and 46.107 through 46.117.

PART 2 - RESPONSIBILITIES

I. The IHS

- A. The IHS acknowledges that it bears full responsibility for the performance of all research involving human subjects covered by this Assurance, including complying with Federal, state, Tribal, or local laws as they may relate to such research.
- B. The IHS will require appropriate additional safeguards in research that involves:
 - 1. fetuses, pregnant women, or human ova *in vitro* fertilization (see 45 CFR 46 Subpart B); or
 - 2. prisoners (see 45 CFR 46 Subpart C); or
 - 3. children (see 45 CFR 46 Subpart D); or
 - 4. cognitively impaired subjects; or
 - 5. other groups requiring special attention, e.g., subjects of genetic research, subjects of research involving radiation, third parties at risk by the research, or potentially vulnerable people.
- C. The IHS, including all its named components (see this MPA, Appendix A), acknowledges and accepts its responsibilities for protecting the rights and welfare of human subjects of research covered by this Assurance.
- D. The IHS is responsible for acquiring appropriate Assurances or Amendments, when requested, and certifications of IRB review and approval for federally sponsored research from all its standing affiliates (see this MPA, Appendix B) and Assurances or Agreements for all others, domestic or foreign, which may otherwise become affiliated on a limited basis in such research.
- E. The IHS is responsible for ensuring that no affiliates cooperating in the conduct of federally sponsored research for which this Assurance applies do so without an appropriate assurance of compliance and satisfaction of IRB certification requirements.
- F. In accordance with the compositional requirements of § 46.107, the IHS has established the IHS IRBs for the IHS components listed in Appendix A and the membership rosters in Appendix C. Certain research supported by the U.S. Department of Education will be reviewed in accordance with the requirements of Title 34 CFR Parts 350 and 356 which require that the appropriate IHS IRBs include one person who is primarily concerned with the welfare of handicapped children or mentally disabled persons.
- G. The IHS will provide both meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

- H. The IHS recognizes that involvement in research activities of any OPRR-recognized Cooperative Protocol Research Programs will involve additional reporting and recordkeeping requirements related to human subject protections.
- I. The IHS is responsible for ensuring that it and all its affiliates comply fully with all applicable Federal, state, and Tribal policies and guidelines, including those concerning notification of seropositivity, counseling, and safeguarding confidentiality where research activities directly or indirectly involve the study of human immunodeficiency virus (HIV) and all other high risk research.

II. Division of Medical Systems Research and Development (DMSRD), and Area Research and Publication Committees (ARPCs)

- A. The jurisdiction of the DMSRD partially overlaps or duplicates the jurisdiction of the ARPCs.
 - 1. The Chair of the ARPC is the Chair of the Area IRB. The Chair does those "office of research administration" functions for research proposals for which the Area IRB has jurisdiction. That jurisdiction includes being the IRB of record for research involving the Area IHS.
 - 2. The Director of DMSRD is the Chair for the Headquarters IRB. The DMSRD Director does those "office of research administration" functions for research proposals for which IHS has jurisdiction.
 - 3. With the concurrence of both the Director of DMSRD and the Area IRB, and documented as a change to this MPA with OPRR approval, the Area IRB may have jurisdiction to review research protocols without a second review by the Headquarters IHS IRB, for all protocols that:
 - a. are not possibly greater than minimal risk; and
 - b. do not involve special groups (see this MPA, Section 2.I.B); and
 - c. are not covered by the FDA regulations (21 CFR Parts 50 and 56).

(The Area IRBs with jurisdiction to review research protocols without a second review by the Headquarters IRB are noted in Appendix A.)
 - 4. The Headquarters IRB has jurisdiction to do a second IHS IRB review, both for all protocols reviewed by Area IRBs that do not have jurisdiction to review some protocols without that second review, and for all protocols that:
 - a. are possibly greater than minimal risk; or
 - b. involve special groups (see this MPA, Section 2.I.B), or
 - c. are covered by FDA regulations (21 CFR Parts 50 and 56).

- B. The DMSRD and ARPCs will receive from investigators all research protocols which involve human subjects, keep investigators informed of decisions and administrative processing, and return all disapproved protocols to them.
- C. The DMSRD is responsible for reviewing for the Headquarters IHS IRB, and the ARPCs are responsible for reviewing for the Area IHS IRBs, the preliminary determinations of exemption by supervisors and for making the final determination based on § 46.101(b)(1-6) or 46.101(i). Notice of concurrence for all exempt research will be promptly conveyed in writing to the investigator. All nonexempt research will be forwarded to the appropriate IHS IRB(s).
- D. The DMSRD and ARPCs will make the preliminary determination of eligibility for expedited review procedures (see § 46.110) for their respective IHS IRBs, following the list of eligible research activities in 46FR8392. Expedited review of research activities will not be permitted where full board review is required.
- E. The Headquarters IRB has final responsibility to determine if an activity, thought not to be research by an Area IRB or by an ARPC for its Area IRB, is research for purposes of the regulations 45 CFR 46. The Headquarters IRB also has final responsibility to determine if research:
 - 1. that had been considered exempt, is not exempt from IRB review based on § 46.101(b)(1-6) or 46.101(i); or
 - 2. that had been considered eligible for review by only Area IRB(s), is possibly greater than minimal risk or involves a special group (see this MPA, Section 2.I.B.) or is covered by FDA regulations (21 CFR Parts 50 and 56); or
 - 3. that had been considered eligible for expedited review, is not eligible (see § 46.110) following the list of eligible research activities in 46FR8392.

The Headquarters IRB will promptly send notice of its nonconcurrence with an Area IRB's or ARPC's determination, in writing to that entity.

- F. By delegation from the Director of the IHS, the Director of DMSRD will review all research (whether exempt or not) and decide whether the IHS will permit the research. If approved by the IRB, but not permitted by the IHS, the Director of DMSRD will promptly convey notice to the investigator and the IHS IRB(s). Neither the Director of DMSRD nor any other office of the IHS may approve a research activity that has been disapproved by the appropriate IRB.
- G. The administration for the IRB of record, i.e., DMSRD or ARPC, will forward certification of IRB approval of proposed research to the appropriate Federal, state, or Tribal department or agency only after all IRB-required modifications have been incorporated to the satisfaction of the IHS IRB(s). If the Area IRB has the jurisdiction to review the proposed research without duplicate review by the Headquarters IRB (see this MPA, Section 2.II.A.3.), that ARPC will also forward a copy of the certification of IRB approval to the DMSRD for its records.

- H. The DMSRD and ARPCs will designate procedures for the retention of signed consent documents for at least three years past completion of the research activity.
- I. The DMSRD and ARPCs will ensure both:
 - 1. that all human subject research which is exempt under § 46.101(b)(1-6) or 46.101(i) does not pose greater than minimal risk to human subjects; and
 - 2. that all such research will be conducted in accordance with (a) the Belmont Report, and (b) the IHS's administrative procedures to ensure valid claims of exemption, and (c) orderly accounting for such activities (see this MPA, Section 1.III.B.).
- J. The DMSRD and ARPCs will maintain and arrange access for inspection of IRB records as provided for in § 46.115.
- K. The DMSRD and ARPCs are responsible for ensuring constructive communication among the research administrators, division and program heads, research investigators, clinical care staff, human subjects, Area and Service Unit Directors, Tribal officials, and other relevant officials to maintain a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.
- L. The DMSRD and ARPCs will arrange for and document in its records that each individual who conducts or reviews human subject research has first been provided with a copy of this Assurance, as well as with ready access to copies of 45 CFR 46, regulations of other Federal departments or agencies as may apply, the Belmont Report, and all other pertinent Federal, state, and Tribal policies and guidelines related to the involvement of human subjects in research.
- M. The DMSRD will report promptly to the appropriate IHS IRBs, appropriate IHS officials, OPRR, and any other sponsoring or reviewing Federal, state, or Tribal department or agency head:
 - 1. any injuries to human subjects or other unanticipated problems involving risks to subjects or others; and
 - 2. any serious or continuing noncompliance with 45 CFR 46, other applicable Federal, state, or Tribal regulations, or requirements of the IRB; and
 - 3. any suspension or termination of IRB approval for research.
- N. The DMSRD will ensure:
 - 1. solicitation, receipt, and management of all assurances of compliance (whatever the appropriate format), and certifications of IRB review (where appropriate) for all affiliates to the IHS (including those listed in Appendix B); and
 - 2. subsequent submission of these documents to the proper authorities as a condition for involvement in human subject research activities sponsored by DHHS, or sponsored or reviewed by any other Federal, state, or Tribal department or agency for which this Assurance applies.

- O. The DMSRD will ensure that all affiliated performance sites, that are not otherwise required to submit assurances of compliance with 45 CFR 46 and other applicable Federal, state, or Tribal regulations for the protection of research subjects, at least document mechanisms to implement the equivalent of ethical principles to which the IHS is committed (see this MPA, Section 1.I.).
- P. When an IHS IRB accepts responsibility for review of research which is subject to this Assurance and conducted by any independent investigator who is not otherwise subject to the provisions of this or other Assurance, the DMSRD will obtain and retain an Noninstitutional Investigator Agreement (NIA) to document the investigator's commitment to abide:
 - 1. by the same requirements for the protection of human research subjects as does the IHS; and
 - 2. by the determinations of the appropriate IHS and non-IHS IRBs.
- Q. The DMSRD assumes responsibility for ensuring conformance with special reporting requirements for any OPRR-recognized Cooperative Protocol Research Programs in which the IHS participates.
- R. The DMSRD will ensure compliance with the requirements set forth in this Assurance and § 46.114 regarding cooperative research projects. In particular, when an IHS IRB relies on another institution with a DHHS MPA, the DMSRD will ensure that documentation of this reliance will be (a) in writing, (b) approved and signed by the Director of DMSRD, (c) approved and signed by the correlative officials of each of the other cooperating institutions, and (d) retained by the DMSRD for at least three years past completion of the related research project. Where an agreement between MPA IRBs is planned, the DMSRD will forward a copy of the required signed understanding to OPRR for inclusion in this Assurance as an addendum.
- S. The DMSRD will be responsible for procedural and recordkeeping audits not less than once every year for the purpose of detecting, correcting, and reporting (as required) administrative and/or material breaches in uniformly protecting the rights and welfare of human subjects as required at least by 45 CFR 46 and as may otherwise be additionally required by the IHS. These audits will cover all IHS IRBs, reviews by other institutions with a DHHS MPA upon which the IHS IRBs relied, and Inter-Institutional Amendments and Cooperative Project Assurances.

III. IHS Institutional Review Boards (IRBs)

- A. All IHS IRBs will review, and have the authority to approve, require modification in, or disapprove all research activities within their jurisdiction (see this MPA, Section 2.II.A.), including proposed changes in previously approved human subject research. For approved research, all IRBs will determine which activities require continuing review more frequently than every twelve months or need verification that no changes have occurred if there was a previous IRB review and approval.

- B. IRB decisions and requirements for modifications will be promptly conveyed to investigators and the DMSRD, in writing. Written notification of decisions to disapprove will be accompanied by reasons for the decision with provision of an opportunity for reply by the investigator, in person or in writing. The investigator may formally appeal an IRB decision only to the IRB(s) with jurisdiction.
- C. In compliance with 45 CFR 46 and provisions of this Assurance, all IHS IRBs will do initial and continuing convened IRB reviews and approvals for each project, unless the DMSRD or ARPCs properly find the project either (a) to be exempt under §§ 46.101(b) and 46.101(i), or (b) to be eligible for expedited review (see § 46.110), following the list of eligible research activities in 46FR8392. Continuing reviews will be done by the IHS IRB(s) of record, and will be preceded by IRB receipt of appropriate progress reports from the investigator, including available study-wide findings. Continuing reviews of projects that were properly approved by expedited review may be done by expedited review; continuing reviews of projects that were approved by a full IRB review must be by a full convened IRB.
- D. All IHS IRBs will observe the quorum requirements of § 46.108(b). In no case will the quorum for an IHS IRB be less than five. At least one American Indian or Alaska Native IRB member whose concerns are primarily in nonscientific areas, and at least one IRB member whose concerns are primarily in scientific areas, must be present both to start every convened IRB meeting, and during the discussion and decision for each protocol.
 - 1. No IRB may have a member participating in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
 - 2. All IHS IRBs must have effective knowledge of subject populations, institutional constraints, differing legal requirements, and other factors which can foreseeably contribute to a determination of risks and benefits to subjects and subjects' informed consent and can properly judge the adequacy of information to be presented to subjects in accordance with requirements of §§ 46.103(d), 46.107(a), 46.111, and 46.116.
- E. All IHS IRBs will determine, in accordance with the criteria found at § 46.111 and Federal, state, or Tribal policies and guidelines for involvement of human subjects in HIV and all other high-risk research, that protections for human research subjects are adequate.
- F. All IHS IRBs will ensure that legally effective informed consent will be obtained and documented in a manner that meets the requirements of § 46.116 and 46.117. The IRB will have the authority to observe or have a third party observe the consent process.
- G. All IHS IRBs will be sufficiently qualified through the experience and expertise of its members, and the diversity of the members' backgrounds including consideration of

the ethnic and cultural backgrounds of members and sensitivity to issues such as community attitudes and Tribal sovereignty, to promote respect for their advice and counsel in safeguarding the rights and welfare of human subjects, especially among American Indian and Alaska Native peoples and communities.

1. All IHS IRBs will include:
 - a. both male and female members; and
 - b. members representing a variety of professions; and
 - c. at least two members whose primary expertise is in a nonscientific area; and
 - d. at least one member who is not otherwise affiliated with the IHS.
 2. Because IHS policy is to promote the self-determination by and cultural integrity of American Indian and Alaska Native communities (P.L. 94-437), all IHS IRBs will include two American Indian or Alaska Native members whose concerns are primarily in nonscientific areas.
 3. Where appropriate, all IHS IRBs will determine that adequate additional protections are ensured for fetuses and pregnant women, prisoners, and children, as required by Subparts B, C, and D of 45 CFR 46. The DMSRD will notify OPRR promptly when membership of any IHS IRB is modified to satisfy requirements of § 46.304 and when any IHS IRB fulfills its duties under § 46.305(c).
- H. Scheduled meetings of all IHS IRBs for review of each research activity will occur not less than every 12 months and may be more frequent, if required by the IRB on the basis of degree of risk to subjects. All IRBs may be called into an interim review session by the Chair at the request of any IRB member, Tribal official, or IHS official to consider any matter concerned with the rights and welfare of any subject.
- I. All IHS IRBs will prepare and maintain adequate documentation of its activities in accordance with § 46.115 and in conformance with requirements of the DMSRD.
- J. All IHS IRBs will forward to the DMSRD any significant or material finding or action, at least to include the following:
1. any injuries to human subjects, or any other unanticipated problems involving risks to human subjects or to other people; and
 2. any serious or continuing noncompliance with 45 CFR 46, other applicable Federal, state, or Tribal regulations, or requirements of the IRB; and
 3. any suspension or termination of IRB approval.
- K. In accordance with § 46.113, all IHS IRBs will have the authority to suspend or terminate previously approved research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

- L. All IHS IRBs will ensure effective input (consultants or voting or nonvoting members) for all initial and continuing reviews conducted on behalf of performance sites where there will be human research subjects. IRB minutes will document attendance of those other than regular voting members. The IRB membership rosters in Appendix C include people who are identified as knowledgeable about any affiliate institution that has entered into an Inter-Institutional Amendment or other Assurance in which a non-IHS IRB relies on one or more IHS IRBs.
- M. When two or more IHS IRBs review the same proposal, the conditions required by one sometimes may differ from those by the other.
 - 1. When two or more Area IRBs each are the IRB of record for a proposed research because it will be done in those Areas, if the IRBs require different conditions, each set of conditions applies to the research done in its Area.
 - 2. When duplicate reviews are done by both the Headquarters and Area IRBs, if the two reviews require different conditions, the conditions are additive (i.e., the total conditions are those by one IRB plus those by the other.)
 - 3. When duplicate reviews are done by both the Headquarters and Area IRBs, if the two reviews each require a condition addressing a similar topic, the condition that is more stringent in protecting the interests of the subject supersedes the similar but less stringent condition.
 - 4. When different IHS IRBs require mutually contradictory conditions, the IRBs will resolve the contradiction between them by negotiation.
- N. All IHS IRBs will act with reasonable dispatch, upon request, to provide full board review of protocols of OPRR-recognized Cooperative Protocol Research Programs (CPRP). The IRB will not employ expedited review procedures for CPRP protocols when they are to be entered into for the purpose of research. Although emergency medical care based on such protocols is permitted without prior IRB approval, patients receiving emergency care under these conditions will not be counted as research subjects and resultant data will not be used for research purposes.
- O. Certifications of IRB review and approval will be forwarded:
 - 1. to the appropriate Federal, state, or IRB department or agency for research sponsored or reviewed by such departments or agencies; and
 - 2. to the Director of DMSRD.

IV. IHS Area Directors, and Associate Director of Headquarters West

- A. Area Directors, through appropriate procedures established within their respective Areas, are responsible to ensure review of research protocols involving IHS Area personnel or resources for ethical considerations, scientific merit, and concordance with the commitment by the U.S. Government and IHS to the self-determination by

and cultural integrity of American Indian and Alaska Native communities (P.L. 94-437).

- B. Each IHS Area will have at least one IRB to review all human subject research. There are 12 Area IRBs. The membership of each Area IRB is appointed by the respective Area Director. The membership of the Headquarters IHS IRB is appointed by the Deputy Director of Headquarters Operations-West.

V. IHS Program Directors

- A. With the concurrence of the Director of DMSRD, Directors of IHS Programs (e.g., Cancer, Diabetes, Mental Health) who have received sufficient IHS training about IRBs and protection of human subjects and communities may be authorized to review protocols and activities to make the preliminary determination if the activity is research, and if so, is the research exempt from IRB review based on § 46.101(b)(1-6) or 46.101(i).
- B. Each authorized IHS Program Director will receive all protocols of research or of activity that may be research involving that program that have not been sent to the Area or Headquarters IHS IRB(s). The Program Director is responsible for the preliminary determination of non-research or exemption based on § 46.101(b)(1-6) or 46.101(i). Notice of concurrence for all non-research activity or exempt research will be promptly sent in writing to the initiator, with a copy to DMSRD and to the appropriate ARPC(s). All nonexempt research will be sent to the appropriate IHS (Area or Headquarters) IRB(s) for review.

VI. Research Investigators

- A. Research investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of this Assurance.
- B. Research investigators who intend to involve human research subjects, and anyone who intends to do an activity that is possibly research, will not make the final determination that the activity is not research and, if it research, that it is exempt from 45 CFR 46, other applicable Federal, state, or Tribal regulations, or certain provisions of this Assurance. The IHS IRBs make that determination (see this MPA, Sections 2.II.A-D.); the Headquarters IRB has final authority to make those determinations (see this MPA, Section 2.II.E.).
- C. Research investigators are responsible for providing a copy of the IRB-approved and signed informed consent document to each subject at the time of consent, unless the IRB has specifically waived this requirement. All signed consent documents are to be retained in a manner approved by the DMSRD or ARPC(s).
- D. Research investigators will promptly report proposed changes in previously approved human subject research activities to the IRB. The proposed changes will not be

initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.

- E. Research investigators are responsible for reporting progress of approved research to the DMSRD or ARPC(s), as often as and in the manner prescribed by the approving IRB(s) on the basis of risks to subjects, but no less than once per year.
- F. Research investigators will promptly report to the IRB any injuries or other unanticipated problems involving risks to subjects and others.
- G. No research investigator who is obligated by the provisions of this Assurance, any associated Inter-Institutional Amendment, or Noninstitutional Investigator Agreement will seek to obtain research credit for, or use data from, patient interventions that constitute the provision of emergency medical care without prior IRB approval. A physician may provide emergency medical care to a patient without prior IRB review and approval, to the extent permitted by law [see § 46.116(f)]. However, such activities will not be counted as research nor the data used in support of research.
- H. Research investigators will advise all appropriate IHS and non-IHS IRB(s), DMSRD or ARPC(s), and the appropriate officials of other institutions (such as hospitals) of the intent to admit to those other institutions any human subjects who are involved in research protocols for which this Assurance or any related Inter-Institutional Amendment or Noninstitutional Investigator Agreement applies. When such admission is planned or a frequent occurrence, those institutions must possess an applicable OPRR-approved Assurance prior to involvement of such persons as human subjects in those research protocols.

VII. Affiliated Institutions and Investigators

- A. Each affiliate to the IHS that is involved in DHHS-sponsored research activities must provide to the DMSRD an appropriate written assurance of compliance with the Belmont Report and 45 CFR 46 (or equivalent protections if a foreign site).
- B. Each affiliate institution must respond to a request by the DMSRD for an Inter-Institutional Amendment or for a Single Project Assurance (standard or modified), when and as appropriate, whichever is most suited to the circumstances.
- C. Each non-institutional affiliate (e.g., a private practice physician not otherwise an employee of the IHS or who otherwise would not ordinarily be bound by the provisions of this Assurance) who is involved in human subject research of the IHS must respond to a request by the DMSRD for a Noninstitutional Investigator Agreement when required.
- D. Performance sites that are not legally inseparable components of the IHS (whether an institutional or non-institutional affiliate) are not authorized to cite this Assurance.

PART 3 - SIGNATURES

I. IHS Endorsements

The officials signing below assure that any research activity conducted, supported, or otherwise subject to DHHS or other Federal departments or agencies that are authorized to rely on this Assurance (Parts 1, 2, 3 and Appendices) or any other sources provided for in this Assurance, will be reviewed and approved by the appropriate IHS IRBs in accordance with the requirements of all applicable Subparts of Part 46, Title 45 of the Code of Federal Regulations, with this Assurance, and the stipulations of the IHS IRBs.

A. Primary Signatory Institution

1. AUTHORIZED INSTITUTIONAL OFFICIAL

Signature: _____ Date: _____
Name: Michael H. Trujillo, MD, MPH
Title: Director
Institution: Indian Health Service
Address: 5600 Fishers Lane
Parklawn Building, Room 6-05
Rockville, MD 20857
Phone: (301) 443-1083

2. PRIMARY CONTACT

Signature: _____ Date: _____
Name: William L. Freeman, MD, MPH
Title: Director
Institution: DMSRD, Indian Health Service
Address: 5300 Homestead Road NE
Albuquerque, NM 87110-1293
Phone: (505) 837-4141

B. Other Signatory Institutions

[none]

FOR DHHS USE ONLY

II. Office for Protection from Research Risks (DHHS) Approval

A. DHHS RECOMMENDING OFFICIAL

Signature: _____ Date: _____

Name: Katherine Duncan, M.D.

Title: Adjunct Medical Officer

Address: Division of Human Subject Protections

Office for Protection from Research Risks (OPRR)

6100 Executive Boulevard

Suite 3B10, MSC 7507

Rockville, MD 20892-7507

Phone: (301) 496-7005

EFFECTIVE DATE OF ASSURANCE: _____

EXPIRATION DATE OF ASSURANCE: _____

B. DHHS APPROVING OFFICIAL

Signature: _____ Date: _____

Name: Clifford C. Scharke, D.M.D., M.P.H.

Title: Chief, Assurance Branch

Address: Division of Human Subject Protections

Office for Protection from Research Risks (OPRR)

6100 Executive Boulevard

Suite 3B10, MSC 7507

Rockville, MD 20892-7507

Phone: (301) 496-7005

Model Volunteer Consent Forms for the Indian Health Service

William L. Freeman, MD, MPH Chair, National IHS IRB
September 14, 1998

Explanation

To help investigators draft the forms needed for their projects, the IHS IRBs developed the attached 8 model volunteer forms for different hypothetical situations. The situations include 4 different research protocols typically seen in IHS, a fifth protocol typical in tertiary-care, and 2 EPI-AID protocols. The protocols, and thus the forms or sheets, range from complex (#1, #3, #5) to simple (#4, #7). The specific hypothetical situations are:

- 1] a randomized, double-blind, placebo-controlled, Phase III clinical trial of an Investigational New Drug vaccine, *i.e.* risk;
- 2] a screening by lab testing of a population for diabetes;
- 3] a survey about domestic violence, *i.e.*
- 4] a simple questionnaire survey of users of a clinic for health service needs;
- 5] a generic open-label single arm protocol to use and assess ribavirin for hantavirus;
- 6] a "youth risk behavior survey" (YRBS); and
- 7], 8] *information sheets*

The last page lists those elements in consent forms required by regulations 45 CFR 46 (marked by @), or needed by only some protocols (unmarked). The part of the regulation covering each element is cited. The list is from a larger checklist used by IHS Area and National IRBs.

We wrote the 6 model Volunteer Consent Forms and 2 information sheets to be understandable by most people. The National Adult Literacy Survey (NALS), whose results were released in early September, 1993, led me to revise the forms again. 1 Let me describe the NALS briefly, and show how it is relevant to consent forms.

In 1992, NALS tested a valid sample of 13,600 US adults for 3 types of applied literacy:

- *prose*
 - *document*
 - *quantitative*
- etc.

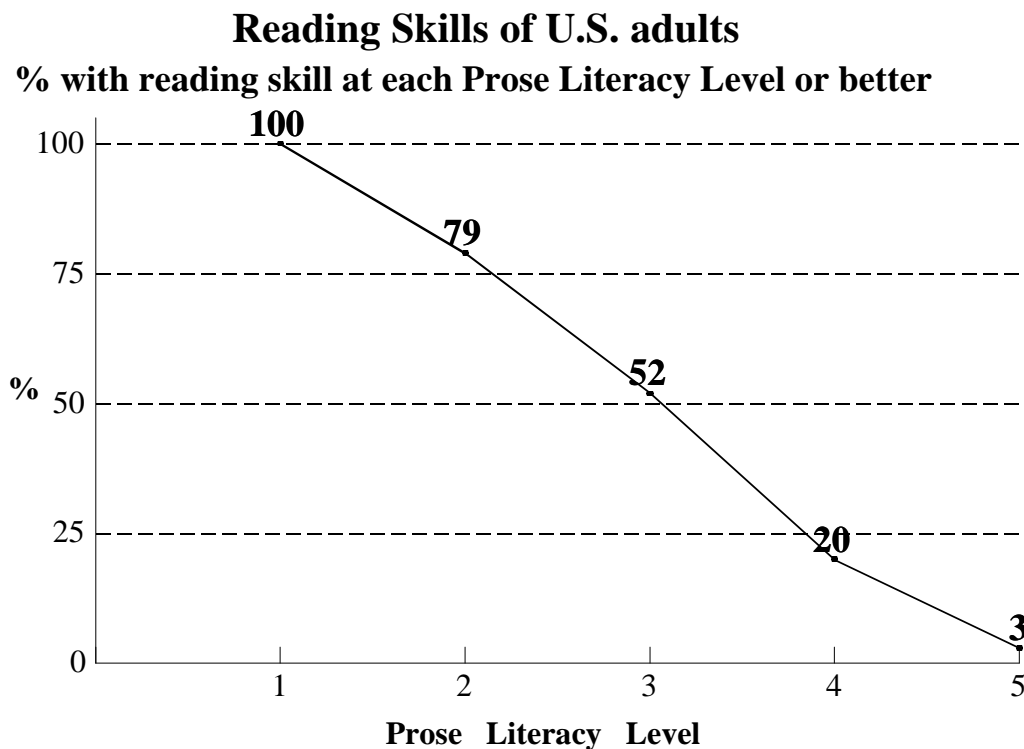
The results of testing applied *prose*

¹ Kirsch IS, Jungeblut A, Jenkins L, Kolstad A. *Adult literacy in America: a first look at the results of the National Adult Literacy Survey*. Washington, DC: National Center for Education Statistics, US Dept. Education; 1993.

NALS divided the results into 5 "Levels" of prose literacy.

- Level 1: not be able to read at all; or "read a relatively short text to locate of single piece of information."
- Level 2: "integrate two or more pieces of information to compare and contrast easily identifiable information"; locate a single piece of information but the passage had several "distractors" ("plausible but incorrect pieces of information").
- Level 3: "make matches that require low-level inferences"; "integrate information from dense or lengthy text that contains no organizational aids such as heading."
- Level 4: "integrate or synthesize information from complex or lengthy passages"; "[c]onditional information is frequently present."
- Level 5: "search for information in dense text which contains a number of plausible distractors": readers must "use specialized background knowledge" to understand part of the text.

Levels 4 and 5 describe many consent forms we have all seen, and written! How many US adults could be expected to understand Level 4 or 5 consent forms? See the graph below.



(Percentages calculated from data in the National Adult Literacy Survey.)

Apparently only 20% of US adults would understand the more dense and complex consent forms we are familiar with. How can consent forms be made understandable to more people?

One possible approach would reverse or omit those factors that contributed to decreased comprehension in the texts used by NALS. Those factors included the following.

Factors that decrease comprehension of prose material used by NALS

1.	Increase in number of items or categories of information
2.	Decrease in the closeness of relationship of the text to the information being tested
3.	Increase in length and density of the text
4.	Increase in amount of background information needed by reader to understand the text
5.	Increase in number of distractors (information apparently similar to, but actually different from, the information being tested)
6.	Decrease in the organization aids of the format of the text.

To reverse these factors above associated with fewer people understanding the NALS material, we drafted the Model Volunteer Consent Forms to meet the following 6 criteria.

1. Be brief, but have complete basic information [*Affects factors 1, 2, 3.*]

The first factor cannot be eliminated entirely, because 45 CFR 46 requires more than a dozen items of information. However, omitting unnecessary or irrelevant items of information will help minimize factor 1, and help reverse factors 2 and 3.

Many potential volunteers do not read long consent forms or information sheets. The longer the form, the fewer the people who read it in its entirety, and the smaller the fraction of the form that is read by the rest. Thus, trying to be more comprehensive by adding more information may result in less information actually transmitted.

The model forms include only the *basic information*

We researchers have a bias: we tend to include too much scientific detail, and to minimize or omit some required elements of 45 CFR 46. The models are designed to counter that bias; they do not try to answer every conceivable scientific question. For example, the first model, for the experimental vaccine, does not have information about how the vaccine was made. (That would be "basic information" only if it were controversial, *e.g.*

all items required by the regulations. We tried to make the model forms include only information closely related to the core information needed to be understood, analyzed, thought over, and remembered by potential volunteers.

"Non-basic information" can be given in a separate handout, perhaps in a Question-and-Answer format. We suggest including a list of questions at the beginning of the handout, to permit people to go directly to those questions they are most interested in.

2. Be less dense, *i.e.*

All of us have encountered quite dense material that is difficult to read and to understand. Readability measures one aspect of density. Several computer programs have 1 or more readability formulas, usually expressed in school "grade" level. The readability formulas are usually a linear relationship of: the average number of words per sentence, and the average number of syllables or letters per word. Thus, a consent form with "ninth grade readability" means that the relationship between words-per-sentence and syllables-per-word of the consent form is similar to that in material read and understood by ninth graders.

Unfortunately, words-per-sentence and syllables-per-word sometimes have little to do with understandability. Rare short words in short sentences may have a mathematical similarity to material read in the lower grades, but be understood only by rare people. Beyond short words and short sentences, ways to improve readability include the following.

- Use active voice rather than passive voice verbs ("We did" rather than "It was done").
- Use common words in general.
- Make clear the links of logical sequences and of cause-and-effect, even if doing so makes the sentence much longer. ("We will do this, because that happened.")

The readability of the first model form, for the vaccine trial, is 8th grade. No sentence is 30 words or longer, while 56% are 14 words or shorter. Only 10% are in the passive voice. The text is just 1285 words, in spite of complexity of the research. Model consent #3 has 8th grade readability; model sheet #7 has 6th grade. All other models have 7th grade readability.

3. Be clear and provide the background information needed. (Use familiar terms, explain unfamiliar terms and concepts, and organize into logical sequences.) [*Affects factor #4.*]

The model forms try to omit specialty terms and concepts not essential for being informed to make a decision, and try to define and explain all new terms needed. The forms strive to be understandable, not scientifically precise. Also, people can comprehend organized new material better than unorganized new material. Thus, organizing new material into succinct blocks, and putting the blocks in a logical clear sequence, helps maximize comprehension. Writers of consent forms should ask "*hat potential volunteer's questions are does s/he not have, but needs, to understand this?*"

4. Use only 1 meaning for important terms; eliminate "distractors." [*Affects factor #5.*]

Distractors include the same word with different meanings; the multiple meanings confuses people. Many consent forms have two such distractors: [1] "risk"; and [2] "benefit."

"Risk" means the *harms inherent in the research to come do* only in the former sense, *i.e. volunteers and community* "risk factors."

"Benefits" means *advantages inherent in the research foregone participation inherent possible benefits of the research for volunteers and community services*" can be used in the non-coercion disclaimer; "reimbursement" or "payment" can be used for participating.

5. Have a format that helps people comprehend and remember the information. [*Affects factor 6.*]

Format can help people comprehend and remember complex material. Research has shown that certain elements of format help improve comprehension. Good format includes:

- Headings
- indents;
- key words in **bold** or underlined;
- vertical lists (instead of run-on lists in long sentences);
- extra spacing between topics;
- repetition (repeat important, difficult-to-understand, points);
- reasonable-size type (not small print to minimize pages);
- lower case, NOT UPPER CASE; and
- plenty of margins and empty space in general. (Think of the daunting insurance-policy statements with their wall-to-wall and top-to-bottom writing in small print.)

These elements of format help the reader:

- [A] to recognize the organization of the consent form;
- [B] to recognize, know, and remember the key points; and
- [C] to go back later to the form to retrieve important information, such as telephone number of the doctor to call if injury occurs.

6. Serve as a script for the face-to-face discussions with the potential volunteers. *[This criterion is not related to the above factors suggested by the NALS.]*

Face-to-face discussions between investigators and potential volunteers are the most important part of the process of informed consent. These model forms are intended to be both the written consent forms and the script for the verbal explanation by the investigators. If the verbal explanation is almost the same as the written form, each will reinforce the other and avoid inconsistency. Thus, each model is actually a combined *form-script*

One benefit of this approach is that the form-script prompts investigators to use simple language for the verbal explanation. Another benefit is that the same form-script can be used for potential volunteers who have difficulty reading, have low literacy, or need a translation--which also increases consistency of explanation among all volunteers. Investigators need develop only one form-script, not two, to permit people of all literacy levels to be potential volunteers. The form-script could also be used to videotape the explanation.

The model form-scripts reinforce both the oral discussion and visual reading. For instance, the bolded headings are the key "take home" points of the information to be transmitted. The form-script approach should result in two editorial benefits.

- 1] Bolded headings attract attention and are remembered. By having key points as headings, the reader more likely will remember the key points. (Bolded headings that are just titles or questions attract attention, but unfortunately are not intended to be remembered.)
- 2] The length is shorter. There is little or no unnecessary verbiage.

Exemplary consent forms may be necessary, but are not sufficient, for informed consent.

Researchers and IRBs should go beyond the consent form in two ways.

First, the quality of the interpersonal communication in the process of consent--the two-way sharing of information by researcher and potential volunteer--is more important than the quality of written forms. The sharing should be two-way; the researcher needs to impart information, as well as find out the level of understanding by potential subjects and elicit questions they may have. IHS IRBs have not devised ways to assure high quality in the process of communication. One way may be that the researchers, the tribal government or personnel from the tribal health department, Health Boards, and IRBs work out consent processes as partners that are culturally sensitive and respectful of each person.

Second, because some research protocols are so distant from the background information possessed by most people, the amount of totally new information required

to be in consent forms for those protocols may overwhelm even maximum clarity of writing. The generic ribavirin form, #5, may be such an example. In such circumstances, 3 added steps may help.

- [1] Allow and encourage more than 24 hours for discussion and a decision. Simply having the person take the consent form home overnight can increase comprehension. ² What people learn from written material varies by the background information they have about the subject. ³ Hence, a researcher could try to increase the background information of potential volunteers before they could understand enough to make an informed decision. *E.G.* discuss the information in 2 stages, at least a day apart. The first stage would focus on the basic information about the purpose; the second stage would summarize and answer questions about the purpose, and then focus on procedures. This approach is feasible when time is not critical, unlike the ribavirin protocol.
- [2] Educate people before they are asked to participate, by publicizing and discussing the protocol repeatedly in the media. One should use as many media channels as possible, *e.g.* meetings, churches, etc. This approach is feasible when the community has high interest in the research.
- [3] For one-on-one discussions with potential volunteers, use media in addition to the printed page, *e.g.* etc.

In summary, we should follow the principles of effective written communication, *i.e.* the 6 factors leading to poor comprehension. We should write consent forms understandable by 70%–80% of the adult population. Even with more than 12 important items required by 45 CFR 46, Level 2 consent forms are possible, and achievable for many research protocols. To give suggestions or comments, or to ask questions, please call or write me at:

5300 Homestead Road NE
Albuquerque, NM 87110–1293
505–248–4141 fax 505–248–4384 william.freeman@mail.ihs.gov

² Morrow G, Gootnick J, Schmale A. A simple technique for increasing cancer patients' knowledge of informed consent to treatment. *Cancer* 1978; 42:793-799.

³ Mosenthal PB, Kirsch IS. Learning from exposition: using knowledge modeling as a basis for assessing student's knowledge. *J Reading*. 1992; 35:668-678.

Model Volunteer Consent Form, #2

Background

A team of service unit health care prevalence of diabetes in the community. The ultimate purpose is to determine geographic or demographic (age and gender) groups have the highest rates of undiagnosed diabetes, random serum glucose final diagnosis. The team obtained technical assistance for project design and sample size calculations.

General Methods:

The team members. The sampling office. This list every selected people and ask them to participate in the study. Anyone positive on a random serum glucose

Is an "Informed Consent" form necessary? Is this truly "research"?

Screening for diabetes is part of clinical care; a detailed process of informed consent is not usually done project really clinical care

Although the project includes clinical care, it is also research, due to its use of sampling and to the purpose of the project. Sampling is done to ensure that the prevalence rates found are valid for the entire community. But sampling is a method of research, not of clinical care. The undiagnosed diabetes, and ho purpose is research, although the research results care.

Informed Consent by potential volunteers:

Informed consent must be obtained before a person's participation. Although finding undiagnosed diabetes

*instance, driver license and insurability may be adversely affected by a diagnosis of diabetes.)
The consent must describe all benefits and risks.*

Community Diabetes Research Project Informed Consent for Volunteers

We ask you to take part in research for the Community Diabetes Project.

The Project is sponsored by the Tribal Health Program and IHS. We want to find out how many people have diabetes but do not know it.

Diabetes means that a person has too much sugar in the blood. Many people in this Tribe have diabetes. Although many people with diabetes are diagnosed in the Clinic, some people may not know they have it. If we know where most of those people live, we can set up stations to screen for diabetes in those Districts.

We want to check 200 adults for diabetes who live in all parts of the Reservation. We picked the people randomly from the Tribal Census, like picking bingo numbers out of a drum.

We want to check your height and weight, and do a blood test for sugar.

If you agree to take part, we will ask some questions about your health and how you are feeling. We then will check your height and weight, and get a drop of blood from you by a finger-stick. We will **test your blood for sugar right away, and tell you the results**. All this takes about 15 minutes of your time.

When we get back to the Clinic, we will put all the results in your chart, for the doctors to see.

If your test shows high blood sugar, we will ask you to go to the Clinic.

The test today does not diagnose diabetes. High blood sugar on the test today means just that you may have diabetes or tend to have it.

If the test today is high, we will make a Clinic appointment for you. **You can get the final tests to check for diabetes there.**

You and the community may benefit if you agree to take part.

You may benefit because you will learn if you have diabetes or not. If you have diabetes but do not know it, the Clinic can help you stay healthy. Our community may benefit because we will be able to plan for better health services.

We want you to know the risks for taking part, as well.

The finger-stick will sting for a couple of seconds. Some people may worry a lot if the test today is high. But a high test today does not mean a person has diabetes for sure. The Clinic will do those tests. And if you have diabetes, the Clinic can help you return to good health

If you have diabetes, you may need to have the Clinic OK your Driver's License each year. Having diabetes also means it is more difficult to get insurance. (But most insurance companies test for diabetes when people apply, anyway.)

We will keep all your information confidential.

All results go right to your Clinic chart for your doctor's use. After that, the Community Diabetes Project will remove all names. Because there are no names, no one can know what your results are from the Project.

If you have questions about this Project, please call Mary Doeswell at ____-____.

You may use a District or Clinic phone for the call, or you can visit her at Tribal Headquarters. If you have a **complaint, grievance, or other concerns** please call Ed Ethics at ____-____-____, or visit him in the Tribal Office. You may use a District or Clinic phone for the call.

Taking part in this study is voluntary.

If you do not take part, you will have no penalty and will lose no care or services by IHS, Tribe, or others. You may stop taking part at any time, with no penalty or loss of any care or services to which you are otherwise entitled.

We will give you a copy of this form.

*I agree to take part in the Tribal Diabetes Community Project. It
my blood for sugar, and put the results in my Clinic chart.*

Volunteer's Signature [or thumb-print]

Date

itness to Consent Procedures [optional for signature]

Date

Signature of Team Member

Date

.....

[Note: The readability of this Form is 7th grade. Consent Forms do not need to be un-understandable!]

IHS Institutional Review Board (IRB) Checklist

P.I.: _____ **Institution:** _____

Title: _____

Primary Reviewer: _____ **Date:** ___ / ___ / ___

4 Basic Steps of IRB Review:

1. **Understand the protocol:** science & methods, and medico-psycho-socio-cultural impacts.
2. **Minimize potential risks:** biological, medical, psychological, social, and cultural harms.
3. **Maximize potential benefits:** to the individual, and to the society [research knowledge].
4. **Ensure that the consent process fully informs potential research participants.**

Summary of findings and recommendations [fill out after completing review]:

	<u>No</u>	<u>n/a</u>	<u>Yes</u>
1. Does the proposal involve <u>special concerns</u> ?	—	—	—
2. Should the proposal be <u>exempt</u> from IRB review?	—	—	—
3. Is the proposal eligible for <u>expedited review</u> ?	—	—	—
4. Should the IRB <u>waive informed consent</u> or <u>some required elements</u> ?	—	—	—
5. Should the IRB <u>waive requirements to document</u> informed consent?	—	—	—
	<u>Yes</u>	<u>n/a</u>	<u>No</u>
6. Are procedures adequate for <u>confidentiality, anonymity, security, privacy</u> ?	—	—	—
7. Are all <u>necessary elements of informed consent</u> included?	—	—	—
8. Are procedures adequate to <u>inform and negotiate consent</u> ?	—	—	—
9. Are procedures adequate to <u>administer informed consent</u> ?	—	—	—
10. If the research is > minimal risk, does <u>scientific merit outweigh risk</u> , and are <u>benefits maximized & risks minimized</u> ?	—	—	—
	<u>No</u>	<u>n/a</u>	<u>Yes</u>
11. Does the research involve <u>children</u> and <u>≥ minimal risk</u> ?	—	—	—
	<u>Yes</u>	<u>n/a</u>	<u>No</u>
12. Does the research meet requirements and recommendations for <u>trials</u> ?	—	—	—
13. Are all appropriate <u>documents from other IRB(s)</u> included?	—	—	—
14. Will the researchers <u>comply with Privacy Act</u> ?	—	—	—
15. Will the researchers <u>comply with IHS and tribal procedures</u> ?	—	—	—
	<u>No</u>	<u>n/a</u>	<u>Yes</u>
16. Additional IRB Decisions:			
A. Should the IRB receive reports from and review this project at intervals shorter than annually?	—	—	—
B. Should the IRB validate reports of compliance from sources additional to the principal investigator [PI]?	—	—	—

- 1. Does the proposal involve special concerns?** Present
- A. Vulnerable potential research volunteers with special protections:
 - 1) Children **[Read Subpart D** if research is greater than minimal risk] _____
Both assent of child and permission of parents required. Exemptions from IRB review apply except for observational research (if researcher is a participant), surveys, or interviews. Research with more than minimal risk but no direct benefit to the child is restricted.
 - 2) Fetuses (and pregnant women) **[Read Subpart B!]** _____
(Pregnant women are not vulnerable.) Research is severely restricted. The IRB must assure appropriate process to select, inform, and obtain consent of volunteers; the father's consent is usually required.
 - 3) Prisoners **[Read Subpart C!, & 28 CFR 512 for Fed. Bureau of Prisons]** _____
Research severely restricted; OPRR must review if > minimal risk; IRB must have a prisoner or prisoner-representative.
 - 4) People with mental impairment [no special regulations] _____
Because informed consent is problematic and the people vulnerable even if ambulatory, this type of research should be limited.
 - B. Influence or possible coercion that unduly entices consent (e.g., excessive compensation, unequal relationship [provider-patient, employer-employee]). _____
 - C. Sensitive information--e.g., child abuse; violence; some infectious diseases; drug abuse; condition could affect insurability, compensation, or litigation. _____
Research records are not medical records, and can be subpoenaed; they can be protected by a Certificate of Confidentiality.
 - D. Screening or diagnosis of diseases with significant potential for loss of insurance or other services, stigmatization, or self-stigmatization. _____
Screen for, e.g., carrier of an incurable genetic disease, HIV.
 - E. The research presents more than "minimal risks." _____
"Risk" means both the magnitude of harms, and the probability of incurring them. "Minimal" risks means risks a person ordinarily encounters in daily life and in routine medical, dental, or psychological exams. For research with more than minimal risk, the IRB should ensure that the research's benefits are maximized and risks minimized, and compare its scientific merit with its risk.
 - F. Genetic research, and research using blood and other body tissues. _____
Risks of genetic research include stigmatization, self-stigmatization, family or community disruption, loss of insurance, discovered misattributed paternity, etc. The protocol must [1] omit identifiers, or [a] inform volunteers of all risks and [b] discard the blood/tissue without testing beyond the protocol; and [2] either not grow perpetual cell lines or report that prospect in consent.
 - G. Deception: major (e.g., mislead volunteers about their health status, the researchers, or research purpose); minor (e.g., incompletely disclose some purpose of the study to avoid biasing the results). _____
 - H. Radiation: may require approval by a Radiation Safety Committee; not permitted in studies of healthy children with no benefit to them. _____

Yes n/a No

Does the project address all special concerns adequately? _____

If "No," explain. _____

_____.

2. Should the proposal be exempt from IRB review? [45 CFR 46.101(b)] Present
 Research subjects/volunteers are involved in only one or more of the following methods.

- [.101(b)(4)] A. Use only existing data, documents, records, or specimens properly obtained: _____
and either
 1) "the information is recorded by the investigator [so that] subjects cannot be identified" in the research data directly or statistically, and no-one can trace back from research data to identify a subject; ()
or
 2) the sources are publicly available. ()
- [.101(b)(5)] B. Research or demonstration service/care programs, e.g., health care delivery: _____
and
 1) the research/demonstration is directly conducted or approved by the head of a US Govt. department or agency, e.g., Director of the IHS; ()
and
 2) it concerns only issues under usual administrative control (48 Fed Reg 9268-9), e.g., regulations, eligibility, services, or delivery systems; ()
and
 3) its evaluation methods (if any) also are exempt from IRB review. ()
- [.101(b)(2)] C. For research not involving vulnerable subjects [prisoner, pregnancy, children, fetus, or mentally impaired], observe public behavior (including participatory observation), or do interviews or surveys or educational tests: _____
and either
 1) the subjects cannot be identified, directly or statistically; ()
or
 2) the responses/observations could not harm the subjects if made public; ()
or
 3) federal statute(s) completely protect all subjects' confidentiality; ()
or
 4) all respondents are elected, appointed, or candidates for public officials. ()
- [.101(b)(3)]
 4) all respondents are elected, appointed, or candidates for public officials. ()
- [.101(b)(1)] D. In educational settings, research or evaluate normal educational practices. _____
- [.101(b)(6)] E. For research not involving vulnerable volunteers [see "C." above], do food research to evaluate quality, taste, or consumer acceptance: *and either*
 1) the food has no additives; ()
or
 2) the food is certified safe by the USDA, FDA, or EPA. ()

Yes n/a No

If not exempt now, can the protocol be made exempt by minor changes? _____
 (If so, consider asking the PI to make those changes.)

For the IRB not to review it, the research must also meet 3 criteria:

- A) If potentially exempt because subjects cannot be identified, the research indeed protects anonymity [see section "6." below]; _____
and
 B) If volunteers give information about others, inadvertent disclosure presents no more than minimal risk to those others. _____
and
 C) If a survey, interview, ed. test, or food research is done in an IHS facility, the information sheet has the IHS disclaimer [section 8.S.]. _____

3. Is the proposal eligible for expedited review, not by the full IRB? [46.110] Present

Expedited review (by the Chair and 1 IRB member) if the protocol is, or includes, only:

- either*
- (per FDA) A. emergency use of an IND therapy for non-research care to a patient; _____
- or*
- B. minor changes in previously approved research within the approved period; _____
- or*
- C. research *both* is not greater than minimal risk *and* involves only: _____
- *continuing review*, and _____ ()
 - either* research found by full IRB to be not greater than minimal risk _____
 - or* enrollment finished & all interventions completed & only long-term f/u _____
 - or* no subjects have been enrolled & no new risks found, *or* only data analysis _____
 - existing data, documents, records, specimens originally for nonresearch purposes _____ ()

If from IHS records or specimens, Privacy Act may apply: see #14, last page.
 - non-exempt research on individual/group behavior or characteristics by surveys, interviews, focus groups, oral histories, program evaluations, human factors evaluation, or studies of quality assurance methods _____ ()
 - collect data of adult/child by noninvasive clinical procedure, *e.g.*, weight, hearing _____ ()
 - collect data by clinical non-radiating devices (MRI, EKG, EEG, ultrasound, infrared, echocardiogram, thermogram, doppler blood flow, measure natural radiation) _____ ()
 - moderate testing of/by exercise, muscle strength, flexibility, or body composition _____ ()
 - research on drugs or devices not needing IND drug or IDE device application _____ ()
 - venipuncture/fingerstick blood < = 2x/wk: healthy non-pregnant adult > 109 lbs (< = 550ml / 8 wks); healthy adult < 110 lbs or child (< = 3 ml/kg or 50ml) _____ ()
 - noninvasively collect hair, nail clippings, deciduous or permanent teeth, gingival dental plaque/calculus, sweat, saliva, amniotic fluid, sputum, placenta [*cultural issues?*], skin/mucosal/buccal cells (*See detailed list for acceptable methods.*) _____ ()
 - collect data from voice, video, digital, or image recordings made for research _____ ()
- Yes n/a No

If not expeditable now, can it be made expeditable by minor changes? _____ _____ _____
 (If so, consider asking the PI to make those changes.)

NOTE: 'expedited' protocols must meet all IRB requirements, i.e., checklist must be filled out.

4. Should the IRB waive the requirement to obtain informed consent, or waive some or all elements of informed consent? [46.116(c) or (d)] Present

- A. Does this project qualify for possible waiver of requirements to obtain, or to include all essential elements of, informed consent? _____
- The research could not feasibly be carried out without the waiver: _____
and either
 - [.116(c)] 1) it is a research or demonstration project _____
that
 - (a) is directed or approved by state, local, or tribal governments, _____
and
 - (b) concerns only administrative/regulatory issues in service programs; _____
 - or*
 - [.116(d)] 2) it is research (e.g., an activity for which consent usually not obtained, or involves deception of the research volunteer, etc.) _____
that
 - (a) involves no more than minimal risk, _____
and
 - (b) will give volunteers pertinent information at the end if appropriate; _____
and
 - (c) the waiver will not adversely affect volunteers' rights or welfare. _____
- If IHS records/specimens are obtained, Privacy Act may apply; see #14, last page.*
- B. If waiver of some or all informed consent elements is permitted, ***should the IRB still require the project to obtain full informed consent?*** Yes No

5. Should the IRB waive requirements to document informed consent? [46.117(c)] Present

- A. Is either characteristic present in this project that permit waiver of the requirement of documenting informed consent? _____
either
- [.117(c)(1)] 1) The existence of signed informed consent forms itself would place the research volunteer at major risk (e.g., potential loss of confidentiality or anonymity of people interviewed about extremely sensitive behavior). _____
 - or*
 - [.117(c)(2)] 2) The research _____
both
 - (a) presents only minimal risk, _____
and
 - (b) involves no procedures which normally require written consent. _____
- B. If a waiver of documenting informed consent is possible, ***should the project still either*** Yes No

- 1) document fully informed consent? _____
 - or*
 - [.117(c)] 2) offer each volunteer a written fact sheet? _____

6. Are confidentiality, anonymity, security, and privacy maintained? Yes n/a No

- A. Are all computer & non-computer data be held in a secure manner? _____
- B. If sensitive identifiable data, is there a Certificate of Confidentiality? _____
- C. Do the procedures protect against the risks sufficiently? _____

7. Are all necessary elements of informed consent included?

		<u>Yes</u>	<u>n/a</u>	<u>No</u>
	@ Items <u>required by regulation [45 CFR 46.116(a)]</u>			
@ [(a)(1)]	A. A clear statement that the study is " <u>research</u> "	___	___	___
@ [(a)(1)]	B. <u>All</u> the research <u>purposes</u> [i.e., protocol's <u>objectives</u>] clearly stated	___	___	___
[(b)(6)]	C. How, why, & how many prospective volunteers are <u>selected</u>	___	___	___
@ [(a)(1)]	D. Expected <u>duration</u> of the volunteer's involvement	___	___	___
@ [(a)(1)]	E. <u>Procedure(s) or treatment(s)</u> to be done	___	___	___
@ [(a)(3)]	F. Reasonably expected <u>benefits</u> to volunteer and others	___	___	___
@ [(a)(2)]	G. Reasonably foreseeable <u>discomfort and risks</u>	___	___	___
[(b)(1)]	H. Especially for experiments, a statement that the treatment(s) or procedure(s) "may involve risks that are currently unforeseeable"	___	___	___
@ [(a)(1)]	I. Which procedure(s) or treatment(s) are <u>experimental</u>	___	___	___
@ [(a)(4)]	J. The <u>alternatives</u> to the research's diagnostic method or treatment	___	___	___
[(b)(4)]	K. Procedure for the <u>orderly termination</u> of a volunteer's participation	___	___	___
[(b)(4)]	1) Consequences of a volunteer's <u>withdrawal</u> from the research	___	___	___
[(b)(2)]	2) When may the researcher <u>terminate</u> a volunteer's participation without the volunteer's consent	___	___	___
[(b)(5)]	L. Plans to <u>inform</u> volunteers of <u>significant research findings</u> during or after the study relevant to their continued participation or treatment	___	___	___
@ [(a)(6)]	M. If > minimal risk: " <u>In case of injury or severe adverse affect...</u> "	___	___	___
@	1) will <u>medical care for adverse affects</u> be given? who? where?	___	___	___
@	2) is <u>compensation for adverse affects</u> available? how?	___	___	___
@ [(a)(6)&(7)]	3) <u>whom</u> should a volunteer contact with injury or adverse affect?	___	___	___
@ [(a)(7)]	N. Who will answer <u>questions about the research itself</u> ?	___	___	___
@ [(a)(5)]	O. How <u>confidentiality</u> (___) or <u>anonymity</u> (___) are maintained	___	___	___
@ [(a)(7)]	P. Who on IRB will answer <u>other concerns, complaints, or grievances</u> ?	___	___	___
[(b)(3)]	Q. <u>Financial</u> factors (<u>extra costs of</u> , or compensation for, participation)	___	___	___
[(b)(3)]	R. <u>Other elements</u> a reasonable person would want to know	___	___	___
	S. If a <u>Certificate of Confidentiality</u> , an appropriate description	___	___	___
@ [(a)(8)]	T. <u>Non-coercion disclaimer</u> . E.G., " <u>Taking part is voluntary. You may refuse to take part without any penalty or loss of care or services by IHS or others. You may stop taking part at any time, without penalty or loss of care or services to which you are otherwise entitled.</u> "	___	___	___

		<u>Yes</u>	<u>n/a</u>	<u>No</u>
8.	Are the procedures adequate to <u>inform and negotiate consent</u>?			
	A. Does the project adequately describe the <u>process</u> of consent:			
	1) informing prospective volunteers (skilled negotiating, unhurried time, setting facilitates information transfer)	___	___	___
	2) assessing prospective volunteers' comprehension	___	___	___
	3) assessing prospective volunteers' autonomy (1A + 1B above)	___	___	___
	4) documenting the consent	___	___	___
	B. Is the consent form included?	___	___	___
	C. Are all other relevant documents included? (e.g., parental permission form___, assent script or form___, telephone script___, introduction or approach letter___, etc.)	___	___	___
9.	Are the procedures adequate to <u>administer informed consent</u>?			
@ [117(a)]	A. Give an information copy of the consent form to all volunteers	___	___	___
@ [408(b)]	B. For children age 0-17, a form and process of <u>parental permission</u>	___	___	___
@ [408(a)]	1) For minors old enough, a process of their <u>assent</u>	___	___	___
10.	If more than minimal risk, does <u>scientific merit outweigh risk</u>, and are <u>benefits maximized and risks minimized</u>? [46.111(a)]			
	A. Is the research " <u>indeterminate risk</u> ," e.g., Phase I, II, or III vaccine or Investigational New Drug/Device [IND] trials? <i>If yes, the research by definition is "more than minimal risk."</i>	___	___	___
	B. Is the research <u>more than minimal risk</u> ?	___	___	___
	C. <i>If yes</i> , are <u>benefits maximized</u> and <u>risks minimized</u> ?	___	___	___
[(a)(1)&(2)]	D. <i>If yes</i> , does the research's scientific merit outweigh its risks?	___	___	___
11.	If research involves <u>children (age < 18) and > minimal risk</u>: [46.405-408]			
[.405]	A. Does the research <u>present the prospect of direct benefit to child</u> ? <i>If yes, local IRB may approve. If no, go to "B."</i>	___	___	___
[.406]	B. Is it <u>both only a minor increase over minimal risk, and will it give vitally important knowledge about child's disorder</u> ? <i>If yes, local IRB may approve. If no, go to "C."</i>	___	___	___
[.407]	C. Does it present opportunity to understand, alleviate, or prevent a <u>serious problem affecting children</u> ? <i>If A. and B. are "no" but C is "yes," protocol must be sent to OPRR for review. If A, B, & C are "no," it is not approvable.</i>	___	___	___

		<u>Yes</u>	<u>n/a</u>	<u>No</u>
12. Does the research meet requirements and IHS recommendations for <u>trials</u>?				
[.111(a)(6)]	A. A monitoring committee for safety (Phase II) or data (Phase III)?	___	___	___
	B. If a <i>controlled</i> trial, will all eligible volunteers be offered the proven treatment after proof of effectiveness is obtained?	___	___	___
13. Are all appropriate <u>documents from other IRB(s)</u> included?				
	Is an entity with an IRB (e.g., state, university, CDC, NIH) involved? <i>If "yes," does the protocol have</i>	___	___	___
	A. Form 596 or letter with MPA #, effective date, and conditions? <i>and</i>	___	___	___
	B. Is the approval still valid, i.e., effective date <u>< 1 year old</u> ?	___	___	___
14. Will the researchers <u>comply with Privacy Act</u>?				
<i>The Privacy Act applies when a <u>non-federal government researcher</u> wants confidential <u>identifiable information</u> from government records [e.g., IHS medical records] <u>without consent</u> of the person. Such records may be disclosed for research, after DHHS:</i>				
<i>a) determined that the use or disclosure does not violate law or policy;</i>				
<i>b) determined that the research 1) could not be accomplished without providing records with individual identifiers; & 2) warrants the risk to privacy;</i>				
<i>c) required the receiving researcher to</i>				
<i>1) establish reasonable administrative, technical, & physical security of all data,</i>				
<i>2) remove or destroy the identifiers of the individual at the earliest possible time, and</i>				
<i>3) make no non-emergency use/disclosure of the data or information without approval;</i>				
<i>d) secured a written statement by the researcher that she/he understands and will abide by the provisions a) through c) above.</i>				
	Does the Privacy Act apply?	___	___	___
	<i>If "yes,"</i>			
	A. Has the researcher complied with the Privacy Act?	___	___	___
15. Will the researchers <u>comply with tribal and IHS policies</u>?				
	A. Will OMB or the tribe(s) approve the questionnaire(s), if indicated?	___	___	___
	B. Will the researchers report timely results to the tribe(s) and IHS?	___	___	___
	C. Will the tribe(s) <u>and</u> RPC review and approve all publications?	___	___	___
16. Additional IRB decisions: [46.103(b)]			<u>No</u>	<u>Yes</u>
[(b)(4)(ii)]	A. Should IRB require reports from this project sooner than annually?	___	___	___
	If "Yes," reason(s): _____			
[(b)(4)(ii)]	B. Should IRB validate compliance reports from sources other than the PI?	___	___	___
	If "Yes," reason(s): _____			
	C. Is this protocol greater than minimal risk? <i>(This assessment is necessary for annual reviews.)</i>	___	___	___

IHS Guidelines for implementing and complying with IHS Policy on specimens

preliminary draft: September 18, 1998

I. Objectives

The objectives of these IHS Guidelines are simultaneously to:

support fully informed Tribal and IRB review and approval of research that will save specimens for future research, or that will use saved specimens;
support fully informed consent by each potential volunteer participant of the research that obtains specimens to be saved;
support future use of specimens that is based both on the merits and soundness of the science, and by the concerns and health priorities of the Tribe[s] involved; and
support the proper obtaining, retention and use of saved specimens that observe the limits and intents of the informed consent by the people from whom the specimens were obtained, and of the approval by the IRB[s] and Tribal government[s].

II. The IHS Guidelines

- [1] All researchers who obtain or use, and all entities that store, specimens obtained with IHS involvement must agree to these Guidelines. IHS will distribute to researchers, specimen banks, and IRBs both the Guidelines and model consent forms for specimens.
- [2] If blood or tissue will be obtained directly from volunteer participants under a research protocol, both the protocol and its consent process and form must specify:
 - the tests to be done under the protocol;
 - if any specimens will be saved.
- [3] If any specimens will be saved, both the protocol and consent form must state the nature of future "secondary uses," and the process to seek approval of the future uses:
 - whether the stored and maintained specimens will included identifiers;
 - class[es] of tests or procedures that may be done on the saved specimens, including DNA tests, or other genetic tests, or growth of perpetual cell lines;
 - if volunteer participants may be contacted in the future by the PI or other researchers;
 - location, duration, and procedures of storage and of disposal;
 - if the specimens are from placenta or umbilical cord, other tissues with strong social meaning or value, or other aspects about which the AI/AN community may be concerned, e.g., patenting specimens or material derived from them.
- [4] The researchers of the original protocol must not permit others to engage in, and must not themselves engage in, secondary use of specimens until they comply with all steps. "Secondary use" includes the following:
 - tests or other uses not explicitly mentioned, either by name or as a class, in the original protocol and consent; or
 - giving or loaning specimens to anyone else. (This does not include other laboratories doing allowed tests for the original researchers; it does include laboratories retaining specimens or doing their own tests.)
- [5] Researchers of the original protocol, and of a new protocol receiving specimens, must track and comply with the limits on the use of each specimen imposed by the consent of the person from whom it was obtained, even if the specimen is anonymous or if the person from whom the specimen was obtained has died.

- [6] All proposed secondary uses of specimens must be reviewed for scientific value by an independent group. The original protocol that stored the specimens must include such review and approval in its procedures. As a nonrenewable resource, specimens should be used up only by research with high scientific value; scientists other than the researcher should judge the scientific value of the proposed use. Specimens also must not be hoarded (to benefit a researcher's career, for instance) but must be shared if it benefits a volunteer or family, Tribe, or society. Those two obligations are especially important for specimens not easily obtained, e.g., by surgery or biopsy.
- [7] All proposed secondary uses of specimens must be reviewed and approved by the Tribal government[s] with jurisdiction. The original protocol that stores specimens must include such review and approval in its procedures.
- [8] All proposed secondary uses of specimens must be reviewed and approved by all participating institution that hold, send, or receive the specimens, using their SPA IRB or MPA procedures. The researcher of the new protocol must send the consent forms under which the specimens were originally obtained with the protocol for review.
- [9] Many "anonymous" specimens have clinical or demographic information about the people from whom the specimens were obtained. IRB review must assess if true anonymity is achieved and maintained, i.e., that identification of some people cannot occur due to combination of demographic or clinical data or linkage to other databases.

[10] If all proposed uses are within the original truly informing consent, see **Table 1**. Within the original truly informing consent means the consent cited the uses as a class (e.g., "kidney function tests") or by name. Related to original study means the stated purposes for which the specimens were obtained. (These two criteria may be different; see Section III, Additional information.) Proposed uses are exempt from further IRB review if they are within the original consent, and related, and anonymous; the determination that they meet all three criteria is by the institution's MPA procedure or SPA IRB, not by the researcher. All other proposed uses within the original consent require "expedited" or full IRB review.

TABLE 1

When all proposed uses of specimens are within the original truly informing consent:

Related to original study	Anonymous	Standard conditions for the new research protocol or plan:
yes	yes	Scientific merit review and approval (i.e., "review, then either approval or veto, of the protocol"); and each institution's review and approval; and notification of Tribe; and publications identify the community only with Tribal consent.
yes	no	Scientific merit review and approval; and IRB review and approval of the protocol's modification; and notification of Tribe; and researchers not contact individuals without their consent; and publications identify the community only with Tribal consent.
no	yes, or no	Scientific merit review and approval; and IRB review and approval; and formal Tribal review and approval; and informed [re]consent by each volunteer participant, unless excepted by the IRB for anonymous specimens; and publications identify individuals only with their consent; and publications identify the community only with Tribal consent.

[11] Proposed uses may be outside the original consent, usually for one of three reasons.
 The original consent did not include future use at all.
 The original consent was too broad--a blanket consent to do any test--and thus was not truly-informing by today's standards. (These two consents are frequent in clinical care or older research.)
 The future use is beyond a reasonably detailed truly-informing consent.
 Future possible uses or protocols are so varied that a table of standard conditions is not feasible. Every proposed use must be approved by all Tribe[s] and IRB[s] involved, and by an independent scientific group.

[12] Many new tests, like genetic tests, require pre-test counseling. If the protocol will do new tests with clinical relevance to people from whom the specimens were obtained, and if the specimens are identifiable, the researchers must specify how and when they will obtain the informed consent of each person to receive--or to not receive--the test results. (Many new tests are not CLIA approved; generally the results of non-CLIA approved tests are not given directly to the volunteer participants or their physicians.)

[13] The entities retaining specimens, and PI and co-investigators of every protocol, that obtain, store, test, or use the specimens must sign a copy of one of the following. The signed agreements extend these Guidelines to laboratories, specimen banks, and researchers that receive, hold, test, or secondarily use any specimens; the original researcher must obtain the same written agreement from them. The originals are sent to the IRB[s] and Tribe[s] involved. If the new protocol is receiving specimens for secondary use, copies of the signed forms are sent to the original researcher.

All researchers will comply with the following for specimens and data in this project:

1. *NOT use the specimens and data received for any purpose other than those stated in this protocol and approved by the Tribe[s] and IRB[s];*
2. *NOT release the specimens, or their associated raw data, to any other person or study, without the prior approval by the IRB[s] and Tribe[s] involved;*
- 3a. *If the specimens or data are supposed to be anonymous, NOT attempt in any way to establish the identity of the subjects of the specimens or data received.*
- 3b. *If the specimens are not anonymous, NOT try to contact any individual or family other than as stated in this protocol, without the prior approval by the IRB[s] and Tribe[s] involved.*
- 3c. *If the specimens are not anonymous, NOT try to obtain clinical or other information from anyone's medical or other records other than as stated in this protocol, without the prior approval by the IRB[s] and Tribe[s] involved.*

[14] Storage of all specimens must provide physical security from unauthorized or inappropriate access. The disposal of specimens must be respectful.

[15] Researchers of the new protocol to use existing specimens have the same obligations as do the researchers of the original protocol. Those obligations generally include:
to present the results of the research to the Tribe[s] involved; and
to seek Tribal review of publications.

[16] Research teams must insure "institutional memory" to comply with requirements after the PI has left. Research teams should also have written agreements with their institutions to define control and responsibility over the storage and disposition of the specimens. The Tribe[s] and IRB[s] involved may need to know those agreements.

[17] IRB[s] and Tribal government[s] may notify funding agencies, supporting institutions, and publishers or editors of violations of these Guidelines that are not resolved.

[18] These Guidelines must be re-examined, and may be modified, as experience develops.

III. Discussion

The IHS has five special considerations, circumstances, and concerns.

Confidentiality and anonymity are more difficult to maintain in small rural communities, as are most IHS sites, than in large urban areas.

Because clinical care data in the IHS are computerized, true anonymity is difficult to achieve, due to possible combinations of computerized clinical data elements.

AI/AN communities have been stigmatized by recent research, which reinforces the fears and distrust that many AI/AN and other people have about research.

Many AI/AN people have special cultural values and concerns related to the use of blood and other tissues.

Tribal governments legally control research done within their jurisdiction. IHS Guidelines must work with each Tribe's Codes and procedures to control research.

Secondary research on blood or tissue specimens is increasingly sophisticated and frequent. Such research may have future benefit to the people and communities whose specimens are tested. For specimens that both are anonymous and exist before the research use, 45 CFR 46 § 101(b)(4) permits research on them without the informed consent of the people from whom they were obtained, because the research appears to carry no risk to them even if the tests are sensitive. However, individual members of a community may be harmed even though the specimens are "anonymous for individuals," if the specimens retain the community's identification or are known to come from that community. The community at risk may be a specific Tribe, a group of Tribes (e.g., "Tribes in the Northwest"), or ethnicity (e.g., "American Indians"). Specimens for which IHS was or is involved in the 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. In the IHS policy, therefore, "anonymous" specimens means "anonymous only for individuals"; the specimens are identifiable for the larger AI/AN community at least.

The term "anonymous for individuals" means that it is impossible for the researcher to identify individuals either:

- directly (e.g., by name); or
- by a combination of data elements.

The term also means that it is impossible for the researcher to identify individuals either:

- from only the data at hand; or
- with other information (e.g., medical records) to which the researcher has access; or
- with information from other people (e.g., people who have access to medical records).

For specimens to be anonymous for the individual, therefore, the researcher must neither have any data, nor have access to any data with the possible cooperation of others, that alone or in combination identify one or more people from whom the specimens were obtained.

A special consideration applies once specimens are in research, i.e., specimens either obtained directly from volunteer participants under a research protocol, or gathered originally by a process of care and now obtained under a research protocol. The original IRB[s] must review and approve every modification of a protocol, by either expedited or full review; see 45 CFR §§ 46.103(b)(4) and 46.110. Later activities modify the research protocol, if they were not stated in the original protocol. Such activities include: giving or lending the specimens to another researcher; using them for tests other than those in the obtaining protocol; or seeking a patent. The original IRBs, therefore, must review and approve such activities as modifications to the original protocol. The IRBs must also determine if the proposed modifications are within the limits of the original informed consent.

There are three basic approaches for informed consent to store specimens.

- [1] One approach is a blanket consent, that permits all future uses of specimens. It maximizes future testing and flexibility, which benefits future progress in science; however it does not recognize possible harms to communities or individuals, e.g., tests for stigmatizing conditions. For example, a protocol and consent form that leftover blood will be stored for "future tests about diseases of importance to AI/AN people" is a blanket consent. It covers too much, from otitis media to alcoholism, from non-stigmatizing to highly stigmatizing conditions. Potential participants being asked to consent to such future use would be uninformed about the risks and benefits.
- [2] Another approach is a detailed consent. At the time the specimen is obtained, each volunteer participant decides whether to permit saving a specimen, what future tests can and cannot be done, and whether to be contacted about results of future tests. The approach maximizes participant control; however the control is exercised when participants lack needed information about the future. That is, detailed consent has three major problems: future tests are too unknown and too varied to list; risks and benefits in the future may differ from those at present; and the current circumstances and values of potential volunteer participants may change in the future, rendering a decision based on current circumstances and values invalid for that future person.

- [3] These Guidelines take a third approach. Each participant decides to permit or not only future use *related to the current research* to which s/he is consenting--uses with values, risks, and benefits likely similar to those of the current research. For instance, consent about specimens left over from in a vaccine trial would ask for narrow future uses, e.g., "future tests about infections important to AI/AN children." As a check, the Tribes and IRBs must also approve all future uses when they are proposed. As a second check, if the future tests use identifiable specimens for purposes beyond the original consent, the volunteer participants may be asked for consent for the new use.

Five examples will help clarify Table 1. Consider sera from a community project screening adults for diabetes (DM), stored with identifiers; the consent permitted future tests to help diabetes or related conditions such as atherosclerotic heart disease or chronic renal failure.

- [1] First row. Researchers want to use the sera (but anonymized), to determine the prevalence in the Tribe of a newly found risk factor for DM.
- [2] Second row. Researchers want to run the same test on the same sera but with identifiers, to match results with each person's chart whether or not they have DM.
- [3] Third row--anonymous, direct public health implications to the Tribe: CDC wants to test the sera anonymously for antibodies to a newly-discovered fatal infection that broke out in the Tribe, to see if there have been subclinical infections in the past. (The Tribe and IRBs must approve the research; re-consent will not be necessary.)
- [4] Third row--anonymous, disease of small importance to the Tribe. Researchers want to test anonymously for the prevalence of a possible new Alzheimer disease gene in this Tribe with rate of Alzheimer disease one-tenth the U.S. rate, to see if the gene also is less prevalent. (The requirements are the same as for [4].)
- [5] Third row--with identifiers, disease of great importance to the Tribe. A new blood test to detect early cancer of the cervix has been proven in non-AI/AN women but not in AI/AN women. Researchers want to run the test on the same stored sera, and get from each women's chart who had cervical cancer. The Tribe's rate of cervical cancer is 10 times the U.S. rate. (The Tribe and IRBs must approve the research; re-consent by each volunteer participants may be necessary. It may be possible, however, to link clinical information about cervical cancer to specimens without seeking re-consent while satisfying the concerns and requirements of the Tribe and IRBs.)

PLEASE GIVE COMMENTS, SUGGESTIONS, OR CRITIQUES TO:

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APPENDIX
IV

SAMPLE AGREEMENT
ITCA-UNIVERSITY OF ARIZONA
(EXCERPT)

THEREFORE, the parties hereto agree as follows:

1. Definitions.

- 1.1 “Confidential Information” means proprietary financial and other information of either party to this Agreement and information about persons, including names, addresses, mental and physical health data, family history and other like information of a private or confidential nature.

6. Standards; Indemnities.

The Project shall be developed in accordance with an established work plan and project schedule as described in the NARCH application. This application sets forth roles, duties and responsibilities in connection with ITCA. The subcontract will also set criteria for the measurement of quality and results of joint efforts, including without limitation, the standards that will be applied to determine acceptance with Section 3.

The Research Intensive Partner represents that the Services performed by its employees, agents and subcontractors, will be of a high quality and performed in a professional manner in accordance with industry standards and practice and in compliance with all relevant federal, state and local laws and regulations. The Research Intensive Partner also represents that the products and services will meet the requirements of this Agreement.

The Research Intensive Partner represents that any and all work of Research Intensive Partner, and all other material resulting from the Services performed by Research Intensive Partner, if not expressly licensed to Research Intensive Partner or reprinted with permission, shall be its original work, has been developed by Research Intensive Partner, its employees, agents and subcontractors, and does not infringe upon or misappropriate any third party’s copyrights, patents, trade secrets or other intellectual property rights or the terms of any license or contract applicable to Research Intensive Partner.

Research Intensive Partner shall, to the extent allowed by law, indemnify, defend and hold harmless ITCA for all losses, damages, claims, actions, and costs (including attorneys’ fees) caused by or arising from negligence or willful misconduct of Research Intensive Partner, its employees, agents or subcontractors, in any way connected to the Project, the Services, or this Agreement, including a breach of this Section 6.

- 7. Confidential Information.** ITCA and Research Intensive Partner may choose, from time to time, in connection with work contemplated under this

Agreement, to disclose confidential information to each other (Confidential Information). All such disclosures must be in writing and marked as Confidential Information. The Parties will use reasonable efforts to prevent the disclosure to unauthorized third parties of any Confidential Information of the other Party and will use such information only for the purposes of this Agreement, and for five (5) years after the termination of this Agreement; provided that the receiving Party's obligations hereunder shall not apply to information that:

- a. is already in the receiving Party's possession at the time of disclosure
- b. is or later becomes part of the public domain through no fault of the receiving Party; or,
- c. is received from a third party with no duty of confidentiality to the disclosing party; or,
- d. was developed independently by the receiving party prior to disclosure; or,
- e. is required to be disclosed by law or regulation.

It is understood by ITCA and Research Intensive Partner that the exceptions a., b., c., and d. above do not apply to identifiable medical and/or personal information developed or acquired during the performance of this Agreement. It is also understood by ITCA and Research Intensive Partner that the exceptions a., b., c., and d. above do not apply to cultural information identified by the participating Tribes as confidential cultural property and information. The participating Tribes and the Research Project Investigators will jointly develop policies and procedures for resolving questions of confidentiality will regard to cultural property. These policies and procedures will be included as an addendum to the subcontracts by June 30, 2002.

Any information that is transmitted orally or visually, in order to be protected hereunder, shall be identified as such by the disclosing party at the time of disclosure, and identified in writing to the receiving party, as Confidential Information, within thirty (30) days after such oral or visual disclosure.

8. **Researchers.** Confidential Information may be acquired from individuals, state or federal agencies, or other sources (collectively "Sources"). The parties acknowledge that acquiring, reviewing or otherwise having access to Confidential Information requires discretion and sensitivity, and a commitment not to disclose the information or use it for any improper purpose. Accordingly, Research Intensive Partner represents that:

- a. All persons employed or otherwise retained on the Project who contact Sources for Confidential Information, or who review or otherwise have access to Confidential Information (each a “Researcher”) shall be fully qualified to do so. Before any such contact, review or access, the parties shall agree to the minimum qualifications that all Researchers will be required to meet.
- b. Research Intensive Partner shall, at its own expense, cause a current criminal background search for any conviction or release from incarceration that occurred within the past seven (7) years to be conducted on each Researcher. For purposes of this Section, “conviction” includes any disposition adverse to a person. Written results shall be provided to ITCA before a Researcher commences services. ITCA, in its sole discretion, shall determine whether to accept the services of such Researcher. The decision of ITCA to decline the services of such Researcher shall not be deemed or construed in any way as a directive to terminate the employment of such person.
- c. Before a Researcher contacts a Source, or reviews or otherwise has access to Confidential Information, he/she shall sign a confidentiality and nondisclosure agreement in a form satisfactory to both parties. Research Intensive Partner shall provide ITCA with a copy of each such executed agreement upon request.

9. Grant Application. The parties acknowledge that future funding for the ITCA AIRCH and tribes may be sought through other grants/organizations. Each party shall use its best efforts to review, comment on, and assist in the preparation of any grant application concerning the initial and future research project(s) and training activities. Each party acknowledges that time is of the essence in performing its obligations under this section.

10. Taxes. Research Intensive Partner shall be solely liable for and shall pay all applicable sales, use, and other taxes or charges incurred in connection with the Services by it. Research Intensive Partner shall be solely liable for and shall pay all costs of conducting its business, including but not limited to any applicable city, county, state or federal licenses, permits, taxes or assessments of any kind. Research Intensive Partner shall, to the extent allowed by law, indemnify, defend and hold harmless ITCA from any of the foregoing.

11. Term; Termination.

- 11.1 The term of this Agreement (the “Term”) shall commence on the Effective Date and shall expire August 31, 2006, unless sooner terminated as provided in Section 11.2.
- 11.2 Notwithstanding the Term, this Agreement may be terminated by either partner, Research Intensive Partner or ITCA, at any time before the Expiration Date by giving sixty (60) business days’ written notice to the other party. Upon receipt of notice of termination from ITCA, the Research Intensive Partner shall not incur any additional expense or perform any Service without the prior written approval of ITCA. Should ITCA terminate this Agreement, the Research Intensive Partner shall be entitled to payment for Services satisfactorily performed by it to the date of termination.

12. Ownership to Materials and Information

- 12.1 ITCA and the participating tribal governments shall hold and maintain all rights to the information, products, data, and all other materials created or produced under the American Indian Research Center for Health. Because of the nature of the collaboration between the Research Intensive Partner and the participating tribal governments and among the Research Intensive Partner, the participating tribal governments and ITCA, it is not likely that the Research Intensive Partner will solely create Products and Materials, as defined herein. In the event that the Research Intensive Partner does solely create Products and Materials, Research Intensive Partner shall grant to ITCA and the participating tribes its rights in those Products and Materials.
- 12.2 It is understood among ITCA, the participating tribal governments and the Research Intensive Partner that no subject inventions, as defined in 37 CFR 401.14, shall result from the participation of the Research Intensive Partner in the Research Services Agreement to establish an American Indian Research Center for Health.

13. Publication

- 13.1 The personnel and students of the Research Intensive Partner and personnel of the participating tribal governments shall collaborate with each other and ITCA on publication or other dissemination of information concerning the American Indian Research Center for

Health. Research Intensive Partner and the participating tribal government or Research Intensive Partner and ITCA shall jointly author such publications and other dissemination of information. ITCA may waive its joint authorship rights if the publication or other dissemination of information does not concern the administration of the American Indian Research Center for Health.

- 13.2 Research Intensive Partner graduate students conducting research under the Research Services Agreement to gather information for use in their theses or dissertations shall, with the assistance of their research advisers, negotiate with the participating tribal government(s) to define the scope of their research and the nature of the information that can be published in their theses and dissertations before they begin their research. These negotiations shall result in a written agreement between the graduate student and the participating tribal government(s) to specify as precisely as possible the nature of the graduate student's research topic and the information that will be published in the resultant thesis and dissertation.

14. Independent Contractor. The Research Intensive Partner is an independent contractor of ITCA. This Agreement shall not create the relationship of employer and employee, a partnership, or a joint venture between ITCA and Research Intensive Partner. Subject to the terms of this Agreement, Research Intensive Partner shall determine the number of days and hours of its work. Research Intensive Partner shall be solely liable for the wages, employment taxes, fringe benefits, work schedules, and work conditions of its employees and agents.