

January 11, 2010

Honorable Kathleen Sebelius, Secretary  
U.S. Health and Human Services (HHS)  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, DC 20201

***Re: National Children's Study (NCS)***

Dear Secretary Sebelius:

On behalf of the U.S. Health and Human Services American Indian/Alaska Native Health Research Advisory Council (HRAC), please accept the following comments regarding the National Children's Study (NCS). While the HRAC fully supports the intent and purpose of the National Children's Study and its long-ranging impact on health care in the United States, the HRAC has identified several areas that could greatly benefit the study and more accurately reflect the American Indian/Alaska Native (AI/AN) population.

The current NCS sampling frame anticipates inclusion of 2,000 AI/AN children, primarily from the following areas:

- Arizona – Apache, Maricopa, and Pinal Counties
- Utah – Salt Lake County
- New Mexico – Valencia County
- Oregon – Marion County
- Washington – Grant County
- Arkansas – Benton County

While the 2,000 American Indian children is a reasonable representation of the total sampling frame and the selected counties do offer valuable information regarding the AI/AN population, it does not sufficiently depict the true health picture of American Indian/Alaska Native communities. During the November 12, 2009 HRAC meeting, representatives highlighted the need to target areas suffering from the worst childhood health conditions in the United States. Specifically, the HRAC representatives cited Shannon and Buffalo Counties in South Dakota, which are located within the Pine Ridge and Crow Creek Reservations, respectively, and are rampant with poverty and poor health outcomes. Additionally, the HRAC identified the need to include Alaska Native communities that more accurately reflect the population.

The HRAC proposes a parallel study that directly targets additional counties and AI/AN populations, which would compliment the current NCS sample. The HRAC would also like to offer the following regarding the AI/AN population:

- Health research participants defined as American Indian or Alaska 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' or meet the BIA definition of American Indian or Alaska Native as provided by a 'Certificate of Degree of Indian Blood.' Self-identification is inadequate and could potentially be inaccurate.
- Sampling protocols that promise to include preservation of DNA and tissue samples must be followed and Tribal Nations educated before, during and after as an on-going partner.
- Special consideration must be given to the treatment of blood and tissue samples
  - Such samples should be treated as “non-renewable resources” and should not be used to develop cell lines to be used or shared in the future without prior consent of AI/AN participants and Tribal Institutional Review Boards (IRBs).
  - Further, researchers must consider the unique practices of Tribal Nations regarding blood and tissue sample disposal. Researchers must work in collaboration with Tribal Nations to develop protocols on collection, utilization, and disposal in a culturally appropriate manner.
- Commitment to Tribal sovereignty and consultation must be maintained.
- Commitment to honoring all necessary protocols regarding research in American Indian and Alaska Native communities, including review by all appropriate Institutional Review Boards (IRBs).
- De-identification of data must be reviewed with Tribal Nations.
- A data sharing agreement with Tribal Nations must be established in partnership with the Tribe before the local study commences.
- Study centers yet to be named could target American Indian and Alaska Native communities.

In closing, the HRAC supports the intent and purpose of the National Children’s Study and is confident that its recommendations can greatly benefit the NCS to ensure a meaningful and accurate study. Should you require additional information, please feel free to contact Cara Cowan Watts or Dr. Donald Warne at 605-721-1922/ext.101 or email him at [dwarne@aatchb.org](mailto:dwarne@aatchb.org). Thank you for your consideration in this matter.

Sincerely,

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