

Annual Report of the
American Indian/Alaska Native
Health Research Advisory Council
(HRAC)

Fiscal Year 2013





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INTRODUCTION

The *Annual Report of the American Indian/Alaska Native Health Research Advisory Council* provides an overview of the American Indian/Alaska Native (AI/AN) Health Research Advisory Council (HRAC) along with its activities and accomplishments in Fiscal Year 2013. The report includes summaries of the HRAC meetings, a list of outreach events, and recommendations that the HRAC submitted to the U.S. Department of Health and Human Services (HHS). A list of current HRAC members and Federal Partners is included as an attachment.

BACKGROUND

OMH was established in 1986, following the release of the *1985 Report of the Secretary's Task Force on Black and Minority Health*. The mission of OMH is to improve the health of racial and ethnic minority populations through the development of health policies and programs that will help eliminate health disparities. OMH advises the HHS Secretary, Assistant Secretary for Health, and other departmental leadership and works collaboratively with other HHS Operating and Staff Divisions, federal agencies, and with other organizations across the country on health-related matters affecting AI/AN, Asian American, Black/African American, Hispanic/Latino, Native Hawaiian, and Pacific Islander populations.

OMH serves as the Executive Secretariat for the HRAC. In this role, OMH is responsible for the administrative and fiscal operation of the HRAC, solicitation and selection of tribal delegates to the HRAC, and for ensuring that delegates and alternates to the HRAC meet Federal Advisory Committee Act (FACA) exemption's requirements.

PRESIDENTIAL MEMORANDA AND EXECUTIVE ORDERS

On April 29, 1994, President William J. Clinton issued the Government-to-Government Relationship with Native American Tribal Governments memorandum to executive departments and agencies. The memorandum reinforced the special relationship between tribal governments and the federal government regarding tribal consultation and sovereignty. The Domestic Policy Council (DPC) Working Group on Indian Affairs requested that each department develop its own operational definition of "consultation" with Indian tribes to meet the requirements of the Indian Self-Determination and Educational Assistance Act. This request, along with other DPC recommendations, ultimately led to the creation of HHS' formal tribal consultation policy on August 7, 1997 – developed to strengthen the government-to-government relationship and ensure that tribes are consulted on matters affecting them.

A revised Executive Order (13175) was issued on November 6, 2000, by President Clinton that reinforced his administration's commitment to tribal sovereignty and the unique government-to-government relationship that exists between the United States Government and tribal governments. Executive Order 13175 directs agencies to establish regular and meaningful consultation and collaboration between tribal nations and the federal government. It directs all federal agencies to coordinate and consult with Indian tribal governments whose interest might be directly and substantially affected by activities on federally administered lands.

In 2009, President Barack Obama issued a presidential memorandum on tribal consultation that reaffirmed his administration's commitment to regular and meaningful consultation and collaboration with tribal officials through implementation of Executive Order 13175. As a result, HHS worked with tribal leaders in the development of a revised tribal consultation policy. Signed in December 2010, this



policy provided more opportunities for tribal input through the development of policies, regulations, and budgets.

FORMATION OF THE HRAC

HHS solicited nominations from tribal leaders in November 2005 to develop the HRAC. The HRAC's role is to facilitate communication between the Department and tribes regarding health research priorities and needs in AI/AN communities. Members of the Council are elected or appointed tribal officials, and include one delegate and one alternate from each of the 12 Indian Health Service (IHS) areas, and four National At-Large Members. Federal partners representing HHS Operating and Staff Divisions also support the Council.

The HRAC was established to fulfill three primary functions:

1. Obtain input from tribal leaders on health research priorities and needs for their communities;
2. Provide a forum through which HHS Operating and Staff Divisions can better communicate and coordinate AI/AN health research activities; and
3. Provide a conduit for disseminating information to tribes about research findings from studies on the health of AI/AN populations.

At the HRAC's first meeting in 2006, the Council elected Councilwoman Cara Cowan Watts and President Cecilia Fire Thunder as co-chairs. The co-chairs served as the leaders and facilitators for several outreach events and general activities. The HRAC members participated in numerous conference calls to plan for and organize activities, including reviewing other HHS advisory models, discussing solicitation of research priorities and needs, and planning for future meetings.

During the second meeting held in Albuquerque, New Mexico, in November 2006, the HRAC reached a collective agreement to focus on three objectives:

1. Establish the HRAC Charter (outlining the purpose, background, and structure of the Council and processes for voting, membership, and leadership);
2. Develop a Discussion Guide (a survey to inquire about health research priorities and needs in Indian Country); and
3. Establish future meeting dates.

HRAC HISTORY

From 2006 to 2012, the HRAC held quarterly conference calls and annual meetings. The topics of continued concern and interest included the National Children's Study, National Institutes of Health (NIH) Tribal Consultation Policy, data sharing, scholarships for Native researchers, and a Native health research database. From these discussions, the HRAC developed and presented recommendations to HHS through letters to the Secretary and testimony at the annual HHS National Tribal Budget and Policy Consultation Sessions.

The HRAC developed a Discussion Guide to help ascertain health research priorities in Indian Country and constructed survey questions to examine healthcare delivery systems and research tribes were conducting. The HRAC members distributed the Discussion Guide to tribal leaders in their respective IHS areas from 2007 to 2009. During that time, the top health concerns reported (but not listed in priority order) were:

- Access to care and coordination of care;
- Behavioral health issues, including domestic violence, substance abuse, suicide, and tobacco use;
- Cancer, cardiovascular disease, diabetes, and obesity;
- Health information technology and systems;
- Lack of funding; and
- Recruitment/retention of highly qualified health care professionals/providers.

The Discussion Guide results provided valuable information to the HRAC from the tribes' perspective regarding health concerns, priorities, and the methodology by which future research should be conducted.

HRAC members attended outreach events to educate and inform tribes of the HRAC's mission and objectives. Events attended included the Annual Native Health Research Conference (2008, 2010, and 2011); National Indian Health Board (NIHB) Annual Consumer Conference (2008, 2011, and 2012); AI/AN Health Policy Conference (2009); IHS/Health Canada Maternal and Child Health Research Meeting (2009); Third National Leadership Summit on Eliminating Racial and Ethnic Disparities in Health (2009); NIHB Public Health Summit (2010); and the HHS Regional Consultations (2011 and 2012). These events provided an opportunity for tribes to collaborate and share their knowledge and experiences regarding the advancement of health care research and its importance in Indian Country.

In addition, the HRAC collaborated with the Administration for Children and Families; Agency for Healthcare Research and Quality (AHRQ); Assistant Secretary for Planning and Evaluation; Centers for Disease Control and Prevention (CDC); Health Resources and Services Administration; Indian Health Service (IHS); Intergovernmental and External Affairs; National Institutes of Health (NIH); Substance Abuse and Mental Health Services Administration (SAMHSA); Tribal Epidemiology Center (TEC) staff; OMH; and external researchers and scientists to advance its knowledge base of health care research and learn how to best provide healthcare services throughout Indian Country.



HRAC Members at April 2009 Meeting



FISCAL YEAR 2013 ACTIVITIES

HRAC RESEARCH ROUNDTABLE

The HRAC Research Roundtable brought together HRAC members, Native health researchers, TEC representatives, and Federal partners to discuss research priorities in Indian Country. On November 29, 2012, the Roundtable took place at NIH. Lieutenant Commander (LCDR) Tracy Branch, OMH, welcomed attendees and introduced Stephen Kutz, HRAC Co-Chair, and Commander (CDR) Jacqueline D. Rodrigue, Deputy Director, OMH. Councilman Kutz welcomed the attendees and thanked the participants, then began the meeting with a traditional prayer and prayer song from the Cowlitz Indian Tribe.

Dr. Joyce Hunter, Deputy Director of the National Institute on Minority Health and Health Disparities, also welcomed the attendees and shared updates on the NIH Guidance on the Implementation of the HHS Tribal Consultation Policy that the 27 institutes and centers must follow.

Meeting attendees heard a background presentation about the HRAC, including its history, priorities, and current activities.

Carolyn Aoyama, Native American Research Centers for Health (NARCH) Director, facilitated a discussion with participants regarding evaluating the NARCH program with a focus on measuring trust that included trust between tribal leaders and research partners.

Dr. Shilpa Amin spoke on behalf of AHRQ's Effective Health Care Program and followed up on a presentation she conducted during the Annual HRAC Meeting in September 2012 by providing more details on the patient-centered outcomes research (PCOR) process. She noted that the HRAC had been discussing research priorities on such broad health areas as cancer and diabetes. She also provided a PCOR Process Tree that the HRAC could consider to identify specific research topics and ultimately develop a written plan of research recommendations. Lastly, she shared a summary of proposed tasks for developing a PCOR plan.

Throughout the Roundtable, the HRAC members solicited recommendations and comments from participants for the HRAC and its Federal partners to consider. Research topics recommended by attendees included:

- Links among human health, human wellness, and environmental health;
- Multiple morbidities, such as the connection among oral health, cancer, and diabetes;
- Food security, including access to food and how climate change affects that access;
- Cancer;
- Motor vehicle fatalities;
- Oral health;
- Alzheimer's disease; and
- Historical trauma.

Other recommendations included:

- Support for accreditation, research, and development of standards for health service agencies;

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- Respect sovereign rights of tribes when biological samples from tribal members are involved in research;
 - Facilitation of an understanding between tribes and the Federal Government on issues related to AI/AN health research and tribal sovereignty;
 - Normalization of evidence-based practices for minority communities and cultures in grant programs;
 - Equity in receiving funding for tribes and other groups that respond to Funding Opportunity Announcements (FOAs);
 - Sufficient time between the release of an FOA and its deadline to allow for tribal resolutions and approval to submit the grant;
 - Requirement of tribal resolutions/letters for any application that proposes to work with Native communities;
 - Increased numbers of Native individuals on standing committees in place of simply sponsoring special reviews;
 - Development of a training module for non-Native review panel participants; and
 - Increased numbers of pre-doctoral and post-doctoral AI/AN researchers in the NIH pipeline.

MEETINGS (TELECONFERENCE AND IN-PERSON)

February 26, 2013

The HRAC held its first teleconference for Fiscal Year 2013 on February 26, 2013. LCDR Tracy Branch welcomed the HRAC to the call. She reported that Dr. J. Nadine Gracia, Director of OMH, had shared at the HHS Secretary's Tribal Advisory Committee January 2013 meeting that the HRAC was concerned about states not recognizing TECs' public health authority status. She informed the STAC members that the HRAC was drafting a letter with recommendations on this issue.

Dr. Alan Trachtenberg, IHS, reported that he had participated in several meetings of the National Children's Study Federal Consortium. He said the HRAC was concerned that the national probability sample did not include the Northern Plains or Alaska and therefore was not fully representative of AI/ANs. A potential solution from the National Children's Study is that out of the 100,000 respondents the investigators intend to follow, they will select 90,000 from the national probability sample. The study will reserve 10,000 for selection with alternate approaches to address other scientific questions and ensure adequate representation, and will begin to address the 10,000 participants in the non-probability subsample in about one year, so the HRAC members have time to consider how to encourage adequate representation of AI/ANs from the Northern Plains and Alaska.

LCDR Branch held conversations with the National Library of Medicine (NLM), in a follow-up to the HRAC discussions at the September 2012 meeting, regarding a Native research database or clearinghouse. Specific questions from NLM included the types of materials in the database, the proprietary nature of those materials, who would create the database, and which individuals would have access to it. Dr. Trachtenberg suggested there is no need for a new database because one exists at the University of New Mexico (UNM) that IHS previously funded. While UNM continues to manage the database, it still needs maintenance. Councilwoman Cowan Watts, who noted there had been previous discussions about that database, said she and Dr. Malia Villegas, National At-Large Alternate, will work together on this issue.



April 30, 2013

The HRAC teleconference call on April 30, 2013, began with Dr. Gracia welcoming new members of the HRAC and thanking the HRAC members for their service and input to HHS, acknowledging their time and dedication.

Michael Percy, National At-Large Delegate, reported a draft letter to the HHS Data Council was being developed by a work group that included Dr. Jay Butler, Alaska Area Alternate, and Tom Anderson, Oklahoma Area Alternate. The letter to the Data Council addressed data ownership, data sharing, and data stewardship—including biologic specimens—and noted the importance of respect for Institutional Review Boards (IRBs), research review committees, and the National Data Warehouse (NDW). The letter also addressed TECs, their data sharing, and data sampling in large data samples. The work group members discussed what to ask from the Data Council, with Councilwoman Cowan Watts replying that the HRAC needs to first ask for an HHS-wide data policy surrounding Indian Country. Dr. Villegas asked if this would be a data-sharing policy with guidelines decided by tribal leaders, adding that the letter could identify four or five specific areas and provide examples of what is working in the field currently.

Councilwoman Cowan Watts reported that at the HHS National Tribal Budget and Policy Consultation Session she attended during March in Washington, DC, the HRAC had a one-on-one session with NIH where they discussed NIH's Guidance on the Implementation of the HHS Tribal Consultation Policy. She also testified during the consultation on HRAC issues and submitted written testimony.

July 29, 2013

The HRAC held its in-person meeting for Fiscal Year 2013 on July 29, 2013, in Rockville, Maryland. Councilwoman Cowan Watts opened the meeting and welcomed new and returning HRAC members and representatives of Federal partners. CDR Jacqueline Rodrigue noted that the HRAC serves as a forum for collaboration between tribal leaders and HHS.

Captain Francis Frazier, Deputy Director, Office of Public Health Support (OPHS) at IHS, highlighted OPHS activities linked to HRAC priorities, including:

- Native American Research Centers for Health. IHS collaborates with the National Institute for General Medical Sciences (NIGMS) to support the NARCH program. The OPHS Division of Epidemiology and Disease Prevention (DEDP) coordinates NARCH activities for IHS. NIGMS provides base funding and liaises with other NIH Institutes; the NIH Center for Scientific Review reviews NARCH applications. The strong relationship between federal research institutions and tribal partners makes the NARCH program successful and provides opportunities for Native students to move into the field of research.

NARCH programs support a wide range of community-based projects for tribes and tribal organizations across Indian Country. There have been minimal reductions in NARCH funding despite federal budget constraints.

OPHS is currently designing the evaluation of the NARCH program, which will include both qualitative and quantitative analysis as well as the HRAC general research recommendations, as appropriate.

- Tribal Epidemiology Centers. The passage of the Indian Health Care Improvement Act under the Affordable Care Act permanently reauthorized the TECs. The DEDP manages the TEC cooperative



agreements and provides oversight for the centers. TEC core functions include data collection, data evaluation, health priorities, recommendations for health services, improvements for the health care delivery system, and technical assistance on epidemiology for tribal organizations.

IHS developed a data-sharing template for TEC activities that does not include personally identifiable information (PII). The Epidemiology Data Mart furnishes that information on a project-by-project basis, with IHS planning to augment the existing template to address PII.

- Division of Program Statistics (DPS). The DPS produces statistical information and publications for IHS. It works closely with internal partners, such as the National Patient Information Reporting System, NDW, and the HHS Office of Information Technology. The DPS also collaborates with partners such as the National Center for Health Statistics.

Councilman Chester Antone, Delegate, Tucson Area, asked how IHS data from the Resource and Patient Management System (RPMS) and non-RPMS data are converted for the NDW. He also expressed concern about the use of residency data to determine Health Professional Shortage Areas and service delivery. The IHS data system does not allow reporting of certain data, and tribal communities have some concern about misuse of the RPMS system. Captain Frazier said OPHS would provide a formal response after a careful review of the Councilman's questions. Councilwoman Cowan Watts noted that HRAC members continued to have questions regarding data access and asked how IHS was working with tribes to develop IRBs. Dr. Trachtenberg stated that the first step is to develop a Tribal Federal Wide Assurance (FWA) and then to create a Tribal Research Review Committee, which is not a formal IRB, but can identify tribal interests in proposed research. IHS IRBs require some form of tribal approval, whether by a tribal IRB or a tribal Council. Some area office IRBs have been transitioned to tribal IRBs or tribal organization IRBs. IHS has free web-based training to help tribes develop a tribal FWA or tribal IRB.

Elizabeth Carr, Tribal Affairs Specialist, Office of Intergovernmental and External Affairs, updated the HRAC on the Intradepartmental Council on Native American Affairs (ICNAA) and its new data priority. ICNAA is undertaking the data initiative (based on testimony the HRAC provided from 2012 and 2013) in conjunction with the HHS Chief Technological Officer to address data sharing, data collection, and data warehousing. ICNAA plans to provide technical assistance to all HHS branches to ensure they are aware of tribal differences and cultural issues pertaining to data collection and data sharing.

Dr. Shobha Srinivasan, Health Disparities Research Coordinator from the National Cancer Institute, NIH, provided an overview of NIH funding opportunities relevant to Native communities with a focus on the "Interventions for Health Promotion and Disease Prevention in Native American Populations" grant program. HRAC members provided feedback on the IRB process, the FOA language pertaining to tacit approval, decreased funding for research centers at minority-serving institutions, and the ethics involved in studying genetic data and biological samples from Native populations.

Dr. Kishena Wadhvani, Director of the Division of Scientific Review, Office of Extramural Research, presented on the AHRQ and Quality Peer Review Grant Process Review. Highlights included his explanation of the five study sections of the Division of Scientific Review, criteria for reviewer selection, and the peer review process.

The HRAC reviewed each of the HRAC priorities, including State/Tribal Epidemiology Centers' Relationship and Public Health Authority Status, the National Children's Study, the HHS Data Council, scholarship opportunities/data sharing, general research recommendations, and the Native Research

Database/Clearinghouse. The HRAC formed work groups to follow up on action items to address these priorities.



HRAC Members at July 2013 Meeting

September 10, 2013

The HRAC teleconference call on September 10, 2013, began with Councilwoman Cowan Watts asking for brief introductions. Dr. J. Nadine Gracia thanked the HRAC members for their service and input to HHS, noting that OMH continues to be strategically focused on the Affordable Care Act — particularly on outreach and education—with the Affordable Care Act a departmental and administration-wide priority. OMH is leading the implementation of the HHS Action Plan to Reduce Racial and Ethnic Health Disparities, and the Enhanced National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care released in April 2013. OMH, through the National Partnership for Action to End Health Disparities, continues to support 10 Regional Health Equity Councils across the country in their work to combat health disparities, using the social determinants of health approach.

Dr. Trachtenberg reported that the Institute of Medicine will convene a review panel for the proposed design of the National Children’s Study. The stratification was formerly geographically based, which resulted in the omission of the Northern Plains and Alaska. The study is now creating a new sampling framework based on hospital and birthing centers. It was suggested that the HRAC ask that Indian hospital births from both tribal and IHS hospitals be included, with oversampling from Indian hospitals. Councilwoman Cowan Watts said that this approach will resolve the identification issue for citizenship.

Dr. Dan Calac, California Area Alternate, referenced Dr. Wadhvani’s presentation during the HRAC Annual Meeting on the AHRQ review process and shared his experience as a reviewer. There were 20 reviewers in his section and all were Native or had worked with Native communities for 10 to 20 years. Dr. Calac appreciated how NIH ensured that reviewers had the relevant background experience and said that reviewers took the review process very seriously. He noted, at times, the proposal information was

not presented in a helpful format. He said that if a reviewer was not familiar with the context of the study, then he recommended reviewers do some background work (such as how the study was developed or where the study's catchment area was located). Dr. Calac offered to serve as a resource, answer questions about the review process, and serve as a reviewer.

OUTREACH ACTIVITIES

The HRAC conducted outreach throughout the year to share its priorities and recommendations, provide updates to tribes on its activities, and gather feedback and input from tribes and tribal communities about research issues, concerns, and priorities. The National Indian Health Board Quarterly Meeting on March 4, 2013, included an HRAC update. Councilwoman Cowan Watts attended the 15th Annual National Tribal Budget Consultation Session on March 7-8, 2013, in Washington, DC, and presented testimony on behalf of the HRAC. She and Councilman Chester Antone provided updates on the HRAC during the HHS Regional Tribal Consultations in Spring 2013, and Councilwoman Cowan Watts presented HRAC information at the 5th Annual Oklahoma City Area Indian Tribal Health Board Public Health Conference on April 16, 2013, in Catoosa, Oklahoma.



**Councilwoman Cowan Watts and Cathy Abramson, NIHB Chairperson
NIHB Quarterly Meeting on March 4, 2013**

ANNUAL HEALTH RESEARCH REPORT

The HRAC produced its Annual Health Research Report, a compilation of findings related to important health research topics in AI/AN communities. This report serves as a resource on research findings, topics, and available federal programs with tribes.

RECOMMENDATIONS TO HHS

The HRAC submitted recommendations to HHS by testimony on March 8, 2013, on issues of concern from the tribal communities that the HRAC represents. In addition, the HRAC submitted a letter of request to the HHS Data Council on July 12, 2013, regarding sharing of tribal health data and a request for a tribal consultation. The HRAC distinguished four major recommendations to HHS and provided some general research recommendations. The details of the testimony are listed below.



TRIBAL EPIDEMIOLOGY CENTERS' PUBLIC HEALTH AUTHORITY STATUS

TECs are having difficulty gaining access to data sets held by state governments even though the Affordable Care Act established these TECs as “public health authorities” (as that term is defined in the Health Insurance Portability and Accountability Act of 1996). The Affordable Care Act also provided new statutory authority for IHS-funded TECs to access “data, data sets, monitoring systems, delivery systems and other protected health information in possession of the Secretary.”

Access to state-maintained data sets is particularly important given the high rates of misidentification of AI/ANs in most state data and resulting publications and use of misinformation concerning AI/AN health status and access to health services. Access to state data sets, such as vital statistics records and the Pregnancy Risk Assessment Monitoring System, is important because access to IHS-provided services varies greatly within the IHS delivery system and many service areas do not have access to IHS-operated hospitals or IHS specialty providers. This results in IHS data alone being insufficient to reflect a more comprehensive picture of AI/AN service utilization and health status in those states.

The HRAC recommends that the Secretary send a letter to the governor of each state and their Departments of Health requesting that they facilitate TEC access to state data and data sets for the purposes of assessing and reporting the health status of AI/ANs in each state for health program and facility planning. Furthermore, when TECs access state data, fees charged should not be higher than those paid by other governmental entities. The HRAC urges states to work with the TECs to provide comparable data on the health status of the general population for benchmarking and to track progress in eliminating health disparities. It also asks that TECs have a place, such as the Office of the Secretary, where they can report any further difficulties in accessing the data and that states be aware of this reporting mechanism.

NATIONAL CHILDREN'S STUDY

While the HRAC fully supports the intent and purpose of the National Children's Study, the study could have more meaningfully included the participation of Tribal Nations and the AI/AN community. Tribal consultation should have been required before the study was planned and funding committed in a manner consistent with longstanding federal policy. Consultation should also be utilized at each new stage of the study so that local tribes are consulted during the planning phase.

The HRAC believes there is still an opportunity at this stage in the National Children's Study to implement the following recommendations:

- Health research participants defined as American Indian or Alaskan Native must present proof of enrollment from a federally recognized tribe as provided in the current “Indian Entities Recognized and Eligible to Receive Services from the United States Bureau of Indian Affairs [BIA]” or meet the BIA definition of American Indian or Alaskan Native as provided by a “Certificate of Degree of Indian Blood.” Self-identification is not adequate;
- Oversampling of AI/AN populations should be done. The target number of 2,000 AI/ANs is not adequate;
- Funding for additional cohorts in Indian Country to meet oversampling and diverse community needs to ensure diversity within Indian Country and to avoid the unacceptable practice of leaving out entire communities such as Alaska Natives and Plains Indians;
- Sampling protocols promised, including preservation of DNA and tissue samples, must be followed and tribes consulted before, during, and after the study as an on-going partner;

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- Commitment to tribal sovereignty must be kept;
 - De-identification of data must be reviewed with tribes;
 - A data-sharing agreement with tribes must be established in partnership with the tribe before the local study commences; and
 - Study centers, yet to be named, should be encouraged to target Indian Country in order to demonstrate outreach efforts to Native communities to enroll Native children into the study and should consult with local tribes before enrollment begins.

NATIONAL INSTITUTES OF HEALTH TRIBAL CONSULTATION POLICY

The HRAC is encouraged that the NIH addressed tribal consultation with the NIH Guidance on the Implementation of the HHS Tribal Consultation Policy. However, the HRAC is concerned about the delays in releasing this guidance to tribes. All tribal leaders should be informed of NIH's efforts and receive a copy of the Guidance for their review as well as any upcoming consultation opportunities.

In addition, more focus should be placed on putting AI/AN leadership throughout the NIH to provide advice on issues of importance to Native communities and to ensure tribes are consulted on priorities, research design, and community-based research.

HHS DATA COUNCIL

The lack of sharing AI/AN-focused research and health data with Tribal Nations continues to be an area of great concern for tribes and their tribal health programs. Having established codes and protocols of research with indigenous peoples reinforces the concept that control of data by individual Tribal Nations is to be respected and considered of paramount importance when conducting research in tribal communities and nations. Moreover, access to data for system assessment and quality improvement is critical for successful self-governance to meet public health needs. Often relationships between academic institutions or government agencies and tribes are strained due to conflicts concerning access to and ownership of tribe-related research data.

The HRAC is concerned that data-sharing agreements, constructed to avoid and prevent unauthorized release of pertinent research information or analysis, as well as tribal mechanisms to protect research conclusions, are being disseminated but not consistently honored. Additionally, tribal laws to protect data or biological specimens may be ineffective when physical controls for access are solely in the hands of a government agency or academic institution. These concerns are amplified when those who control access to data and specimens are not aware of or do not respect the sovereignty of Tribal Nations in determining the management and use of the sensitive human tissue samples and health data.

True ownership of intellectual property may be difficult to determine. "Data stewardship" usually falls to academic or government partners rather than tribal governments. Thus, tribes must rely on these trusted partners to maintain data integrity and security as well as prevent release of information or materials without prior tribal approval. Funding agencies and academic institutions must be made aware of this stewardship role when working with tribal data or research materials and be cooperative in relinquishing data sets back to the tribal partner at the conclusion of the study, data analysis, or at the request of the tribal community.

Researchers approaching tribes with proposals should be accustomed to working within the community's infrastructure when seeking approval of a project. Researchers should know many tribes now have well-established IRBs with strict policies and procedures for handling the review, approval, or



disapproval of research conducted within their tribal boundaries and organizations. Many tribes also utilize Research Review Committees or Tribal Councils to review new protocols. In certain cases, the regional IHS IRBs may have jurisdiction to review and approve proposed projects. In either scenario, the ownership of data should always be delineated and a data-sharing agreement executed, which clearly states that data is owned by the tribal government, community, or organization, while the academic or government partner acts only as an authorized steward. The tribal IRB (or the IHS IRB) must be involved in all discussions involving any sharing of research data, publications, manuscripts, etc.

IHS maintains the NDW that contains clinical data from tribes across the United States. The data stored within this database are important for tribal health planning and program assessment by tribes, so access to these data is critical. IHS serves as a custodial guardian of these data sets but should not be considered the owner of these data. At present, access to these data sets by the tribes is difficult.

TECs have taken the lead in requesting access to the NDW, acting on the behalf of tribes and in their best interests. The TECs must partner with individual tribes to gain prior approval for the data stewardship and analysis. TECs can request data sets at the service unit or area-wide level, with data aggregated so as not to individually identify the Tribal Nations. There have been seven data-sharing agreements executed between the IHS and the TECs through mid-February, 2013, with little actual progress evident in the sharing of tribal data sets with the TECs or individual tribes. The TEC works with data for multiple purposes, including tribal health system planning and process improvement.

To address these concerns, the HRAC requested that HHS convene a tribal consultation with the HHS Data Council to develop a department-wide policy on data management in Indian Country. This policy should address ownership and dissemination of data collected from tribal communities and provide a basis of mutual understanding and expectations between tribal leaders and research partners in both academia and the federal health agencies.

The HRAC encourages HHS to pay particular attention to examples of successful partnerships that have affirmed the sovereignty of tribes and tribal health organizations.

- The Alaska Area Specimen Bank is a repository of biological specimens and clinical data collected through health research projects conducted among Alaska Native people. The Alaska Area Specimen Bank is owned by the Alaska Native people, administered by the Alaska Tribal Health System, and managed under the stewardship of the CDC's Arctic Investigations Program on the Alaska Native Health Campus in Anchorage.
- The University of Oklahoma and the Chickasaw Nation Department of Health have established a data-sharing partnership. A memorandum of understanding and a business associate's agreement were signed to put into action a plan to create a database from de-identified health records for public health research, tribal planning, and resource development. The database will be used to study population level health issues related to chronic disease, infectious disease, and climate change. The negotiated agreement places full ownership of data with the tribal partner and joint oversight of individual research projects by the university and tribal IRBs.

The HRAC believes review of these successful partnerships can form the basis of an effective national policy to become the norm throughout Indian Country, rather than the exception.



GENERAL RESEARCH RECOMMENDATIONS

The HRAC is aware of the high and disproportionate rates of morbidity and mortality experienced by AI/ANs; therefore, many of the recommendations focus on addressing the health disparities that continue to plague Indian Country. Additionally, the HRAC would like to recommend that HHS increase its activities to address the suicide epidemic in AI/AN communities, including the research of the root causes of the epidemic.

In order to address the health concerns identified by the HRAC, research should focus on: data quality and accuracy to address under-representation of AI/ANs in population health data; the lack of access to health care services for AI/ANs in both rural and urban settings; the lack of incorporating traditional health care practices and traditional diets; the efficacy of health promotion/disease prevention activities; and the lack of health insurance coverage for AI/ANs. The HRAC has identified and recommends several research priorities (the list is not prioritized), including:

- Quantification of chronic disease prevalence (such as cancer, heart disease, and diabetes) and associated risk factors (including obesity, diet, and physical activity) through sustained support of prospective studies among AI/AN populations;
- Reduction of chronic disease risk factors reduction;
- Intentional and unintentional injuries;
- Evaluate methods to improve awareness and treatment of hypertension;
- Stroke prevalence/prevention;
- Methamphetamine prevalence/prevention;
- Evaluation of the use of emerging technologies (such as telemedicine, electronic health records, and health information exchanges) for the provision of care;
- Health services research (such as utilization of prenatal care, preventable hospitalizations, and emergency room utilization, etc.);
- Autoimmune disorders;
- Suicide prevention;
- The readiness of tribal governments for public health accreditation; and
- Health care reform impact and effectiveness.

In addition, efforts should be made to support research aims that attempt to understand exposure to risk and vulnerability to AI/AN health over the lifespan, due to social determinants such as social exclusion, marginalization, and inequality. Research should address the complex interactions between health determinants and long-term exposure to risk unique to AI/ANs as an indigenous population and resulting from misguided federal Indian policy.

It is important to stress that all research conducted should be evidence based, and to the extent possible, utilize community-based participatory methods. Tribal governments are the rightful owners of their respective data, and therefore all efforts should be undertaken to ensure tribal governments are consulted before such data are shared with any entity. In addition to health concerns and research priorities, many barriers exist regarding research activities in Indian Country. These barriers could be addressed by:

- Increasing cultural sensitivity among researchers;
- Increasing the number of AI/AN researchers, possibly through additional funding through the IHS Health Professions Scholarship Program and Loan Repayment Program (CDC and NIH, specifically, for research positions);

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- Improving the accuracy of data related to AI/ANs and the interoperability of data among HHS Operating and Staff Divisions;
 - Increasing the amount of available comparative data by making oversampling a priority to provide this data for comparison;
 - Improving infrastructure among AI/AN tribal governments to increase tribal capacity to carry out research and/or implement recommendations identified through research;
 - Increasing the amount of community-driven research;
 - Providing IHS with a research funding line item to support research by and for AI/ANs;
 - Adopting HHS-wide minimum standards and requirements for a tribal data-sharing agreement in which the language states that federally recognized tribes, as sovereign nations, must be acknowledged as the exclusive owners of indigenous knowledge, biogenetic resources, and owners of intellectual property, and that data collected from tribal citizens within the community setting must be returned to the community from which it was obtained (the tribe is the only entity that has the authority to decide how the data will be used in the future, and thus must retain ownership and control over the data upon the study's conclusion); and
 - The establishment of single data sources where, for example, the federal government maintains several AI/AN data sources through IHS, the Bureau of Indian Affairs, the Centers for Medicare & Medicaid Services, CDC, NIH, SAMHSA, the U.S. Census Bureau, and several others and a single, integrated Internet-accessible website with data available to calculate simple statistics, such as incidence and prevalence rates, etc., would assist in identifying areas of focus within AI/AN communities. Additionally, the resource could provide access to published data as well.

While the HRAC would like to see more grants awarded directly to tribal governments, it realizes that academic institutions and research organizations are often the most suitable awardees for certain highly technical and advanced research grants. Unfortunately, when academic institutions and research organizations are awarded grants for research affecting AI/AN communities, no uniformity or requirements exist for collaboration and cooperation with tribal governments. The HRAC recommends that grant requirements include demonstrated cooperation and collaboration with tribal governments, such as with the submission of a tribal resolution. While some grant awardees may consider such a requirement burdensome, numerous resources exist to reduce any burdens on grant awardees. Resources that are readily available to assist include the HRAC, other AI/AN federal advisory bodies, inter-tribal organizations, area Indian health boards, TECs, and numerous others.

The HRAC also recommends that agencies allow more time between when the FOA is released and the application deadline. Tribes and tribal organizations typically have internal requirements, such as Tribal Council approval through a resolution, to meet before developing and submitting a proposal. These meetings may only be held monthly, so a 30-day response period to a funding announcement is not enough time. The HRAC also recommends that a "Dear Tribal Leader" letter be sent out as an early announcement before a funding announcement is released to allow additional preparation time.

In addition to requiring tribal collaboration and cooperation as part of grant funding requirements, it is important to have grant reviewers that have demonstrated experience with tribal governments and who are culturally sensitive. Such reviewers can ensure that grant applications adequately include collaboration and cooperation components as well as evaluate grant applications from the AI/AN community, which may have extensive subject matter experience but fewer academic credentials and degrees. The HRAC recommends a training module be developed and shared to assist non-Native reviewers.

ATTACHMENT A:

MEMBER AND PARTNER LIST FOR FY 2013 - 2014

HRAC CO-CHAIRS

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HRAC Co-Chairs, Cara Cowan Watts and Stephen Kutz

MEMBERS

2013 Area Representatives	2014 Area Representatives
<p>Great Plains Area Delegate: Vacant Alternate: Vacant</p>	<p>Great Plains Area (formally the Aberdeen Area) Delegate: Patrick Marcellais Councilman, Turtle Mountain Band of Chippewa Indians Alternate: John Black Hawk Chairman, Winnebago Tribe of Nebraska</p>
<p>Alaska Area Delegate: Ileen Sylvester Vice President of Executive & Tribal Services, Southcentral Foundation Alternate: Jay Clarence Butler Senior Director, Division of Community Health Services, Alaska Native Tribal Health Consortium</p>	<p>Alaska Area Delegate: Ileen Sylvester Vice President of Executive & Tribal Services, Southcentral Foundation Alternate: Jay Clarence Butler Senior Director, Division of Community Health Services, Alaska Native Tribal Health Consortium</p>
<p>Albuquerque Area Delegate: June Shaw Tribal Council Member, Mescalero Apache Tribe Alternate: Joycelyn Dutchie Tribal Council Member, Southern Ute Indian Tribe</p>	<p>Albuquerque Area Delegate: Vacant Alternate: Vacant</p>
<p>Bemidji Area Delegate: Aaron Payment Tribal Chairman, Sault Ste. Marie Tribe of Chippewa Indians Alternate: Vacant</p>	<p>Bemidji Area Delegate: Aaron Payment Tribal Chairman, Sault Ste. Marie Tribe of Chippewa Indians Alternate: Vacant</p>
<p>Billings Area Delegate: Patty Quisno Councilwoman, Fort Belknap Indian Community Alternate: Darrin Old Coyote Chairman, Crow Nation</p>	<p>Billings Area Delegate: Patty Quisno Councilwoman, Fort Belknap Indian Community Alternate: Darrin Old Coyote Chairman, Crow Nation</p>
<p>California Area Delegate: Daniel Calac Chief Medical Officer, Indian Health Council Alternate: James Crouch Executive Director, California Rural Indian Health Board</p>	<p>California Area Delegate: Daniel Calac Chief Medical Officer, Indian Health Council Alternate: Vacant</p>



2013 Area Representatives	2014 Area Representatives
<p>Nashville Area Delegate: Sandra Yarmal Health Director, Passamaquoddy Tribe Pleasant Point Alternate: Tihtiyas (“Dee”) Sabattus Health Policy Analyst, United South and Eastern Tribes, Inc.</p>	<p>Nashville Area Delegate: Sandra Yarmal Health Director, Passamaquoddy Tribe Pleasant Point Alternate: Tihtiyas (“Dee”) Sabattus Health Policy Analyst, United South and Eastern Tribes, Inc.</p>
<p>Navajo Area Delegate: Madan Poudel Health Services Administrator, Navajo Nation Alternate: Roselyn Begay Program Evaluation Manager, Navajo Nation</p>	<p>Navajo Area Delegate: Rex Lee Jim Vice President, Navajo Nation Alternate: Larry Curley Executive Director, Navajo National Division of Health</p>
<p>Oklahoma Area Delegate: Cara Cowan Watts Tribal Council Representative, Cherokee Nation Alternate: Tom Anderson Tribal EpiCenter Manager, Oklahoma City Area Inter-Tribal Health Board</p>	<p>Oklahoma Area Delegate: Cara Cowan Watts Tribal Council Representative, Cherokee Nation Alternate: Tom Anderson Tribal EpiCenter Manager, Oklahoma City Area Inter-Tribal Health Board</p>
<p>Phoenix Area Delegate: Diane Enos President, Salt River Pima-Maricopa Indian Community Alternate: Violet Mitchell-Enos Health and Human Services Director, Salt River Pima-Maricopa Indian Community</p>	<p>Phoenix Area Delegate: Diane Enos President, Salt River Pima-Maricopa Indian Community Alternate: Violet Mitchell-Enos Director, Health and Human Services, Salt River Pima-Maricopa Indian Community</p>
<p>Portland Area Delegate: Stephen Kutz Councilman, Cowlitz Indian Tribe Alternate: Stella Washines Council Member, Yakama Nation</p>	<p>Portland Area Delegate: Stephen Kutz Councilman, Cowlitz Indian Tribe Alternate: Vacant</p>
<p>Tucson Area Delegate: Chester Antone Councilman, Tohono O'odham Nation Alternate: Vacant</p>	<p>Tucson Area Delegate: Chester Antone Councilman, Tohono O'odham Nation Alternate: Vacant</p>



2013 National At-Large Members	2014 National At-Large Members
<p>Delegate: Andrew Joseph, Jr. Chairman, Human Services Committee, Confederated Tribes of the Colville Reservation Alternate: Vacant</p>	<p>Delegate: Vacant Alternate: Vacant</p>
<p>Delegate: Jefferson Keel Lt. Governor, Chickasaw Nation Alternate: Malia Villegas Director, Policy Research Center, National Congress of American Indians</p>	<p>Delegate: Jefferson Keel Lt. Governor, Chickasaw Nation Alternate: Malia Villegas Director, Policy Research Center, National Congress of American Indians</p>
<p>Delegate: H. Sally Smith Chair of the Board of Directors, Bristol Bay Area Health Corporation and Alaska Representative of National Indian Health Board Alternate: Stacy Bohlen Executive Director, National Indian Health Board</p>	<p>Delegate: H. Sally Smith Chair of the Board of Directors, Bristol Bay Area Health Corporation and Alaska Representative of National Indian Health Board Alternate: Stacy Bohlen Executive Director, National Indian Health Board</p>
<p>Delegate: Michael Percy Epidemiologist, Choctaw Nation Health Services Authority/Chickasaw Nation Alternate: Mickey Percy Executive Director of Health Services, Choctaw Nation of Oklahoma</p>	<p>Delegate: Michael Percy Epidemiologist, Choctaw Nation Health Services Authority/Chickasaw Nation Alternate: Mickey Percy Executive Director of Health Services, Choctaw Nation of Oklahoma</p>

FEDERAL PARTNERS

2013 Federal Partners	2014 Federal Partners
<p><i>Administration for Children and Families</i> Delegate: Anne Bergan Office of Planning, Research and Evaluation Alternate: Hilary Forster Office of Planning, Research and Evaluation Alternate: Molly Irwin Office of Planning, Research and Evaluation</p>	<p><i>Administration for Children and Families</i> Delegate: Anne Bergan Office of Planning, Research and Evaluation Alternate: Hilary Forster Office of Planning, Research and Evaluation</p>
<p><i>Agency for Healthcare Research and Quality</i> Delegate: Wendy Perry Senior Program Analyst</p>	<p><i>Agency for Healthcare Research and Quality</i> Delegate: Kishena C. Wadhvani Director, Division of Scientific Review Alternate: Vacant</p>
<p><i>Assistant Secretary for Planning and Evaluation</i> Delegate: Sue Clain Indian Health Desk Officer Alternate: Ansalan Stewart Program Analyst</p>	<p><i>Assistant Secretary for Planning and Evaluation</i> Delegate: Sue Clain Indian Health Desk Officer Alternate: Ansalan Stewart Program Analyst</p>
<p><i>Centers for Disease Control and Prevention</i> Delegate: Delight Satter Associate Director, Tribal Support Alternate: Kimberly Cantrell Deputy Associate Director, Tribal Support</p>	<p><i>Centers for Disease Control and Prevention</i> Delegate: Delight Satter Associate Director, Tribal Support Alternate: Kimberly Cantrell Deputy Associate Director, Tribal Support</p>
<p><i>Health Resources and Services Administration</i> Delegate: Michelle Allender-Smith Director, Office of Health Equity Alternate: Chrisp Perry Public Health Analyst, Office of Health Equity</p>	<p><i>Health Resources and Services Administration</i> Delegate: Michelle Allender-Smith Director, Office of Health Equity Alternate: Chrisp Perry and LCDR Gwenivere Rose Public Health Analysts, Office of Health Equity</p>
<p><i>Indian Health Service</i> Delegate: Alan Trachtenberg Research Director, United States Public Health Service Alternate: Carolyn Aoyama Senior Consultant, Women’s Health and Advanced Practice Nursing</p>	<p><i>Indian Health Service</i> Delegate: Mose A. Herne Director, Division of Planning, Evaluation, and Research Alternate: Vacant</p>



2013 Federal Partners	2014 Federal Partners
<p><i>National Institutes of Health</i> Delegate: John Ruffin Director, National Institute on Minority Health and Health Disparities Alternate: Joyce A. Hunter Deputy Director, National Institute on Minority Health and Health Disparities</p>	<p><i>National Institutes of Health</i> Delegate: Yvonne Maddox Acting Director, National Institute on Minority Health and Health Disparities Alternate: Joyce A. Hunter Deputy Director, National Institute on Minority Health and Health Disparities</p>
<p><i>Office of Minority Health*</i> Delegate: J. Nadine Gracia Deputy Assistant Secretary for Minority Health and Director Alternate: CDR Tracy Branch Public Health Advisor</p>	<p><i>Office of Minority Health*</i> Delegate: J. Nadine Gracia Deputy Assistant Secretary for Minority Health and Director Alternate: CDR Tracy Branch and Rick Haverkate Public Health Advisors</p>
<p><i>Substance Abuse and Mental Health Services Administration</i> Delegate: Sheila Cooper Senior Advisor for Tribal Affairs</p>	<p><i>Substance Abuse and Mental Health Services Administration</i> Delegate: Sheila Cooper Senior Advisor for Tribal Affairs</p>

*HRAC Executive Secretariat



For Additional Information on the HRAC:

Please Contact:

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