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Research Ethics and Indigenous Communities

Allyson Kelley, MPH, CHES, Annie Belcourt-Dittloff, PhD, Cheryl Belcourt, BA, and Gordon Belcourt, MPH, DHL

Institutional review boards (IRBs) function to regulate research for the protection of human participants. We share lessons learned from the development of an intertribal IRB in the Rocky Mountain/Great Plains Tribal region of the United States.

We describe the process through which a consortium of Tribes collaboratively developed an intertribal board to promote community-level protection and participation in the research process. In addition, we examine the challenges of research regulation from a Tribal perspective and explore the future of Tribally regulated research that honors indigenous knowledge and promotes community accountability and transparency.

We offer recommendations for researchers, funding agencies, and Tribal communities to consider in the review and regulation of research. (*Am J Public Health*. 2013;103:2146–2152. doi:10.2105/AJPH.2013.301522)

RESEARCH ETHICS WITHIN

American Indian and Alaskan Native (AIAN) communities require a careful appreciation and respect for the areas of distinction and commonality that characterize appropriate use of scientific methodology within this sociocultural context. Conducting research in an ethical manner within indigenous communities necessitates an active awareness of the extent to which federal government agencies and affiliated institutions have oppressed, discriminated against, and engaged in culturally biased practices with these communities.¹ Examples include forced relocation of Native American people and punishment for their spiritual and cultural practices, forced removal of Native American children to boarding or residential schools, and in some cases direct warfare.^{2,3}

The impact of these practices extends to the present-day health of indigenous people, who experience health disparities that stem from racism, loss of native language, loss of land, and complex socioeconomic factors.^{4,5} Prior to their contact with European settlers, North American

indigenous people had socioeconomic, spiritual, and linguistic structures that supported an indigenous worldview, that is, a perceptual understanding of the world based on holistic, cyclical, sacred, and spiritual connections.^{6,7} However, European contact influenced indigenous people's worldviews, and Western European perspectives on science and reason have since ruled supreme. The Western scientific paradigm focuses on problems with solutions and dismisses any metaphysical explanations for reality.⁸

Colonization threatened the identity, culture, religious beliefs, and epistemological views of indigenous people⁹ and led to the extinction of many Tribal nations that were vastly outnumbered and struggling with significant mortality associated with newly encountered infectious diseases. This diminished indigenous population faced a multitude of threats to its sovereign nation status, and Native American populations ironically became labeled as “minority” groups on their own homelands.¹⁰ Contemporary AIAN populations represent about

2% of the US population¹¹ and are political entities with treaty rights and human rights to sovereignty; however, they continue to be classified simply as a minority group. Collectively they experience some of the nation's most severe and extreme health disparities¹² with respect to type 2 diabetes,¹³ unintentional injuries, cardiovascular disease,¹⁴ suicide and suicidal ideation,¹⁵ homicide, and certain forms of cancer.^{16,17}

Many Native American scholars and Tribes attribute the etiologies of these disparities to the sequelae of colonization that denied Tribal nations the right to continue their precontact life ways and indigenous science systems.^{2,14,18,19} For example, the loss of Native American lands attributable to forced reservation relocation acts decreased the availability of traditional healthy diets and increased indigenous groups' consumption of unhealthy store-bought and commodity foods. Unhealthy diets, chronic stress, and decreased physical activity contribute to epidemic rates of obesity and type 2 diabetes in AIAN populations.²⁰

Some have viewed research involving AIAN groups as an



extension of colonization, given the ethnocentric foundation of Western scientific principles and their application within indigenous contexts.^{10,21} Indigenous groups' mistrust of research is based on a history that failed to honor Native American people, traditions, cultures, and communities. For example, researchers at Arizona State University collected DNA from members of the Havasupai Tribe²² ostensibly to study diabetes, but instead used the DNA to examine mental illness and theories about where the Tribe originated that conflicted with Tribal creation stories and spiritual beliefs.²³

Approximately 28 institutional review boards (IRBs) serving Tribal nations are currently registered with the Office of Human Research Protection²⁴; they include Tribal research and epidemiology centers, urban and rural Indian health boards, Tribal colleges, Indian Health Service (IHS) centers, and Tribal governments.²⁴ Of these boards, 2 serve in a dual role, as an IHS area IRB and a Tribal IRB.²⁵ To serve community interests and conform to federal human participants protection regulations (as defined in 45 CFR 46²⁶), most Tribal IRBs have been established according to federal requirements.²⁷ Additional protections include community-level protections, protocol reviews by cultural committees or elders, publication and dissemination agreements, agreements related to monetary benefits, and Tribal consideration of the meaning of research questions. (Although beyond the scope of this article, there are a number of

other ways in which Tribes may engage in research regulation, including community advisory boards, research ethics boards, and subcommittees appointed to review research protocols.²⁷)

Among many other areas of divergence, the definition of research differs between Tribal traditions and federal regulations. Indigenous research methodologies are based on healthy relationships between researchers, communities, and participants that include respect, reciprocity, and responsibility.²⁸ Current federal guidelines for human participant research do not address the multiple challenges and possibilities associated with indigenous research contexts. Research is defined in 45 CFR 46 "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."²⁶ However, prioritizing indigenous people's worldview⁶ requires specific adaptations to the definition and regulation of research. This begins with Tribes, as sovereign independent nations, defining what research is and then creating policies that address gaps in federal research protection guidelines.²⁹⁻³¹

There is not 1 shared definition among Tribes of what constitutes research, just as there is not 1 language or spiritual tradition that represents all Tribes, communities, and ways of knowing. An activity defined as research by a Tribal community may not be defined as such by a researcher from an academic institution or funding agency. Moreover, indigenous communities may not be

aware of a particular study because it does not meet the federal definitions of research^{26,29} and therefore does not undergo a formal review and approval process. An example of how the federal definition of research fails to protect Tribal community sovereignty is ethnographic research involving interviews with Tribal members. Although some IRBs may not consider this human subject research if the individual is not identified or does not provide informed consent, Tribal communities consider any activity involving histories, intellectual property, or the participation of community members Tribal research. Tribal IRBs are necessary to regulate research because of federal and Tribal differences in how human participant research is defined and the rights of Tribes as sovereign nations.

In 2006, Tribal leaders from the Rocky Mountain–Great Plains region decided that the best way to protect Tribal values and interests would be to establish an intertribal IRB to coordinate research regulation among constituent Tribes.

ESTABLISHMENT OF THE INTERTRIBAL BOARD

Meetings with Tribal leaders, academic partners, Tribal program directors, state and federal legislators, and national Indian policy organizations, facilitated by a consortium of different Tribes, occurred over the course of 3 years (2006–2008). These meetings were both formal and informal; their primary goal was to identify the context by which research was occurring in indigenous communities, the process

according to which research was regulated, and the need for Tribal IRBs based on Tribal definitions of research. In some cases, this required Tribal members to share their experiences and provide evidence on research proposals in which individuals who were not members of Tribes wrote letters of support for research activities on behalf of Tribal communities. These letters were used by academic institutions to acquire funding on behalf of Tribal communities without the approval of elected Tribal leaders, who are the primary authorities representing their respective Tribes.³² There was a need for research regulation that would maximize community benefits and minimize harms.

Tribal leaders and programs stressed the need for research that, in addition to maximizing community benefits, would translate into increased knowledge based on Tribal research priorities and strategic health, environmental, and educational plans.³³ Tribal leaders also indicated that clear documentation of the Tribe's rights to the data and to the publication of the data was needed. On June 17, 2009, elected Tribal leaders signed a resolution for the development of an intertribal regional IRB, housed at an intertribal consortium (ITC), that would address Tribal community issues and rights. Once the justification for an intertribal IRB was established, ITC personnel sought input from experts.

The ITC developed relationships with 3 Tribal IRB experts: Beverly Becenti Pigman, chair of the Navajo Nation Human Research Review Board; Francine Romero Gachupin, former chair of the Albuquerque Area Southwest Tribal IRB; and



William Freeman, chair of the Northwest Indian College IRB and formerly with the IHS National IRB. ITC personnel traveled to the areas where the Tribal IRB experts resided, and the Tribal experts answered a series of questions about how to develop an intertribal IRB that would promote indigenous values and community participation. In all cases, the experts and their partners shared their resources, manuals, training plans, templates, and ideas about the Tribal IRB process.

Several agencies and institutions also contributed, including the IHS national IRB, the Billings Area Indian Health Service, the Rocky Mountain Tribal Epidemiology Center, and Native American Research Centers for Health, as well as cultural committees, Tribal colleges, universities, and hospitals. Other contributors included elected Tribal leaders, Tribal health program directors and staff, and indigenous scholars and researchers.

ITC staff found slightly different recommended approaches to developing an intertribal IRB. For example, the requirements in terms of researchers' involvement with community members in the research process varied. In some cases, Tribal IRBs required presentations by researchers to the IRB and fees to process research protocols according to the degree, educational, and professional status of the researcher. There were differences in the point at which IRBs reviewed research protocols; one expert indicated that there was no need to review a protocol until it had first been reviewed by an institutional IRB. The reason is that if a protocol does not meet institutional IRB standards for

approval, which are less stringent than those of a Tribal IRB, then the Tribal board will not approve it in any event.

Another difference was in the types of research reviewed. One IRB reviewed only health-related research. In another, the primary focus was on health, but that IRB decided ultimately which types of research it would review on a case-by-case basis. The other IRB focused on a variety of research areas, covering studies in such areas as the environment, natural resources, and education in addition to health-related investigations. Differences were found between Tribal IRBs in the level of flexibility required for an intertribal IRB; there was not a "one-size-fits-all" approach to regulating research in indigenous communities.

There were similarities between IRBs with respect to application criteria, including documentation of budget, Tribal leader approval, publication rights, data rights, and evidence of community involvement. Although the criteria for review generally followed federal guidelines,³⁴ 2 of the IRBs required the principal investigator, rather than a staff person, to attend the IRB meeting, present the proposed research, and answer questions posed by IRB members.

ITC staff reviewed research and regulation contexts according to equity of resources (e.g., budgets, facilities, expertise, and capacity) and the extent to which the research encouraged transparency. The ITC analyzed federally funded research grants that identified the "community" or target population as 1 or more of the

consortium's member Tribes. The ITC interviewed Tribal and program leaders and found that federal grant funds were most commonly used to pay the salaries of individual Tribal workers.³³ Tribal leaders were not aware of research in their communities and believed that there was a disconnect between the kinds of research occurring on reservation lands and the research needed to support indigenous communities.^{29,33-36} It was determined that the intertribal IRB would become the delegated IRB for the IHS areas and facilities, as well as in instances in which 2 or more ITC member Tribes were involved in a study.

Tribes in the region had relied on the IHS area IRB to regulate research; however, in 2009, the area IRB was transferred to the national board located at IHS headquarters in Rockville, Maryland. Over a 2-year period, the ITC worked with the IHS area director and IHS personnel to develop a plan for transferring the area IRB from IHS headquarters back to the region. This decision framed the process in which the intertribal IRB would be structured; the board would review human participant research, culture- and community-related protocols, and grant-sponsored projects focusing on Tribal data or communities.

The ITC is led by elected Tribal leaders from 10 large land-based, federally recognized Tribes with large populations and one Tribe that is not federally recognized. The ITC serves its constituents through policy development, research oversight and regulation, program development, and facilitation of partnerships.³⁵ Twelve

individuals voluntarily serve on the intertribal IRB, of whom 7 are members of constituent Tribal nations affiliated with the ITC.

Tribal members have received training in behavioral research, biostatistics, and issues related to education, health, and vulnerable populations. The intertribal IRB chair is an elected Tribal leader, and the co-chair has a doctorate degree and extensive research experience. Two of the members, one an indigenous scientist and the other a Tribal IRB advocate with a medical degree, serve as mentors and policy advisors to the intertribal IRB. In addition, a multicultural female medical doctor was recruited to serve on the board. The board meets a minimum of 4 times per year at the ITC office and communicates as needed throughout the year via such means as teleconferences and e-mails. The intertribal IRB reviews approximately 15 new research protocols each year and provides annual reviews and publication reviews for active protocols.

ASSESSMENT OF RESEARCH REGULATION PRACTICES

The ITC followed a 6-step process to assess the context and adequacy of existing research regulation practices. These steps may be useful for Tribes, consortia, and policymakers to consider when developing research regulations or assessing the adequacy of their current research review process (see the box on the next page).

Four of the region's 10 constituent member Tribes had their own active IRB, located at a Tribal college.²⁴ The intertribal IRB met with



the Tribal IRBs to determine how to partner with them to regulate research practices. The intertribal board identified the types of research reviewed and existing policies or laws. We found that Tribal councils may themselves authorize a given research project or may delegate a Tribal college, IHS area IRB, research review board, or Tribal program to review projects according to content and local expertise. The ITC contacted universities, funding agencies, and hospitals and found that there were variations in the level of community involvement required and in the Tribal approval process. Several researchers and institutions cited such variations as a barrier.

Tribes must determine whether the current level of research regulation is adequate to protect against potential risks in a given community. The ITC found that the current level of regulation was inadequate. In several cases, Tribes were involved in studies in which an institutional IRB, with no Tribal representation, regulated the research. In some cases, Tribes signed an authorization agreement and were not aware that the agreement would allow an outside IRB to regulate the research.

After the context and adequacy of research regulation have been assessed, Tribes can begin developing their own policies and procedures to regulate research. Development of formal regulation policies is an ongoing process that requires continuous training of IRB members, community members, and Tribal leaders. The ITC found the experiences of Tribal IRBs, the generosity of research professionals, and the knowledge

of IRB experts valuable in this process. The steps listed in the second box on this page may be useful for Tribes interested in developing an IRB or intertribal board. Although these steps are not exhaustive, they provide a framework through which Tribes and Tribal consortia can begin the process of increasing community participation in the regulation of research.

PROTOCOLS AND IMPLEMENTATION

Tribes interested in developing an IRB should review the step-by-step registration process and

specific training, policy, and implementation requirements while seeking support from established Tribal IRBs or intertribal boards (see the boxes on this page). Policies associated with research regulation include a Tribal definition of research and guidelines relating to areas such as ethics (community vs individual protection), equity, and transparency (see the box on the next page).

Tribal leaders, policymakers, researchers, and community members increasingly recognize the need for community participation in the regulation of research. Results from the 3-year intertribal IRB process confirm

the importance of community involvement and Tribal sovereignty in the regulation process.

Ongoing efforts to educate policymakers and funding agencies are needed to protect communities from risk. Honoring Tribal sovereignty requires that researchers be aware of the unique conditions and laws that govern Tribal nations. Community members should be involved in all aspects of the research process, and community-based participatory research approaches promote planning, data gathering and dissemination of data^{37,38}; however, these approaches do not adequately

Steps for Determining Whether an Institutional Review Board (IRB) or Intertribal IRB Is Appropriate in the Tribal Context

1. Identify the context in which research involving Tribal members or communities is regulated
2. Determine whether the level of regulation is adequate for the potential risks involved
3. Assess the views of Tribal leaders, community members, and researchers on research regulation
4. Create a working group under the direction of Tribal leaders to assess areas of need relating to the development of formal research regulations, policies, or an IRB
5. Review the existing policies and practices of the Indian Health Service area IRB, Tribal consortia, and the local Tribal IRB
6. Encourage community-level protections and formal research review processes as appropriate (based on steps 1-5)

Steps Involved in Developing an Institutional Review Board (IRB) or Intertribal IRB

1. Educate Tribal leaders, Tribal programs, community members, and researchers about the importance of indigenous community participation in the regulation of research
2. Recruit IRB committee members and identify what they will do and who they represent
3. Develop a plan for IRB implementation and communication based on gaps identified in the determination phase outlined in the first box
4. Develop or adopt policies and procedures for research regulation to protect indigenous communities from risk
5. Register the IRB with the Office of Human Research Protections
6. Train new committee members on IRB processes
7. Provide information about the IRB to academic institutions, researchers, policymakers, programs, and affected indigenous community members
8. Seek new members, training opportunities, partnerships with universities, and funding that will continue to support the functioning of the IRB



Protocols Associated With the Establishment of an Intertribal Institutional Review Board (IRB)

- **Definition of research:** An individual Tribe's definition of research supersedes the intertribal IRB definition and is used when protocols are submitted to the intertribal board. The intertribal IRB defines research as a human process with an intent to address a question, condition, phenomenon, event, or problem in a community for the purpose of describing knowledge or promoting new knowledge.
- **Ethics (community vs individual protection):** The intertribal IRB requires researchers to provide documentation of community involvement and how their research will benefit a Tribe. Researchers must include all locations where research will be conducted and how the results will be disseminated to Tribal programs, leaders, and other interested individuals. Research involving cultural knowledge, language, and practices requires written approval and the involvement of a Tribal historic preservation committee.
- **Equity:** The intertribal IRB promotes equity by gaining input from elders and community members, incorporating traditional knowledge and beliefs, and advocating for allocation of resources in Tribal communities. The board requires researchers to outline the benefits of their research for the community.
- **Transparency:** The intertribal IRB requires researchers to submit the following: (1) a 1-page abstract of the proposed research in simple and clear language, (2) curricula vitae for the researchers and staff and a description of their experience working with Tribal communities, (3) a signed resolution for all Tribes involved, (4) signed letters of support from individuals authorized to support research at a given facility or location, (5) documentation of IRB approval from other institutions or organizations, and (6) a detailed budget and allocation of funds for the community. Researchers must also provide copies of informed consent procedures and forms.

address the need for community participation in regulation of research or in the review process.³⁹

The intertribal IRB requires investigators to submit a protocol application for review by the board before a proposal is submitted to a funding agency for consideration. In addition, the board requires that investigators submit all protocols involving ITC member Tribes for review and approval. This includes protocols that are classified as exempt according to 45 CFR 46.101(b), as well as activities that are not classified as "research" in the federal definition. Providing the intertribal IRB with the opportunity to review all research, grants, and programs involving ITC member Tribes, regardless of protocol status (e.g., exempt, expedited), allows community members to engage in the regulation of activities that may be viewed as research by a Tribe but may not be viewed as such according to the federal definition.

Members of the intertribal IRB are committed to a long-term process that advances indigenous knowledge and protects sensitive information related to the cultural and social aspects of

Tribes. As Tribal members are becoming more involved in the regulation of research, they are calling for more research accountability and clearer benefits to the community. This includes shared resources, inclusion of community and cultural knowledge, documentation from Tribal leaders and program directors on the types of research they support, and data ownership rights and publication plans.³²

CONCLUSIONS AND NEXT STEPS

More efforts are needed to address the unique context of and considerations for Tribal regulation of the research process from an indigenous worldview.^{6,40,41} In the future, this may include federal guidelines that honor indigenous knowledge. Education is needed for academics, students, institutions, funding agencies, and others about research on indigenous communities and publication of findings. This can be achieved through early discussions and ongoing communications with researchers about Tribal

sovereignty and community protections. Researchers from all disciplines and backgrounds must be accountable to the community rather than only to their institution.

Although the intertribal board stresses that community-based or Tribally directed participatory research is the preferred approach for conducting research, there is disagreement among indigenous communities and academic organizations about what constitutes such an approach.^{35,37,42,43} Many research protocols incorporate aspects of the community-based participatory research approach to demonstrate community involvement and support, but an individual's support should not be interpreted as community or Tribal support. Moreover, individual support does not provide the level of protection afforded by a Tribal IRB.

Thus, the involvement of community members in a given research project, along with their relationship with the researcher, funding agency, and employer, must be considered. An intertribal board can reinforce the need for accountability;

however, this requires a fundamental shift among all disciplines (health, ecological, educational, social, and political) in the ways in which research is developed and implemented in and with indigenous communities. Including community participation in research regulation is a natural progression in building community ownership and involvement in research.^{38,44}

Federal funding agencies have recognized the importance of community involvement in research, and these agencies encourage institutions to use the community-based participatory research⁴⁵ approach when working with indigenous communities.³² This recognition, however, falls short of addressing how and when Tribal communities should engage in reviews of research. It is not helpful to have a community involved in developing a research protocol based on community-identified needs if there are no IRB members with the contextual knowledge necessary to approve or reject the protocol.

As Tribes learn more about the importance of research regulation,



researchers may learn more about the indigenous worldview and the values that Tribes seek to uphold. This process offers the promise that indigenous communities will reclaim and transfer their balance of mind, body, spirit, and context to future generations.⁴⁶ ■

About the Authors

All of the authors are affiliated with the Rocky Mountain Tribal Institutional Review Board, Billings, MT. Allyson Kelley is with the Department of Public Health Education, University of North Carolina, Greensboro. Annie Belcourt-Dittloff is with the Department of Pharmacy Practice, University of Montana, Missoula. Cheryl Belcourt and Gordon Belcourt are with the Montana-Wyoming Tribal Leaders Council, Billings, MT.

Correspondence should be sent to Cheryl Belcourt, Montana-Wyoming Tribal Leaders Council, 175 N 27th St, Suite 1003, Billings, MT 59101 (e-mail: belcourt@mtwytlc.com). Reprints can be ordered at <http://www.ajph.org> by clicking on the "Reprints" link.

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Contributors

A. Kelley originated the article and led the writing process. A. Belcourt-Dittloff contributed to writing the article and researched the literature. C. Belcourt contributed to writing and reviewing the article. G. Belcourt contributed to the writing of the article. All of the authors reviewed drafts of the article.

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Moving Forward: Breaking the Cycle of Mistrust Between American Indians and Researchers

Christina M. Pacheco, JD, Sean M. Daley, PhD, MA, Travis Brown, Melissa Filippi, PhD, K. Allen Greiner, MD, MPH, and Christine M. Daley, PhD, SM

American Indians (AIs) have some of the poorest documented health outcomes of any racial/ethnic group. Research plays a vital role in addressing these health disparities.

Historical and recent instances of unethical research, specifically the Havasupai diabetes project, have generated mistrust in AI communities. To address the concerns about unethical research held by some AIs in the Heartland (Midwest), the Center for American Indian Community Health (CAICH) has launched a series of efforts to inform AIs about research participants' rights.

CAICH educates health researchers about the importance of learning and respecting a community's history, culture, values, and wishes when engaging in research with that community. Through community-based participatory research, CAICH is also empowering AIs to assert their rights as research participants. (*Am J Public Health*. 2013;103:2152–2159. doi:10.2105/AJPH.2013.301480)

AMERICAN INDIANS

(AIs) have some of the poorest documented health outcomes of all racial and ethnic groups in the United States,¹ including some of the highest rates of obesity, diabetes, and premature death. AIs also have significantly lower screening rates for cancers and other diseases.¹ They are often overlooked by health care policy-makers and the public health community. Rising mortality rates highlight the urgent need for effective preventive efforts and therapeutic approaches in this underserved group.² Research is necessary to evaluate and create the most effective clinical and public health approaches.

HISTORY, HISTORICAL TRAUMA, ETHNOCIDE, AND GENOCIDE

Investigators need to consider the roles of history, historical trauma, ethnocide, and genocide when conducting research with AI communities. Over the past few centuries, many AIs were forcibly removed

from their homelands by governmental authorities and resettled in areas unfamiliar to them.³ Native languages and religious practices were banned. For example, the Courts of Indian Offenses, created by Commissioner of Indian Affairs Hiram Price on the basis of instructions from Secretary of the Interior Henry M. Teller on December 2, 1882, “discouraged” certain “heathenish” AI cultural practices, including certain dances, rituals, and use of traditional healers.⁴ These regulations were amended over time to include other offenses, such as unauthorized leaves of absence from the reservation.⁴

Policies were introduced to “kill the Indian, and save the man,” a phrase coined by Captain Richard H. Pratt, founder of the Carlisle Indian Industrial School. From the late 1800s to the early 1900s,⁵ AI children were forcibly removed from their families and sent to federal Indian boarding schools, where they were subjected to the federal government's Indian Education Program, designed explicitly to extinguish Indian cultures.^{5,6}

Between 1946 and 1964 (the period known as “Termination”), the federal government tried to end its trust relationship with AI nations established by treaties and executive orders, thereby terminating their status as sovereign nations.⁷ The cornerstone of this Termination-era legislation was House Concurrent Resolution 108 (HCR 108), adopted by Congress on August 1, 1953.⁸ HCR 108 mandated that when a tribe was terminated:

1. tribal lands were transferred to tribal members, third parties, private trusts, or the state;
2. all federal programs were abolished, including health and education programs;
3. state legislative jurisdiction and judicial authority were imposed;
4. state tax exemption was ended; and
5. tribal sovereignty was extinguished.^{8,9}

During Termination, 109 tribes were terminated, approximately 2 500 000 acres of tribal land