American Indian and Alaska Native Health Research Advisory Council (HRAC)

Annual Meeting
Monday, July 29, 2013
Indian Health Service, Rockville, Maryland

HRAC Tribal Delegates and Alternates

Ileen Sylvester, Alaska Area Delegate
June Shaw, Albuquerque Area Delegate
Aaron Payment, Bemidji Area Delegate
Patty Quisno, Billings Area Delegate
Daniel J. Calac, California Area Delegate
Sandra Yarmal, Nashville Area Delegate
Cara Cowan Watts and Tom Anderson, Oklahoma Area Delegate and Alternate
Stephen Kutz, Portland Area Delegate
Chester Antone, Tucson Area Delegate
Jennifer Cooper, National At-Large Member (proxy for H. Sally Smith)
Malia Villegas, National At-Large Member Alternate
Michael Peercy, National At-Large Member Delegate and Emily Rowton (proxy for Michael Peercy)

HRAC Federal Partners

Kishena C. Wadhwani, Agency for Healthcare Research and Quality (AHRQ)
Sue Clain and Ansalan Stewart, Assistant Secretary for Planning and Evaluation (ASPE)
Miatta Dennis, Centers for Disease Control and Prevention (CDC)
Chrisp Perry, Health Resources and Services Administration (HRSA)
Michael Bartholomew, Frances Frazier, Kirk Greenway, Alan Trachtenberg, and Wilbur Woodis, Indian Health Service (IHS)
Elizabeth Carr, Intergovernmental and External Affairs (IEA)
Judith Arroyo, Juliana Blome, Theresa Brockie, Sheila Caldwell, Gail Dutcher, Kathy Etz, Nancy Jones, Carla Pruitt, Shoba Srinivasan, and Emmanuel Taylor, National Institutes of Health (NIH)
Tracy Branch, Rick Haverkate, Mildred Hunter, and Jacqueline Rodrigue, Office of Minority Health (OMH)
Sheila Cooper, Leon Leader Cherge, and Rod Robinson, Substance Abuse and Mental Health Services Administration (SAMHSA)

Other Attendees

Kendra King Bowes, Native American Management Services, Inc.
Don Bland, Manny Casañas, and Deborah Thornton, Professional and Scientific Associates

Todd J. Wilson, Crow Nation Health & Human Services

Invocation

- Councilman Chester Antone opened the meeting with an invocation.

Opening Remarks

Cara Cowan Watts, MS, HRAC Chair and Oklahoma Area Delegate
CDR Jacqueline D. Rodrigue, MSW, Deputy Director, Office of Minority Health

- Councilwoman Cara Cowan Watts opened the meeting and welcomed new and returning HRAC members and representatives of federal partners.
- CDR Jacqueline Rodrigue welcomed HRAC members on behalf of OMH Director, Dr. J. Nadine Gracia, who was unable to attend, and noted that the HRAC was established as a forum for collaboration between tribal leaders and HHS. CDR Rodrigue informed the HRAC that the current priorities of the OMH are outreach and enrollment for the Affordable Care Act (ACA), the HHS Disparities Action Plan, and the National Partnership for Action (NPA). She outlined the five goals and four components of the NPA and noted that the 10 Regional Health Equity Councils (RHECs) have American Indian and Alaska Native (AI/AN) representation and are involved in ACA outreach and enrollment.
- LCDR Tracy Branch provided information on meeting procedures for Federal Advisory Committee Act (FACA) exempt committees and clarified the distinction between tribal and federal processes. It was noted that all HRAC members are tribal leaders or have authority delegated to them by a tribal leader. Everyone at the meeting was a federal representative or a tribal leader.
- Councilwoman Cowan Watts noted that only delegates are authorized to speak. If an alternate wishes to speak, the delegate would step aside for that moment.

Welcome and Indian Health Service Updates

CAPT Francis Frazier, Deputy Director, Office of Public Health Support (OPHS), IHS

CAPT Frazier highlighted OPHS activities that are linked to HRAC priorities, as follows:

- Native American Research Centers for Health (NARCH): 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 serves as the interface with other NIH Institutes. NARCH applications are reviewed by the NIH Center for Scientific Review (CSR). NARCH research is conducted by and for tribes, and the strong relationship between federal research institutions and AI/AN tribal partners is what makes NARCH so successful. NARCH also provides opportunities for Native students to move into the field of research.

  NARCH supports 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. The HRAC general research recommendations will be

incorporated into the evaluation, as appropriate. Other activities over the next several months include NARCH VII grant awards, NARCH VIII application reviews, and close-out of NARCH V projects.

- Tribal Epidemiology Centers (TECs): The reauthorization of the Indian Health Care Improvement Act under the ACA permanently reauthorized the TECs. The DEDP manages the TEC cooperative agreements and provides oversight for the centers. TEC core functions are data collection; data evaluation; identifying health priorities; making recommendations on health service needs; improving the health care delivery system; and providing technical assistance on epidemiology for tribal organizations.

  IHS developed a data sharing template for TEC activities that does not include personally identifiable information (PII). That information can be obtained on a project-by-project basis from the Epidemiology Data Mart, and IHS plans to augment the existing template to address PII.

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

CAPT Frazier introduced the DEDP Director, Michael Bartholomew, and the DPS Director, Kirk Greenway, who were available to respond to questions.

Questions and Answers

- Dr. Daniel Calac noted that IHS area offices appear to be the primary mode for disseminating information and asked what methods were used to disseminate information at the community level. CAPT Frazier replied that IHS typically disseminates information through the area offices. The DEDP and DPS also have direct links to all area statistical officers and TECs. Dr. Calac noted that the new Chief Medical Officer for the California Area was doing an outstanding job of meeting with the tribes and IHS clinics to get a feel for the needs in the area. A federal representative noted that the NIH updated its NARCH web page to make it more interactive. As soon as NARCH awards are announced, people in the community can see what projects are being funded.

- Councilman Antone 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 (HPSAs) and service delivery. The IHS data system does not allow certain data to be reported, and tribal communities have some concern about misuse of the RPMS system. CAPT Frazier said OPHS would provide a formal response after a careful review of the Councilman's questions. He noted that OPHS uses data from approximately 650 sites to calculate user populations; about 25 of those are non-RPMS sites. Kirk Greenway agreed that the Councilman's questions would require a detailed technical response. He added that it was not possible for any single person to be identified because tribes are using many different non-RPMS systems, and there is no consistency for analysis. Some data elements could result in an individual not being counted in the user population (e.g., treatment was provided at a non-

reportable clinic, or the person did not reside within the health service delivery area). The patient's data could be used for research, even if that person was not counted for the user population.

- Councilman Antone requested an update on the standards regarding PII and expressed concern about the continuum of care from IHS to tribal programs. He also requested a description of how the work load analysis is done, especially with regard to the division of resources. CAPT Frazier replied that the IHS template was in the early stages of development. He could not provide detailed information, because the process had not been cleared through the Office of the Director. Mr. Greenway stated that the process for work load analysis varied by area. In the Tucson Area, the Area Fiscal Officer would have access to work load reports generated by the RPMS PART Administrator as well as reports that are available on the NDW website. The manner in which the work load research is disseminated would require a detailed written response, which Mr. Greenway would provide.
- Councilman Antone asked if any statistics were available on breaches of PII data, and whether those breaches were significant or minimal. He noted that this information was important for those who are developing systems. CAPT Frazier stated that he would develop a formal response to the Councilman's questions after gathering information from multiple offices.
- Dr. Malia Villegas asked three questions: 1) Have IHS and HHS begun to discuss what the President's open data policy would mean for Indian Country? 2) What is the status of the IHS scholarship to promote medical specialist training, given the sequestration and budget cuts? 3) What is the status of funding for the Native Research Network (NRN), whose annual conference was cancelled this year? CAPT Frazier replied that there was no decrease in the number of scholarships for health professionals. There are multiple categories of scholarships, but the overall number of awards was unchanged. NRN funding was impacted by government-wide restrictions regarding meetings and travel. IHS is actively exploring ways to assist with the conference. CAPT Frazier would refer the question regarding the open data policy to senior staff, because it involved multiple offices.
- Councilwoman Cowan Watts stated that the HRAC requested data on scholarships several years ago in order to determine unmet need. IHS provided data on the number of people who were funded through the various scholarship programs; the number who applied; the number who were eligible, given that non-Indians also apply; and the number of eligible applicants who were funded. She noted that some scholarship programs were open to state-recognized tribes, which puts additional pressure on the IHS budget because those groups do not have a federal-tribal relationship. She asked whether IHS had reviewed the issue of funds being awarded to non-Indians and requested updated data on scholarships. CAPT Frazier stated that he would provide data on the number of applicants, the number of eligible applicants, and the number of awards.
- Councilwoman Cowan Watts stated that the HRAC continued to have concerns regarding data access and asked how IHS was working with tribes to develop Institutional Review Boards (IRBs). Dr. Alan Trachtenberg stated that the first step is to develop a tribal Federal Wide Assurance (FWA). The next step is to create a Tribal Research Review Committee, which is not a formal IRB but can identify tribal interest in research that is proposed. IHS IRBs depend on 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.

- Councilwoman Cowan Watts asked whether IHS was working with tribes to make sure that tribal subjects are protected for other uses of data, such as for public health practice. Dr. Trachtenberg replied that the IHS privacy officer reviews any use of data. Data coming from a particular tribe are considered to be the property of the tribe, and use of the data requires tribal approval, even if the tribe is not identified.
- Councilwoman Cowan Watts asked Dr. Trachtenberg for additional information on IHS technical assistance to tribes regarding best practices. Dr. Trachtenberg replied that the web page for the IHS research program has a list of tribal IRBs. Tribes in Oklahoma and Alaska and the Navajo Nation are at the leading edge in terms of formal tribal governmental approval. Mr. Greenway added that the IHS approval process for data requests from outside researchers includes a number of checks and balances. Criteria include whether a valid tribal governmental entity reviewed and approved the request; whether the research would benefit IHS patients; and whether the terms are legally binding on all parties. The approval process at the national level looks at factors that are outside the scope of the TECs and is not intended to disrupt or interfere with TEC activities.
- Councilman Stephen Kutz noted that masters and doctoral students often want to do individual research in Indian Country. Their requests are reviewed by the tribal IRB, and the researcher gets a letter from the tribal council or other documentation. However, universities do not have a good track record of enforcing the IRB requirements when a student does not follow the agreement. What redress do tribes have when this occurs? Dr. Trachtenberg encouraged tribes to call him if they have a problem, because the federal government often has more leverage with universities. IHS tries to enforce the provisions of IRB approval, including any publications resulting from the research and what happens with the data afterwards. Councilwoman Cowan Watts stated that this issue is related to a bigger action item regarding recognition of tribal IRBs. The HRAC will save that discussion for another time.
- Dr. Calac noted that a recent publication of the California NARCH addressed the issue of community-based IRBs and relationships with universities.
- Chairperson Aaron Payment noted that his tribe was in the process of developing a tribal IRB. In the meantime, they enter into a contractual arrangement with students that requires the institution where they are doing their research to agree that they will not disaggregate the data. The agreement confers jurisdiction to the tribal court. Dr. Trachtenberg stated that the tribal court would be a good venue. It is also important to get the tribal code on the books.

Approval of Outstanding Items

- A quorum was confirmed for the meeting.
- Dr. Calac moved to approve the notes of the February 26 and April 30 conference calls, as provided in writing. The motion was seconded by Councilman Antone and carried by unanimous voice vote.

- Councilwoman Cowan Watts opened the floor for nominations for Chair and Co-Chair. She noted that her elected position as a member of her tribal council extends until August 2015. She would be honored to continue in her position as Chair, and she encouraged other members to consider serving in a leadership role.
- Councilman Kutz stated that he also has two years left in his elected position as a member of his tribal council and would be open to continuing to serve as Co-Chair.
- Councilman Antone moved that Councilwoman Cowan Watts and Councilman Kutz continue in their current positions. No second was required.
- Chairperson Payment moved to close the nominations. The motion was seconded by Dr. Calac and carried by unanimous voice vote.
- Councilman Kutz noted that the HRAC operates as a "tag team," and all members are important.

Secretary's Tribal Advisory Committee (STAC)
Chester Antone, HRAC Tucson Area Delegate

Councilman Antone provided an update on the STAC, as follows:

- A matrix that outlines grants for which tribes are eligible to apply has been completed and is posted on the STAC website.
- The STAC held a tribal caucus before its meeting with the Secretary.
- One of the issues that it brought to the Secretary was state recognition of TECs as legitimate entities to receive data. The Secretary wanted to know which states did not recognize the TECs.
- The STAC confirmed Head Start funding as one of its top priorities.
- A Congressional study is being conducted to determine whether the Navajo Nation can conduct its own Medicaid program on the reservation. The STAC requested that the Secretary intervene to improve relationships between states and tribes regarding Medicaid expansion.
- The STAC created a workgroup on tribal-state relationships.
- The STAC work group on children and families and the ACA subgroup are looking for new members.
- Two issues specific to Arizona were included via resolutions to the STAC that were submitted in February. A response was received for one resolution regarding a waiver of certain ACA requirements for existing health care providers on reservations.
- The STAC expressed concern that IHS was not exempt from sequestration and federal budget cuts.

Chairperson Payment stated that the matrix of funding sources was an excellent resource for practitioners.

HHS Intradepartmental Council on Native American Affairs (ICNAA) and Data Priority

Elizabeth Carr, Tribal Affairs Specialist, Office of Intergovernmental and External Affairs

Ms. Carr provided an overview of a data initiative undertaken by the ICNAA in conjunction with the HHS Chief Technological Officer, as follows:

- A draft plan has been developed that addresses data sharing, data collection, and data warehousing and is based on HRAC testimony from 2012 and 2013.
- The ICNAA will provide technical assistance to all HHS branches to ensure that they are aware of tribal differences and cultural issues pertaining to data collection and data sharing.
- The plan will include a data clearinghouse. ICNAA is currently looking for a site.
- Ms. Carr was unable to share details of the draft plan, because it had not been approved. Implementation of the plan is a multi-year process that will begin in September. The HHS Secretary, ICNAA Director, and HHS Data Council are all on board. The ICNAA looks forward to working on the plan and welcomes feedback from the HRAC.

Questions and Answers

- Dr. Villegas asked if the data plan would foster cross-agency coordination, as implied in the President's open data policy. She noted that measurement of small populations is a pervasive issue, with multiple issues related to sampling. Support from the Secretary would be helpful. Ms. Carr said she would take note of Dr. Villegas' comments.
- Dr. Trachtenberg asked if the ICNAA was aware of the data archive at the University of New Mexico (UNM). Ms. Carr said the ICNAA was developing a preliminary process and would tap the UNM archive as well as other resources.
- Councilwoman Cowan Watts noted that the participation of the HHS Data Council creates an opportunity to translate technical IRB issues into tribal language, and vice versa. It is important to ensure that this issue is on the table. Ms. Carr asked Councilwoman Cowan Watts to contact her directly.
- Councilwoman Cowan Watts noted that oversampling was a major point in the HRAC's written testimony. Ms. Carr stated the ICNAA would discuss that issue with their data specialist and offered to provide an update at a future meeting. Councilwoman Cowan Watts proposed to include this as a standing agenda item for future HRAC meetings. Councilman Kutz stated that the issue should also be included on the agenda for conference calls.
- Chairperson Payment stated that one of the challenges of his dissertation is the sampling of a small population. There have to be alternative ways to sample data and draw conclusions, even with a small *n*. He looked forward to participating in this exciting initiative.
- Dr. Villegas emphasized the importance of tribal sovereignty and the federal trust responsibility and asked if there would be any discussion at the federal level of how the federal trust extends to provision of data. Ms. Carr replied that ICNAA was well aware of tribal sovereignty and the tribal consultation process.
- Councilwoman Cowan Watts stated that one of the HRAC's early priorities has been to conduct a literature review and prepare a compilation of all research conducted in Indian Country. The HRAC had been in discussions with the University of New Mexico and

recently were back in communication. UNM is waiting to hear about funding from NIH to do some work to the database although the HRAC is not sure to what extent. The HRAC had also contacted the National Library of Medicine to discuss a database. It would be helpful if the ICNAA could facilitate that process.

- Councilwoman Cowan Watts asked if the data plan would address ACA issues that would impact Indian Country, such as the definition of Indian and the lack of sampling or data. She expressed concern that without adequate research, tribes would be implementing outcomes based on the broader population that might not be relevant for them. She asked if tribes should be asking that question, and, if so, who would answer it.
- Councilman Kutz noted that under the ACA, the federal government is requiring states to use outcome-based research models when they develop their plans. Most states do not know if the outcomes have been normalized for AI/AN populations, or they cannot provide that information. Tribes should be allowed to use promising practices, or research should be funded to demonstrate that the models work for AI/ANs.
- Councilman Antone stated that TECs are crucial. Public health authorities need to recognize tribal data as a complement to state and federal data. Tribes have trouble getting grants because tribal data are not recognized, and they do a disservice to themselves if they use non-tribal data.
- Councilwoman Cowan Watts stated that the HRAC would like to have input on the data plan. She and LCDR Branch will follow up with Ms. Carr in writing to schedule a meeting for early October to discuss this with the ICNAA.

National Cancer Institute (NCI)

Shobha Srinivasan, PhD, Health Disparities Research Coordinator

Dr. Srinivasan provided an overview of NIH funding opportunities that are relevant to Native Americans, as follows:

- Interventions for Health Promotion & Disease Prevention in Native American Populations: This is the major Native American research program at NIH. Partners include seven Institutes, plus the Office of Behavioral and Social Sciences. Research areas of interest include: cancer; heart, lung, and blood; alcoholism and alcohol abuse; drug abuse; mental health; nursing; and environmental health sciences.
- The Effect of Racial and Ethnic Discrimination/Bias on Health Care Delivery: NCI is partnering with the National Heart, Lung, and Blood Institute (NHLBI) on this program. Funding is currently available, and NIH would welcome applications from Native American researchers.
- Practical Interventions to Improve Medication Adherence in Primary Care: Nine Institutes are participating in this program. It would be helpful to have more Native researchers in the review groups.
- Behavioral Interventions to Address Multiple Chronic Health Conditions in Primary Care: This program responds to a desire voiced by Native communities to avoid a siloed approach to disease outcomes. NIH could include more Native Americans in the study sections.

Dr. Srinivasan provided additional details on the Native American research program, as follows:

- The first round of applications was strong, with a 20 percent success rate. The participating Institutes will conduct a conference call on August 8 with the Principle Investigators (PIs) of all six funded studies.
- The program focuses on multilevel design to target individual behaviors and social and institutional levels (e.g., familial and tribal). Interventions should be consistent with community values and may include traditional health, medical, and/or cultural practices. Projects should adopt an ecological approach so the interventions can be sustained.
- The Funding Opportunity Announcement (FOA) requires researcher-tribe agreements, emphasis on health promotion, and a mixed-methods model, with an emphasis on qualitative design to adapt and/or develop interventions.
- The program adopts a health equity model and a social determinants of health agenda in an effort to move toward social justice.
- There is one more round of funding, with letters of intent due on April 15, 2014, applications due on May 15, 2014, and reviews conducted in Fall 2014. NIH hopes to reissue the program announcement.

Dr. Srinivasan stressed that NIH is committed to promoting Native American research, both in terms of developing programs and conducting reviews. The funding announcement for the Native American program states that data belong to the tribes and do not have to be made public, which is a new position for NIH. Dr. Teshia Solomon is working with NCI to develop a web-based Native public health program to create liaisons between communities and researchers.

NIH would welcome input from tribes and tribal communities on IRB and approval processes, creating a research agenda that will enable dissemination of interventions, addressing the role of genetics and biological samples in research, and developing a network of Native researchers who can train the next generation.

Questions and Answers

- Ileen Sylvester stated that the Alaska IRB is run by IHS and they review all research as an IRB, but tribal leadership has the final approval of anything within their jurisdiction. Their research department is developing their own Native researchers. Their primary care system is incorporating behavioral health and is looking at pharmacogenetic research within the hospital. The Alaska area has research agreements to ensure that they have control of data, and it is good to see that HHS agencies recognize tribal authority. It would be helpful to know what types of studies NIH is funding.
- Dr. Villegas raised three issues: 1) FOA language pertaining to tacit approval is a concern. NCAI has had ongoing conversations about how to ensure there is meaningful research productivity using NIH funds, while ensuring tribal sovereignty over data. NARCH research shows that appropriate tribal projects have the same levels of productivity. 2) The focus on health equity creates the potential for more tribal-to-tribal and Native-to-Native comparisons. 3) The President's 2014 budget decreased funds for research centers at minority institutions. Dr. Srinivasan replied that the tacit approval language is a challenge. NIH will hold a series of workshops on ethics and the IRB process in October. An internal group will develop a

white paper for that meeting that will provide suggestions and broad guidelines on how to move forward. Another NIH representative stated that the AI/AN Interest Group at NIH will seek tribal consultation on that issue. Dr. Srinivasan stated that tribal-to-tribal comparison is where NIH is headed. The FOA for the Native American program states that researchers do not have to have preliminary data for the group they are studying. Regarding budget cuts, Dr. Srinivasan stated that NIH funding has been maintained at the current level.

- Councilman Antone asked how tribal communities could make progress in addressing the social determinants of health. Dr. Srinivasan replied that education is an important aspect, including health literacy. Health literacy is measurable by looking at changes of behavior in terms of health practices, such as prenatal and postnatal care. She stated that interventions should not require people to go out of their way or disrupt their daily life. The challenge is developing good measures that are valid in the community.
- Councilman Kutz asked whether NIH Institutes work together to address areas of common interest. For example, a number of Institutes might be interested in looking at non-narcotic alternatives to deal with chronic pain in Indian Country. Dr. Srinivasan stated that the NIH hopes that the Native American program will lead to cross-cutting interventions that will have applications to multiple disease outcomes.
- Dr. Calac stated that it is essential to provide researchers with a road map regarding how to work with IHS or tribal IRBs. In Southern California, some projects have done an excellent job of introducing research topics to tribes, especially in the area of genetics and biological samples. These studies can be very fruitful for Native communities. Native American study sections should be convened for every study, because they provide exposure to a wide range of research topics and to individuals with diverse backgrounds and expertise.
- Chairperson Payment stressed the need for a careful dialog about the ethics involved in studying genetic data and biological samples from Native populations. Inferences based on superficial knowledge can have negative consequences. Data need to be protected on an ongoing basis, from collection through reporting.
- Dr. Trachtenberg acknowledged the importance of getting NIH to recognize tribal ownership of data. He noted that several Institutes at NIH study issues related to chronic pain.
- Councilwoman Cowan Watts stated that additional NIH contacts should be added to the list of federal partners to receive agenda items for HRAC meetings. She suggested that Dr. Srinivasan work with Dr. Trachtenberg on IRBs and approval processes. She noted that a recent Canadian document and the work of the National Congress of American Indians (NCAI) regarding the role of genetics and biological samples in research could be helpful.

Election of HRAC Chair and Co-Chair

LCDR Tracy Branch, MPAS, PA-C, Public Health Officer, Office of Minority Health

- LCDR Branch noted that Councilman Antone had moved that the existing Chair and Co-Chair remain in their positions, and a subsequent motion to close the nominations was made by Chairperson Payment, seconded by Dr. Calac, and passed by voice vote.

- Chairperson Payment made a motion to accept by unanimous proclamation the nomination of Cara Cowan Watts and Stephen Kutz as Chair and Co-Chair, respectively. The motion was seconded by Ms. Sylvester and carried by unanimous voice vote.
- LCDR Branch thanked Councilwoman Cowan Watts and Councilman Kutz for the work they had done and would continue to do on behalf of the HRAC.

Agency for Healthcare Research and Quality's Peer Review Grant Process
Kishena C. Wadhwani, PhD, MPH, Director, Division of Scientific Review, Office of Extramural Research, Education and Priority Populations

Dr. Wadhwani provided an overview of AHRQ's peer review process, as follows:

- AHRQ is focused exclusively on health service research, such as how to minimize medical error, how to reduce medical costs, or how to increase health parity. This type of research includes many stakeholders.
- The AHRQ extramural research team has four components: receipt and referral, review staff, program staff, and grants management.
- The Division of Scientific Review (DSR) has five study sections, each focused on a different type of research. There is some overlap in research areas, which provides flexibility for AHRQ.
- Standing review committees are chartered, and reviewers are appointed for multi-year terms. A Special Emphasis panel is convened if an application does not fit within a standing committee, or if AHRQ is reviewing many applications simultaneously.
- The AHRQ peer review process is based on laws. Peer review practices are based on scientific expertise, behavior, and culture of the study section. Core values are scientific and technical competence; fairness and objectivity; and transparency and consistency.
- The Scientific Review Officer (SRO) manages the scientific aspects of the review process and is the Designated Federal Official for each peer review group meeting. The technical aspects of the review are managed by a Program Analyst (PA), who reports to the SRO.
- Criteria for reviewer selection include scientific competency; dedication to high-quality, fair, and even-handed reviews; demonstrated ability to work collegially in a group setting; and experience in grant/contract review.
- Scientific competence is the primary consideration in assembling review panels. A secondary consideration is the diversity of the review panel, based on gender, racial/ethnic background, and other factors.
- The first level of review is based entirely on the scientific merit of the application. Reviewers do not consider program relevance (unless stated in the FOA), policy issues, funding levels, anticipated budget reductions, comparisons with other applications, or information that is not presented in the application.
- Peer review rules protect the confidentiality of the review process and ensure that reviewers do not have any conflict of interest.

- Reviewers evaluate and score each application according to five core criteria: significance and originality; investigator(s); innovation; approach (methods and data); and environment (facilities and resources).
- Reviewers also consider additional criteria that are not scored, including: protection of human subjects from research risks (data safety and monitoring plans); inclusion of women, racial/ethnic minorities, and AHRQ priority populations; privacy and security protections for patients; budget requested; degree of responsiveness to the FOA; importance and impact; and data sharing plan (if applicable).
- Each application is assigned to three reviewers for written comments. Following the group discussion of each application, the panel makes a budget recommendation and each reviewer scores the application privately.
- Applications deemed to have scientific merit are given a priority score ranging from 1 (exceptional, no weaknesses) to 9 (poor). Applications that receive a 1, 2, or 3 are likely to be funded.
- Following the peer review meeting, the SRO prepares summary statements for all applications. The summary statement provides official feedback to the applicant conveying the issues, critiques, and/or comments that were raised during the review of his/her application, as well as the overall impact score and percentile ranking, budget recommendations, and administrative notes.

Questions and Answers

- Dr. Villegas asked whether reviewers receive any cultural relevance training. Dr. Kihswani replied that AHRQ provides training on how to conduct a review and what constitutes conflict of interest. Candidates can be placed on an *ad hoc* committee for one or two reviews, which allows AHRQ to observe them before granting them permanent status.

HRAC Recommendations/Priorities for Upcoming Year

Councilwoman Cowan Watts led a review of current HRAC priorities, as follows:

State/Tribal EpiCenters Relationship and Public Health Authority Status

- Councilwoman Cowan Watts reported that this issue was discussed at the June meeting of the STAC. HRAC members should gather facts from their areas so the Secretary can determine how to move forward.
- Councilwoman Cowan Watts highlighted issues that were identified in Oklahoma, including varying levels of cooperation, fees to access data, and data that are not tribal-specific. She offered to share Oklahoma's findings with HRAC members and the federal partners.
- LCDR Branch reported that preliminary inquiries with tribal representatives indicated that relationships were problematic in 15 states. OMH can provide that information to the Secretary, but additional information would help to support broader recommendations.
- Dr. Trachtenberg noted that the new DEDP Director, Dr. Bartholomew, might be interested in discussing this issue with the TECs.

National Children's Study

- Councilwoman Cowan Watts noted that the HRAC had concerns about inclusion of AI/ANs.
- Councilman Kutz said it would be important to understand how to get a representative sample of Native children into the study. Key issues are the point of entry and the process for inclusion.
- Dr. Trachtenberg said there would not be a dedicated sample for AI/ANs, but there is still a strong chance to get into the 10 percent that will be set aside for "other populations." The national probability sample does not include the Northern Plains and Alaska, which excludes a significant proportion of the AI/AN population. The NCS will recruit 90,000 children from locations where babies are delivered, using the national probability sample. The remaining 10,000 will be recruited through prenatal and preconception programs. There is a need to advocate for some of the 10,000 to be AI/ANs from the Northern Plains and Alaska. The director of the study is very sympathetic to getting a more representative sample, but many groups will compete for inclusion in the 10,000. The timeframe for input from national communities might be extended due to new legislation requiring further review of the methodology. Another issue is how the Vanguard Study will determine tribal affiliation or Indian status of the 90,000. Recruitment by obstetric providers may limit the ability to recruit Native mothers. Dr. Trachtenberg recommended that Teshia Solomon be included on the agenda for the next workgroup conference call to discuss the Vanguard Study and how they are currently recruiting.
- Dr. Villegas stressed the need for consensus on where things stand and the process going forward. A number of issues regarding sampling and recruitment will link to decisions on oversampling and inclusion. LCDR Branch previously offered to have the Office of Minority Health Resource Center (OMHRC) look for other studies that oversampled AI/AN populations. Dr. Villegas suggested that the working group look at how these studies included Native populations in appropriate ways. HRAC can provide some leadership and focus on this issue.
- Councilwoman Cowan Watts noted the delay in the process of recruiting the 90,000 and stated that the HRAC should use this time to clarify what it wants and how to get there.
- Councilman Antone suggested that HRAC members use their connections within the federal system to voice their concerns and advocate for their position.
- Dr. Trachtenberg stated that if the number was large enough, there would be no need to be concerned. One problem of a multi-tiered, national probability sample is that the country is broken up into regions. The probability of a region being selected is based in large part on population density. To the degree that American Indians tend to live in areas of low population density, there will almost always be a risk of undersampling. A strict probability approach leads to inequity due to population structure. That issue needs to be addressed on a larger level, and it is why the Council should ask for oversampling.
- Judith Arroyo stated that there may be ways of sampling that are cost effective. For example, it might not be possible to include Alaska Natives in outlying areas, but those living in the major cities could be included in the sample.
- Dr. Trachtenberg noted that IHS provides a significant amount of prenatal care in Alaska.

- Councilwoman Cowan Watts suggested that the HRAC identify where it has a point of entry, bring people together to clarify their target areas, and then communicate its position.
- Chairperson Payment expressed concern that the sample for the Native population would be too small to draw any meaningful conclusions. He felt it would be important to be on the record that the study will be of limited value for Native populations. The HRAC might need to do something to ensure that studies are conducted that take Native people into account.

HHS Data Council

- Councilwoman Cowan Watts noted that the HRAC recently sent a letter to the co-chairs of the HHS Data Council expressing concerns about the sharing of tribal health data with Tribal Nations and requesting a consultation to develop a department-wide policy on data management in Indian Country. The letter will be distributed to all HRAC members.
- Councilwoman Cowan Watts asked LCDR Branch to send a copy of the letter to Elizabeth Carr.

Scholarship Opportunities

- Councilwoman Cowan Watts noted that the HRAC was awaiting a response from IHS on its report. It would be helpful to ask federal partners for assistance in clarifying the definition of AI/AN for potential funding mechanisms across HHS along with the types of funding available and website address for further information. She proposed a six-month timeframe for this action item.
- LCDR Branch stated that the request and timeframe were reasonable. She noted that funding for all HHS programs is competitive.
- Councilman Kutz proposed that all HRAC members reach out to local universities and develop memoranda of understanding (MOUs) that would set aside scholarships for Indian students.
- Dr. Trachtenberg noted that the Rocky Mountain Tribal/Billings Area IRB had been successful in developing MOUs with Montana State University. When Montana State University gets a research proposal involving AI/ANs they will refer it to the Rocky Mountain Tribal/Billings Area IRB to see if they were aware of the proposed research.
- Councilwoman Cowan Watts stated that it would be useful to have examples of best practices in this area. Dr. Trachtenberg noted that Cheryl Belcourt would be the point of contact for the Rocky Mountain Tribal/Billings Area IRB.
- Dr. Villegas noted that NIH has a three-month fellowship for tribal researchers at the doctoral or post-doctoral level to learn about IRBs.
- Dr. Calac asked about research opportunities for Native Americans at the CDC. Miatta Dennis replied that the CDC does not have a specific program focused on AI/ANs. The CDC Tribal Office has funded three Native students to attend a meeting; Ms. Dennis did not know whether they were from federally recognized or state-recognized tribes. Delight Satter or Kimberly Cantrell could provide more information. The CDC website (www.cdc.gov) lists minority research opportunities.

- Councilman Antone noted that Dean Seneca from the CDC regularly sends emails with information on internships at CDC and Morehouse College.
- Dr. Calac noted that the California NARCH Student Development project has about 30 students in in the research pipeline who are dedicated to returning to their communities. This project could be a good model.
- Chairperson Payment noted that a Presidential Executive Order signed shortly after passage of the Indian Self-Determination and Education Assistance Act of 1975 gives preference to members of federally recognized tribes. Some scholarships go to students who do not meet the definition of Indian, and some students who are eligible for tribal membership do not get funding because they are not enrolled in a tribe. Mechanisms should be developed to check for membership in a federally recognized tribe so that scholarship funds go to Indian students. He explained that tribes can provide letters stating descendancy if rolls are currently closed.

Data Sharing

- The recommendation in this area was addressed in the discussions of the HHS Data Council, State/EpiCenter Relationship, and the ICNAA data plan.

General Research Recommendations

- Dr. Calac noted that tribes are doing a better job of prolonging the lives of elders. This leads to an increase in issues that are related to longer life, such as dementia and falls. Tribal communities do a good job of caring for elders, but there is a growing unmet need to provide better end-of-life and hospice care.
- Councilwoman Cowan Watts noted that the first bullet in this section of the priorities document captured what the HRAC has accomplished to date in terms of identifying research priorities. The second bullet identified patient-centered outcomes research (PCOR) as a key focus area going forward. She stressed that it was critical for the HRAC to address this issue, because it would directly impact the quality of care that patients receive in Indian Country.
- Councilman Kutz noted that the HRAC requested a list of research conducted in Indian Country in order to identify gaps and determine where further work is needed. He believes that the NIH has done some work on this.
- Dr. Trachtenberg stated that recent work on the care of patients with multiple chronic conditions (MCC) fits in with PCOR and highlights the efficiencies of a coordinated approach. This could be very relevant for Native populations, and the HRAC might want to consider it as a priority.
- LCDR Branch stated that the OMHRC received requests from organizations that were looking for studies of multiple chronic diseases. Data are extremely limited, and there are few studies for Indian Country. The HRAC might want to highlight this issue as a research priority. Dr. Trachtenberg stated that Bruce Fink is the IHS expert in this subject.
- Dr. Villegas emphasized the importance of cross-cutting issues and systems-level research, such as a study of services received by Native American veterans at the Veterans Health Administration compared to IHS; development of translation and dissemination research; and

the impact of research on policy. She also stressed the importance of studying the link between human health and environmental health in Native communities, which would promote research on multiple diseases as well as cross-disciplinary research.

Native Research Database/Clearinghouse

- Councilwoman Cowan Watts stated that the work group needs to review what NIH has already funded through the UNM Native Research Database and report back to the HRAC regarding action steps.
- Ms. King Bowes reported that the work group had not yet outlined what the database would include. Previous discussions with UNM identified what was included in their database.
- Councilwoman Cowan Watts asked for volunteers to conduct a review of the research literature and other relevant information to develop a general framework for the database including a list of database fields.
- LCDR Branch said she would send a memo to all voting members requesting their assistance in developing the framework for the database. Daniel Calac and Malia Villegas volunteered to coordinate the effort.

HRAC Charter Revisions

LCDR Branch led a review of the HRAC charter, as follows:

- One key issue that keeps coming up is where the HRAC fits in the hierarchy of HHS advisory and consultative committees. IEA has been trying to bring all advisory groups and committees into alignment, which will include making charters consistent with the STAC charter.
- The STAC charter includes several provisions that the current HRAC charter does not address, including hierarchy of selection criteria, term limits, and rotating terms.
- The current system for determining a quorum does not take vacancies into account. Basing the quorum on a percentage of filled seats, rather than a specific number, would provide more flexibility.
- The current charter does not clearly define the term "tribal leader," and some terms are used interchangeably.
- The current charter does not clearly indicate that it supersedes the original charter, and some provisions are different (e.g., the current charter states that members are appointed by tribal leadership, while the original charter states that members are selected by the IHS).

Councilwoman Cowan Watts noted that the current charter does not include a conflict of interest statement regarding appointment of new members, and the proxy process is not clear.

LCDR Branch stated that OMH would form a workgroup to revise the HRAC charter. In addition to HRAC members, the work group would include representatives from the HHS Office of the General Counsel (OGC) and IHS. Stephen Kutz, Cara Cowan Watts, Aaron Payment, Chester Antone, and Jennifer Cooper (for Sally Smith) volunteered to serve on the workgroup.

LCDR Branch said she would create a template based on the STAC charter. Jennifer Cooper requested a redline between the two charters to show differences.

Federal Partner Updates

- ACF: The agency did not provide a written update, so the HRAC requested a report be provided after the meeting.
- AHRQ: The agency's written update was included in the meeting materials.
- ASPE: The ASPE did not provide a written update. The HRAC requested a report after the meeting.
- CDC: Ms. Dennis reviewed highlights of the written update included in the meeting materials. She noted that the CDC Director/ATSDR Administrator, Dr. Thomas Frieden, spoke at the Oklahoma City Area Inter-Tribal Health Board on July 11, 2013.
- HRSA: Chrisp Perry reviewed highlights of the written update included in the meeting materials. He noted that HRSA is preparing for a tribal consultation meeting to be held in conjunction with the National Indian Health Board's Consumer Conference in August. HRSA's tribal consultation policy is available at http://www.hrsa.gov.
- IEA: The agency did not provide a written update. The HRAC requests an update in writing.
- OMH: In addition to the written comments, LCDR Branch noted that the OMH Resource Center conducts research free of charge on behalf of minority communities. (e.g., data search, literature review, funding opportunities). It can also identify funding opportunities and provide technical assistance on issues such as board development and review of grant applications that were not funded. More details are available at info@minorityhealth.hhs.gov, or 800-444-6472. LCDR Branch will send details by email.
    - Councilman Antone asked who was given the assignment pertaining to fetal alcohol spectrum disorders. LCDR Branch stated that Dr. Gracia was reaching out to agencies that deal with this issue, which include CDC, SAMHSA, and NIH. Councilman Antone stated that he brought this issue to the tribal consultation in March. Without a diagnosis, it is not possible to seek reimbursement. With a diagnosis, treatment qualifies for preventive health coverage under the ACA.
    - Councilman Antone asked why OMH is not part of the HHS tribal consultation process. LCDR Branch stated that OMH is included in the Office of the Assistant Secretary for Health (OASH) briefing; it does not play a specific role in the consultation, unless there is a specific request. OMH plays a more active role in regional consultations.
- SAMHSA: Sheila Cooper provided information beyond what was included in the written update. She noted that SAMHSA is not a research organization, although it collects a great deal of data on its programs. SAMHSA is developing a communications strategy for tribes and outreach to Indian Country regarding the services that the agency can offer. SAMHSA participates in the ICNAA, which includes a liaison from each agency within HHS. ICNAA members can be valuable resources for the HRAC. SAMHSA is establishing a common data platform to consolidate data from evaluations and performance reports.

- NIH: Councilwoman Cowan Watts has questions that she will pose to Dr. Srinivasan regarding Kaiser Permanente to find out if tribes are involved. Also, she will follow up in regards to the mercury fish sample tissue study that is at the Grand Lake Watershed and being conducted by the University of Oklahoma and Harvard. Cara confirmed with the Cherokee Nation IRB that they were not contacted nor have they been participating in this study, which is a concern.

Review of Day, Next Steps, and Closing Comments

- Councilwoman Cowan Watts noted that there were many action items for follow-up and exciting new opportunities. Work on IRBs and the charter revision would ensure that the HRAC's work is not lost.
- LCDR Branch stated that HRAC members would receive copies of presentation slides and handouts by email so they can share them with their alternates and constituencies.
- Councilwoman Cowan Watts stated that environmental health was an important parking lot issue. Dr. Trachtenberg suggested that the Federal Interagency Working Group on Environmental Justice could be a resource in this area. Councilwoman Cowan Watts asked him to provide information to LCDR Branch so she could distribute it to members.
- Councilman Kutz reiterated his concern about the impact of the reduction of funds on Tribal EpiCenters, which are an important element of the public health system in Indian Country. LCDR Branch stated that she brought this up with Dr. Joyce Hunter, but she referred her to Dr. Ruffin. Dr. Gracia is following up with Dr. Ruffin regarding this action item.
- LCDR Branch stated that the next conference call would take place on September 10 or 12 at 3 p.m. Eastern time, depending on Dr. Gracia's availability. Dr. Trachtenberg noted that he would not be available on September 12.
- Chairperson Payment noted that the National Indian Health Board's 30th Annual Consumer Conference would take place August 26-29 at Grand Traverse Resort in Michigan. Information is available at http://www.nihb.org.

Action Items

- IHS Updates:
  - CAPT Frazier will provide a written response to Councilman Antone's questions regarding 1) conversion of RPMS and non-RPMS data, 2) the use of residency data to determine Health Professional Shortage Areas (HPSAs) and service delivery, and 3) breaches of PII data.
  - Kirk Greenway will provide a written response to Councilman Antone's question regarding work load research.
  - CAPT Frazier will provide a written response to Dr. Villegas' question regarding the impact of the open data policy on Indian country.
- ICNAA and Data Priority:
  - Councilwoman Cowan Watts will contact Ms. Carr regarding the issue of translating technical IRB issues into tribal language.
  - The issue of oversampling will be added as a standing agenda item for HRAC meetings and conference calls.

- Councilwoman Cowan Watts will schedule a meeting with ICNAA for early October to discuss the data plan.

- HHS Data Council:
  - LCDR Branch will send a copy of HRAC's letter to Elizabeth Carr and to all HRAC members.

- Native Research Database/Clearinghouse:
  - LCDR Branch will send a memo to all voting members to request their assistance in developing the framework for the database.
  - Daniel Calac and Malia Villegas will coordinate the effort.

- HRAC Charter Revisions:
  - Stephen Kutz, Cara Cowan Watts, Aaron Payment, Chester Antone, and Jennifer Cooper (for Sally Smith) will serve on the charter revision workgroup.
  - LCDR Branch will create a template based on the STAC charter.

- Administrative:
  - Add NIH tribal contacts for each Institute and Center to the list of federal partners to receive the agenda and materials for HRAC meetings.
  - Distribute presentation slides and handouts to HRAC members.
  - Distribute information on the Federal Interagency Working Group on Environmental Justice to HRAC members.