

DRAFT AGENDA
**Research for Native Health, Strengthening Partnerships, Promoting Trust
and Increasing Communication**
August 22-23, 2007

- 07:00 **Registration**
- 08:00 **Opening Session (Majestic)**
Blessing TBD
Welcome
- **Zachary Taylor, MD, MS**, Regional Health Administrator, Office of Public Health and Science Region VIII
 - **Bernard A. Schwetz, DVM, PhD**, Director, Office for Human Research Protections (OHRP)
 - **Phillip L. Smith, MD, MPH**, Director, Division of Planning, Evaluation and Research, Indian Health Service
- 08:30 **Community Participation in Clinical and Public Health Research (Majestic)**
- **Chuck Q. North, MD, MS**, Chief Medical Officer (Acting), Indian Health Service
- 09:00 **Plenary 1. Research for Native Health, (Majestic)**
To provide an understanding of how tribal sovereignty, spirituality and cultural issues impact health and human research in American Indian communities.
- **Philip S. (Sam) Deloria, JD**, Director, American Indian Graduate Center
- 09:45 Break
- 10:00 **Plenary 2. The Value and Benefit of Research (Majestic)**
Discuss issues related to community research protections and community and sovereign rights.
Speaker:
- **Doris Cook, MPH**, Native Research Network, Aboriginal Ethics Policy Development
- 10:45 **Plenary 3. Institutional Review Board Expectations & Regulations (Majestic)**
To discuss/review HHS human subject regulations, the Indian Health Service IRB process and tribal processes developed to meet expectations.
Speakers:
- **Bernard A. Schwetz, DVM, PhD**, Director, Office for Human Research Protections (OHRP)

- **Alan Trachtenberg, MD, MPH**, Administrator, Indian Health Service National Institutional Review Board
- **Marsha Rernleitner**, Coordinator, Aberdeen Area IHS Institutional Review Board
- **Beverly Becenti-Pigman**, Chair, Navajo Nation Human Research Review Board
- **Connie Garcia, MA**, Director, Reach 2010 Program, Albuquerque Area Indian Health Board
- **Sohail Khan, MBBS, MPH, CIP**, Chair, Cherokee Nation Tribal Institutional Review Board
- **Zeenat Mahal, MBBS, MS**, Director, ITCA Epidemiology Center, Inter Tribal Council of Arizona, Inc. (Moderator)

12:15 Luncheon (Provided in Tower Exhibit)
Traditional Flute Performance by Louis Teufel-Shone

01:30 **Plenary 4. The Real Story: Living through the Institutional Review Board (IRB) Process, experiences, expectations, challenges and controversies. (Majestic)**
Speakers will provide insights on the Institutional Review Board process from several perspectives.

1. Researcher/Investigator
Donald Warne, MD, MPH, Clinical Professor, College of Law, Arizona State University (ASU)
2. University IRB panelist
Mark Yarborough, PhD, University of Colorado at Denver and Health Science Center (invited)
3. Tribal Institutional Review Board Chair (Tribal College/Tribal Nation)
Dave Oreiro, MEd, Vice President for Administrative Services, Northwest Indian College
4. Community based researcher/investigator
Dolores Subia Bigfoot, PhD, Assistant Professor of Research, Department of Pediatrics, University of Oklahoma Health Sciences Center

03:30 **Break**

03:45 **Breakout Sessions**
Workshop 1. *Creating an Institutional Review Board (IRB): The Basics. (Vail)*
This session will review the regulatory requirements regarding the establishment and operation of an IRB and discuss the collaboration and communication essential for research in American Indian Tribal communities.
Speakers

- **Kevin Nellis, MS, MT (ASCP)**, Office for Human Research Protections (OHRP)
- **Beverly Becenti-Pigman**, Chair, Navajo Nation Human Research Review Board
- **Zeenat Mahal, MBBS, MS**, Director, Epidemiology Center, Inter Tribal Council of Arizona, Inc. (Moderator)

Workshop 2. *Community Readiness & Research Partnerships. (Savory)*

Discussion of the process tribal communities have gone through to develop working relationships with academia/research

Speaker

- **Marridie J. Craig**, Director, White Mountain Apache Tribal Health Board/Johns Hopkins University
- **Tina Cooper, MD**, Chief Medical Officer, Chickasaw Nation/University of Oklahoma
- **E. Joyce Naseyowma-Chalan, MPH**, Associate Director, Center for Native American Health, University of New Mexico (Moderator)

Workshop 3. *Research Readiness & Trustworthiness (Capitol)*

Discussion of the process academia/research communities have gone through to develop working relationships with tribal communities

Speakers

- **Nicolette I. Teufel-Shone, PhD**, Associate Professor Mel and Enid Zuckerman College of Public Health
- , University of Arizona/Hualapai Tribe
- **Speaker TBD**
- **Marsha Rernleitner**, Coordinator, Aberdeen Area IHS Institutional Review Board (Moderator)

Workshop 4. *Human Protections, What Does It Mean? (Terrace)*

This session will provide a review of the ethical principles of human subject protection and discuss the “real world” challenges related to those principles and research involving American and Alaska Native participants.

Speakers

- **Shirley Hicks**, Director, Division of Education and Development, Office for Human Research Protections (OHRP)
- **Dolores Subia Bigfoot, PhD**, Assistant Professor of Research, Department of Pediatrics, University of Oklahoma Health Sciences Center
- **Adeola Jaiyeola, MD, MPH**, Director, Northern Plains Epidemiology Center (Moderator)

Workshop 5. *Review of Drug and Device Regulations (Biltmore)*
This session will review FDA's regulatory requirements for drug, biologic, and device research and address some of the challenges in conducting FDA-regulated research in American Indian and Alaska Native communities.

Speakers

- **Jean Toth-Allen, PhD**, Good Clinical Practice Program, Office of the Commissioner, Food and Drug Administration
- **Sohail Khan, MBBS, MPH, CIP**, Chair, Cherokee Nation Tribal Institutional Review Board

Workshop 6. *Identifying Translating and Disseminating Tribal Health Research Priorities (Beverly)*

Discussion on the role of the researcher in publication of data, and the role of the researcher assisting the tribal community in identifying resources to address problems that are discovered from the research process

Speakers

- **Spero Manson, PhD**, Professor of Psychiatry and Director of American Indian and Alaska Native Programs, University of Colorado at Denver and Health Sciences Center
- **Lorenzo Olivas, MPH**, Regional Minority Health Consultant, OPHS, Region VIII (Moderator)

05:00 Adjourn Day One

Day Two

07:30 **Registration**

08:00 **Opening Blessing**

- TBD

Welcome and Day One Summary

Zachary Taylor, MD, MS, Regional Health Administrator, Office of Public Health and Science Region VIII

08:30 **Plenary 1. Research and Human Protections, Challenges of the Past, the Present, and for the Future (Majestic)**

(A case study: Havasupai Tribe and Arizona State University)

To provide participants with three perspectives; the challenge of informed consent, IRB and ethics and new models for partnerships and community participation

Speakers

- **Robert Lyttle, JD**, Attorney, Tilousi vs. Arizona State University (ASU)
- **Don Watahomigie**, Havasupai Tribal member
- **Alan Trachtenberg, MD, MPH**, Administrator, Indian Health Service National Institutional Review Board
- **Donovan D. Brown, SR. JD**, Assistant Attorney General, Department of Justice, Navajo Nation (Moderator)

10:00 **Break**

10:15 **Plenary 2. Emerging Topics in Human Research (Majestic)**

- Genetics, Serum Banking, Specimen Use
Terry Powell, Administrator, Alaska Area IHS Institutional Review Board
Yvonne Higgins, PhD, Director, Human Research Protection, University of Pennsylvania
- Community Consent
William L. Freeman, MD, MPH, CIP, Director, Tribal Community Health Program, Northwest Indian College
- Urban-Based Research
Mei Castor, MD, MPH, Medical Epidemiologist, Urban Indian Health Institute, Seattle Indian Health Board
- Data Ownership and Dissemination of Information
Jim Crouch, MPH, Executive Director, California Rural Indian Health Board
- **Delight E. Satter, MPH**, Director, American Indian and Alaska Native Research Program, UCLA Center for Health Policy Research (Moderator)

12:00 **Lunch on your own**

01:30 **Breakout Sessions (Vail)**

Workshop 1. Data Ownership and Use

Discussion about the issue of “ownership of data”, what the expectations are of the tribes and investigators; and how data and research findings are presented, or not, to the research community

Speakers

- **Zeenat Mahal, MBBS, MS**, Director, Epidemiology Center, Inter Tribal Council of Arizona, Inc.
- **Jim Crouch, MPH**, Executive Director, California Rural Indian Health Board
- **Christina Perez, MN, FNP, RN**, Regional Minority Health Consultant, OPHS Region IX (Moderator)

Workshop 2. Genetics, Serum Banking & specimen collections
Discussion on how tribes have developed codes and regulations to address human research **(Savory)**

Speaker

- **H. Sally Smith**, Chair, National Indian Health Board
- **Beverly Becenti-Pigman**, Chair, Navajo Nation Human Research Review Board
- **Terry Powell**, Alaska Area IHS Institutional Review Board (moderator)

Workshop 3. Community Consent, Individual Rights and Research with non-tribal entities. **(Capitol)**

This session will briefly review the ethical principles and regulatory requirements related to consent, discuss the concept of community consent, and provide examples of how research can respect both the individual rights and community concerns in Urban Settings.

Speakers

- **Mei Castor, MD, MPH**, Medical Epidemiologist, Urban Indian Health Institute, Seattle Indian Health Board
- **Delight E. Satter, MPH**, American Indian and Alaska Native Research Program, UCLA Center for Health Policy Research
- **Shirley Hicks**, Director, Education and Development, Office for Human Research Protections (OHRP) (Moderator)

Workshop 4. Behavioral Health and Genome Mapping **(Beverly)**

Speakers

- **Spero Manson, PhD**, Professor of Psychiatry and Director of American Indian and Alaska Native Programs, University of Colorado at Denver and Health Sciences Center
- **William L. Freeman, MD, MPH, CIP**, Director, Tribal Community Health Program, Northwest Indian College
- **Nicolette I. Teufel-Shone, PhD**, Associate Professor, Mel and Enid Zuckerman College of Public Health, University of Arizona/Hualapai Tribe, Arizona (Moderator)

Workshop 5. *Additional Protections for Vulnerable Populations—Children, Prisoners, Pregnant Women and others* **(Biltmore)**

This session will review the additional regulatory requirements for research involving pregnant women, prisoners, emancipated adolescents, and children and discuss the challenges that IRBs face when reviewing research with these vulnerable populations in Native American communities.

Speakers

- **Lyndi Lahl, RN, MS**, Public Health Analyst, Division of Education and Development, Office for Human Research Protections (OHRP)
- **Billie Jo Kipp, PhD**, Research Assistant Professor, Center for Native American Health, Family & Community Medicine, University of New Mexico
- **Gayle Diné Chacon, MD**, Director, Center for Native American Health, University of New Mexico
- **Henry Delgado, MS**, Regional Minority Health Consultant, Region VI (Moderator)

03:00

Break

03:20

Plenary: Future Partnerships and Dialogues (Majestic)

H. Sally Smith, Chair, National Indian Health Board

Carole Anne Heart, Executive Director, Aberdeen Tribal Chairmen's Health Board

Phillip L. Smith, MD, MPH, Director, Division of Planning, Evaluation and Research, Indian Health Service

04:30

Closing Remarks and Closing Prayer (Majestic)

Zachary Taylor, MD, MS, Regional Health Administrator, Office of Public Health and Science Region VIII

Bernard A. Schwetz, DVM, PhD, Director, Office for Human Research Protections

Phillip L. Smith, MD, MPH, Director, Division of Planning, Evaluation and Research, Indian Health Service