

**American Indian/Alaska Native Health Research Advisory Council (HRAC)  
Quarterly Conference Call  
September 10, 2013**

**HRAC Tribal Delegates and Alternates**

- Ileen Sylvester and Jay Butler, Alaska Area Delegate and Alternate
- June Shaw, Albuquerque 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
- Violet Mitchell-Enos, Phoenix Area Alternate
- Chester Antone, Tucson Area Delegate
- Michael Peercy, National At-Large Member Delegate
- Malia Villegas, National At-Large Member Alternate

**HRAC Federal Partners**

- Wendy Perry, Agency for Healthcare Research and Quality (AHRQ)
- Alan Trachtenberg, Indian Health Service (IHS)
- Tracy Branch, J. Nadine Gracia, and Jacqueline Rodrigue, Office of Minority Health (OMH)
- Kellie Gilchrist, Health Resources and Services Administration (HRSA)
- Christina Daulton, National Human Genome Research Institute (NHGRI)
- Juliana Blome, National Institute of General Medical Sciences (NIGMS)
- Carla Pruitt, National Institute on Minority Health and Health Disparities (NIMHD)
- Winnie Martinez, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

**Other Attendees**

- Emily Rowton, Choctaw Nation of Oklahoma
- Todd Wilson, Crow Nation
- Kendra King Bowes, Native American Management Services, Inc.
- Jordan Casañas, Professional and Scientific Associates
- Christy Duke, United South and Eastern Tribes, Inc.

**Call to Order and Introductions**

- Introductions and facilitation: Cara Cowan Watts, Co-Chair
- A quorum was reached on the call before voting occurred.

**1. Welcome and Updates**

- Dr. J. Nadine Gracia welcomed new members of the HRAC and thanked the HRAC members for their service and input to the Department of Health and Human Services (HHS). She acknowledged the time and dedication that each member puts into this important council.

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- OMH continues to be strategically focused on the Affordable Care Act (ACA) and in particular with outreach and education. The ACA is a departmental and administration-wide priority. OMH is also leading the implementation of the HHS Action Plan to Reduce Racial and Ethnic Health Disparities including the Culturally and Linguistically Appropriate Services (CLAS) standards that were released in April of 2013. OMH, through the National Partnership for Action to End Health Disparities (NPA), is continuing to support 10 Regional Health Equity Councils (RHECs) across the country in their work to combat health disparities and using the social determinants of health approach.
- Dr. Gracia noted that she represents Dr. Howard Koh at the Secretary's Tribal Advisory Council (STAC) meetings, which will next be held on September 17-18, 2013. This is an opportune time to update the STAC on the work of the HRAC. Lieutenant Commander (LCDR) Tracy Branch keeps Dr. Gracia informed on HRAC activities.
- Councilman Chester Antone asked Dr. Gracia and LCDR Branch about the consultation he had requested. LCDR Branch replied that she sent an email back to Councilman Antone with some additional questions the day before the call. He asked if they were looking at a particular month and LCDR Branch let him know not yet.
- Dr. Malia Villegas stated that the President's Open Data Policy was issued on May 9 and focused on transparency around data. She asked Dr. Gracia what this means for OMH and HHS's policy and how tribal consultation might be maintained. Dr. Gracia replied that OMH supports data collection efforts and participates on the HHS Data Council, but they will get back with additional information regarding this particular policy.

## **2. HRAC Annual Meeting Minutes Approval**

- Eileen Sylvester provided clarification on the Institutional Review Board (IRB) process in Alaska. The Alaska Area 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. She asked that this information be reflected in the meeting summary.
- A motion was made by Eileen Sylvester to approve the meeting minutes with the one clarification. The motion was seconded by Councilman Antone. Councilwoman Cowan Watts noted that a final email copy of the summary would be sent out with the clarification in case there are any objections, clarifications, or concerns. The HRAC voted on the motion and the group approved.

## **3. Action Items Updates**

- LCDR Branch provided updates on action items resulting from the Annual Meeting. She shared information with Elizabeth Carr in follow up to the Intradepartmental Council on Native American Affairs (ICNAA) data priority. They are now working out a mechanism for communication.
- In regards to the development of an IRB Workgroup, Dr. Alan Trachtenberg stated that he was unsure of the workgroup charge and he cannot lead the group but is willing to support the group. He is also confused as IHS has an IRB, but it is not an

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HHS IRB. The HHS structure is not up for discussion except for rule changes on the common rule concept of a Super IRB. Dr. Villegas shared that the National Congress of American Indians Policy Research Center submitted a Native American Research Centers for Health 8 (NARCH-8) grant on infrastructure to give best practice models, which might be something of interest to the HRAC. Councilwoman Cowan Watts suggested looking at IRB best practices both nationally and internationally. She also stated that there is not a single report that captures all the information needed for tribal leaders. Dr. Villegas said that a one to two pager synthesizing the resources across HHS for tribal leadership might be helpful. There is also a fellowship with the National Institutes of Health (NIH) around IRB development right now. It was suggested to reword the action item to read: "This workgroup is newly formed and will look to develop recommendations on the development of tribal IRB resources."

- Dr. Dan Calac will provide information on the AHRQ review process from his experience as a reviewer. This will be met by his presentation later in the call.
- For the action item, "HRAC needs to identify for purposes of the National Children's Study (NCS) what the HRAC ask is," LCDR Branch mentioned that she is getting push back and there needs to be a better idea of how the HRAC and Indian Country would use the NCS to help justify the act for oversampling. Dr. Trachtenberg noted that he has new information and will discuss further in the agenda.
- Elizabeth Carr requested a copy of the Data Council letter and this has been completed.
- Councilman Steven Kutz is to provide a copy of a sample MOU between a tribe and university regarding scholarships.
- The HRAC requested funding opportunities for 2014. LCDR Branch stated that she can email information as announcements come out, but it would be helpful to find out if there is a particular contact within the tribe or area that can help disseminate information rather than filling up the inboxes of the HRAC members. Email LCDR Branch with contacts that should receive funding opportunity information.
- Dr. Villegas noted that the Research Database Workgroup has not begun to identify fields for the database, but she recently met with the University of New Mexico coordinator to discuss this project.
- For the charter revision, LCDR Branch is still working on making edits and comments. She was successful in finding some historical documents on how wording came about for points of reference.
- Councilman Kutz had inquired about funding cuts from NIH to Epidemiology Centers (EpiCenters). LCDR Branch is working through Dr. Gracia with Dr. John Ruffin to find out information on the funding cuts.
- For the map development action item, a singular map is needed that shows the HHS regions, IHS Areas, HRAC member locations, NARCH grantees, and Contract Health Service Delivery Area (CHSDA). Dr. Trachtenberg noted that there is a CHSDA map on the web that can be used.
- It was suggested that Action Item #12, to provide a listing of tribal IRB's, may need to roll up under the IRB workgroup action items.

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- Regarding the NIH Tribal Consultation Implementation Guidance action item, there have been some emails with concern about passive approval language within the document. The group agreed that this was something to look at down the road in terms of recommendations.
- Another action item around the NIH Implementation Guidance is finding out the status of implementation. LCDR Branch noted that Dr. Joyce Hunter has been unable to participate in recent HRAC activities so this will remain an open action item.
- Environmental research was discussed at the last HRAC meeting and LCDR Branch wondered if this should now be one of the priorities of the HRAC. Councilwoman Cowan Watts said that this should be held to discuss further.
- One item that will be added to the action item list is the State/EpiCenter letter to the Secretary. Secretary Sebelius asked during the last STAC meeting for a list of the states that were not in compliance with the federal mandate. LCDR Branch queried the EpiCenters and compiled all information received into a spreadsheet, which she sent for feedback to Councilwoman Cowan Watts, Michael Peercy, Jay Butler, and Councilman Kutz.
- Councilwoman Cowan Watts requested that any action item be sent out individually via email.

#### **4. Work Group Updates**

- National Children's Study Workgroup: Dr. Trachtenberg stated that the response from the National Children's Study to the HRAC is now antiquated by new events. The Institute of Medicine (IOM) has been tasked with convening a review panel for the proposed study design. The stratification was formerly geographically based, which resulted in the Northern Plains and Alaska being omitted. That sampling frame has now been thrown out and they are creating a new sampling frame which is hospital center and birthing center based. Dr. Trachtenberg suggested that the HRAC now ask that strata for Indian hospital births be included for both tribal and IHS hospitals. Additionally, strata from Indian hospitals should be oversampled. Councilwoman Cowan Watts noted that this would resolve the identification issue in terms of citizenship. Dr. Trachtenberg said this information was mentioned verbally and it seemed pretty certain this was the direction they were now going. He also confirmed with the contract statistician that federal hospitals, like IHS, would take part. The statistician thought it was a reasonable request that such a strata be created. Dr. Villegas said that Emily White Hat attended the public meeting on August 16 and she would send out information provided at the meeting. The new approach was not mentioned during the meeting, but the 100,000 total was still planned with part of that including the 10,000 subsample. Dr. Trachtenberg said that the 90,000 from the new sample frame will be at hospital centers and birthing centers. If there is a strata for Indian hospitals and an oversample as part of the 90,000 then we do not have to ask for the 10,000. Dr. Villegas replied that it would be ideal, but she's not sure that will happen. She noted that there will be another meeting in October and the new plan will be finalized in January. She wondered if the HRAC should submit a letter in support of this new approach as public comments can still be made. Dr. Trachtenberg will send the NCS Director an email and see if he can put this new approach in

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writing. Councilwoman Cowan Watts agreed that would be helpful and that the HRAC could then determine if they need to write a letter. Dr. Trachtenberg thinks a letter is still needed asking for strata for Indian hospitals and then oversampling of those strata.

- Native Research Database Workgroup: Dr. Villegas reported out during the action item section and she will provide an update once more details are available.
- Charter Workgroup: LCDR Branch will be sending an updated version via email so the workgroup members can review and provide comments.
- IRB Workgroup: This group was discussed during the action item updates.

## **5. Panel Review Experience**

- Dr. Calac noted that Dr. Kishena C. Wadhvani provided a presentation during the HRAC Annual Meeting on the AHRQ review process, but he wanted to comment on his experience. Last year there were 60-70 R01 proposals for research studies submitted to NIH for formal review in consideration of funding. These proposals were broken up into different committees. There were 20 people in his section and all were Native or had been working with Native communities for 10-20 years. Dr. Calac thought that NIH did very well in making sure that those reviewing had background experience and that they took the review process very seriously. The people within his section came from diverse backgrounds and lived in Native Country for a long time, but at times information was lost in translation in how it was presented. Dr. Calac found it imperative that if a reviewer didn't know something about the study or context of the study that a little bit of homework was needed without becoming biased, such as how the study was constructed, the community where the study was being performed, etc.
- LCDR Branch asked how Dr. Calac initially became involved. Dr. Calac stated that about 5 years ago he became Principal Investigator at the NARCH facility in California and his selection was a result of being in that position. Dr. Calac offered that he is available to serve as a resource and to answer questions as needed. Dr. Trachtenberg asked that Dr. Calac send contact information for his local IRB.

## **6. Wrap Up**

- Councilwoman Cowan Watts requested that each action item be sent out to prompt the owner and that she and Councilman Kutz can be carbon copied to help keep items moving.

## **7. Adjournment**

- The conference call meeting was adjourned at 4:13 PM Eastern.