



Report

The Tribal and Urban Indian Research Ethics Workshop (TUIREW) was held on March 1 and 2, 2012, at the University of Washington (UW) Waterfront Activities Center. The focus was to bring key stakeholders together to share diverse perspectives on the regulatory processes and oversight of research involving American Indians and Alaska Natives and their communities in the Northwest area. We incorporate use of the terms “Tribal and Urban Indian” (T/UI) and “Native” with respectful reference to the rich diversity of indigenous peoples that dwell in this region.

The workshop included 46 individuals from local Tribes, Indian Health Service, urban Indian organizations, non-profit groups serving Native people, and Tribal colleges. Native and non-Native faculty, staff, and students representing the UW, Washington State University, and Portland State University also participated.

Overarching goals for this gathering were to (1) learn about existing research review processes in Tribal, urban Indian, and university systems, (2) discuss challenges and strategies for developing appropriate local review processes, and (3) explore needs and opportunities for aligning community and university research review.

Ground rules were introduced for creating a safe environment to express different, and sometimes opposing views on related topics including: *defining research benefit, Indian or Tribal identity, or interpretation of regulatory guidelines.* The TUIREW organizing team also acknowledged that this would be the *start* of an important conversation. One that might clarify critical questions and provide space for co-learning, but may not result in a one-size-fits-all model to meet the research process needs of diverse groups represented.

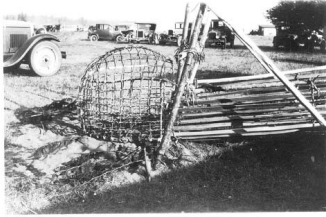
TUIREW goals

- *Learn from Tribal and Urban Indian organizations how they regulate research in their communities*
- *Discuss how research processes develop in different communities*
- *Discuss best practices and processes for informed consent*
- *Identify potential needs for alignment of research review and oversight systems*
- *Showcase Native student research*
- *Foster productive dialogue on critical TUIREW issues*

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Tribal and Urban Indian Research Ethics Workshop



PROCESS and AGENDA

Workshop organizing team



Rosalina (Rose) James PhD, is an enrolled member of the Lummi Tribe and a Duwamish descendent. She has many relatives living in urban and reservation communities throughout the Puget Sound area. Rose is an Acting Assistant Professor in UW Dept Bioethics and Humanities. She teaches an undergraduate course on Responsible Conduct of Research, and her work focuses on ethics of tribal and urban Indian health research partnerships with academic universities.

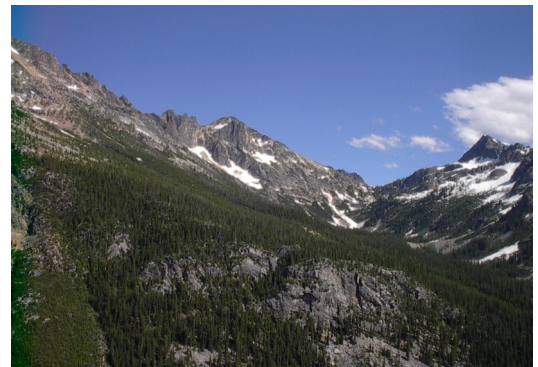


Abigail Echo-Hawk MPS, (Pawnee) has extensive experience working with Native communities as tribal liaison for UW Partnerships for Native Health and the Institute for Translational Health Sciences, and as Chair of Seattle Women's Commission. Ms. Echo-Hawk's interests include culturally based health communication through digital storytelling, tribally-guided research regulatory systems, and community-based participatory research. She has worked across academic and community levels to navigate research conduct that honors tribal sovereignty and community involvement. Abigail lives in Seattle with her husband and two sons.



Ariana Kaci MA, married into a Kabyle family (an indigenous group from Algeria) in 2004. Ariana recently graduated from the UW Bioethics Masters of Arts program and the UW International Bioethics, Social Justice and Health Law Graduate Certificate program. Her Bioethics MA project was a community-based research study on care of the Kabyle elders in Algeria. Ariana assisted organization of this workshop and report as part of work with the Center for Genomics and Healthcare Equality. She is also currently a Review Coordinator for an IRB Committee in the UW Human Subjects Division (HSD) where she has worked for eight years.

Caleb Dunlap BA, is from the Fond du Lac Band of Lake Superior Chippewa. He has worked in Tribal public health and prevention research. Mr. Dunlap has served as Project Assistant for the Urban Indian Health Institute at Seattle Indian Health Board and currently is a Program Manager for Chief Seattle Club. Caleb describes himself as a "Nerdy Native", and is dedicated to using his experience and skills for improving the overall health of Native people.



PROCESS and AGENDA

Making space for respectful dialogue



Colville Tribal member Annette Squetimkin-Anquoe (Traditional Health Liason, Seattle Indian Health Board) set the tone on day one by asking the Creator to open our minds and hearts to hear each others words, and for strength to use this new knowledge in ways that help our Native people. Annette then led the group in prayer

and song facing East where the sun rises.

Dr. Rose James provided a welcome and gave background on how the workshop idea came about. The TUIREW was designed to initiate critical dialogue on research ethics that affect Native people and the various communities where they

have family, loved-ones, work, and where they have a connection with the land and culture.

Sponsorship for the TUIREW was provided by the *Center for Genomics and Healthcare Equality*, a National Institutes of Health Center focused on ethical, legal, and social implications of research. We also received critical manpower and moral support from the *UW Institute for Translational Health Sciences Community Outreach and Research Translation Core* and the *UW Human Subjects Division*. The idea of creating space to explore the landscape of Tribal and urban Indian research processes was introduced by members of the *Advancing Indigenous Research Ethics in Practice and Policy*, a committee of Native and non-Native researchers and staff invested in developing research processes that support indigenous health.

Abigail Echo-Hawk facilitated the workshop. She kicked things off with the story of an initiative to bring an ambulance to her small, rural village in Alaska. Money was raised, staff was hired and trained. When the special unit arrived it was in operation for six months and then parked by the side of the road where it still sits today. Without engagement and direction from the local community, well-intentioned efforts by outside groups can result in good work that simply runs out of gas.

PROCESS and AGENDA

Agenda overview

The organizing team planned for mixed formats to promote open and inclusive communication.

Following introductions, **Day one** of the agenda included presentations on research processes from perspectives of an urban health organization and the Indian Health Service focused on reservation-based communities. Presenters Ralph Forquera (Seattle Indian Health Board) and Thomas Weiser (Portland Area Indian Health Board) touched on the needs, challenges, and hopes for research to promote health and wellness. Presenters also provided background on the operations and goals of their own internal review processes. These were followed by small group discussion centered around informed consent scenarios that elicited some of the challenges involved in meaningful engagement of people participating in research. Each group reported back a sum-

mary of discussion highlights, including suggestions or models for addressing issues raised in the scenarios.

After lunch, Ms. Echo-Hawk led a survey of TRUIEW participant audience health research priorities, and perceived needs for Native research participant oversight in academic and T/UI environments. These anonymous results were displayed in real-time for the workshop audience to view where responses were in common or divergent based on demographics and affiliation.

A meal blessing was provided by Cynthia Gamble (*Chehalis*) and the group enjoyed an informal reception buffet dinner.

After breakfast, **Day two** opened with an overview of themes that emerged from the small group discussions by Ms. Echo-Hawk. A presentation by Susan Brown Trini-

dad (CGHE qualitative researcher and member of a UW Institutional Review Board committee) gave an overview of historical research ethics cases and information on federal regulations concerning human subjects research. This was followed by Ron Whitener's (*Squaxin Island*) presentation on a project that modeled a process for building a research review system with a small rural tribe, and outcomes from this project.

Student presentations by Corinna Tordillos (Tlingit/Northern Cheyenne), UW pre-medicine undergraduate, and Adam Murry (*Chiracahua Apache*), Portland State University Psychology doctoral student, were highlights of the day. Corinna and Adam were honored with Pendleton blankets by workshop organizers for their work as emerging leaders dedicated to T/UI community health and wellbeing.

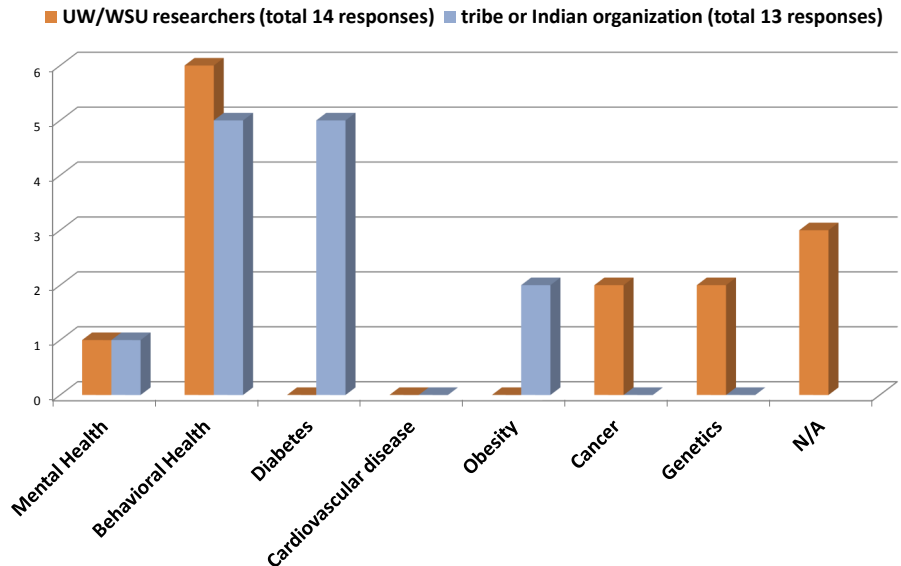


PROCESS and AGENDA

Audience survey and outcomes

A brief set of survey questions was administered to poll workshop attendees on general views of health research priorities and to recognize the varied experiences with T/UI human subjects research regulation represented. Using Turning Point interactive PowerPoint response system (www.turningtechnologies.com), aggregate results were displayed on an overhead screen in bar or pie chart format. The polling exercise made visible baseline differences and overlap of T/UI and university responses, orienting the group to the diverse interests of individuals taking part in the workshop conversations.

What is your research priority?

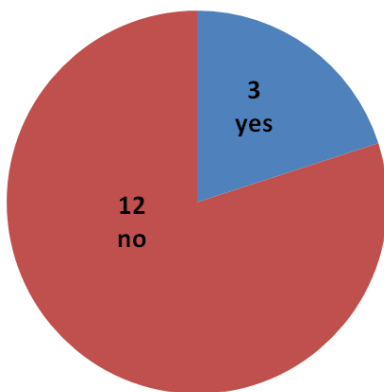


“This was the first time I heard about urban Indian organizations. The difference between urban and rural was eye-opening.”

—university staff

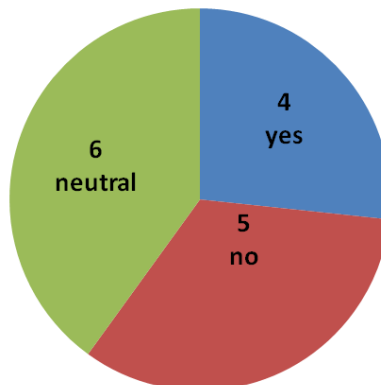
University researchers/staff:

Do you feel you are fully aware of the research processes of Native groups you work with?



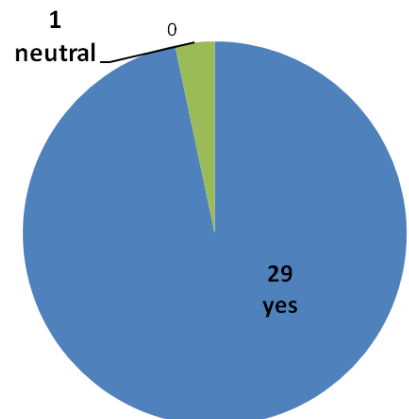
Tribal/Urban Indian groups:

Are the current research studies being conducted in your community properly regulated by academic IRBs?



All:

Do you think there should be a tribal/urban Indian community representative on academic IRBs?



PROCESS and AGENDA

Overview of community research review processes

Abigail Echo-Hawk provided a general overview of tribal and urban Indian community research review processes.

Institutional Review Boards (IRBs) are regulatory bodies that oversee the protection of individuals participating in research involving human subjects. University-based IRBs came into place due to a history of research abuses, such as a study of Inupiat alcohol use in Barrow, Alaska (Foulks, 1979). A high profile press release publicized headliner statements such as “What we have here is a society of alcoholics”. The people of Barrow and nearby communities experienced stigmatization and significant political and economic repercussions based on the release of researcher conclusions that did not include local community input.

As sovereign nations, tribes have the right to regulate research conducted on their lands. Tribes and urban Indian groups use research and data collection to document program needs and generate resources that will help achieve health goals, but protection of the community is critical.

Examples of community research regulatory processes:

- *Oglala Sioux Tribe Review*

Board. Representatives convene monthly to review, facilitate, and monitor research, surveys, assessments, etc, that take place within the boundaries of the Pine Ridge Indian Reservation. The OSTRB has the power to review and approve or disapprove grant proposals, informed consent forms, recruitment materials, publications, and presentations. The Principal Investigator is required to personally present the proposal. Approval is unlikely for any study that has been funded prior to presentation and discussion with the board.

- *Aberdeen Area IHS IRB* is the federally accredited Indian Health Service (IHS) human subjects research review process for South Dakota tribes. They require investigators to receive local tribal council or health board approval before accepting an application. Submitting a proposal to this IRB and other tribal bodies at the same time is an option, but the IHS typically prefers to review the informed consent documents and may suggest changes.
- *Health Boards and research committees.* Various types of

boards and ad-hoc groups advise, review, and approve human subjects research in tribal and urban Indian communities. Review by these groups may be guided less by federal research regulations versus the local community and institutional context (ie: urban Indian clinic), with a focus on the potential for direct health benefit and minimizing harm to local peoples. These groups may advise tribal council on the research proposal

- *Elder’s Council* may provide guidance on respectful language, protocol, and cultural representation. Health Boards and research committees sometimes direct researchers to Elders for advise on whether the proposal addresses community health priorities.
- *Tribal Council.* A lead researcher presents the proposal summary such as goals, recruitment process, expected outcomes, resource needs, potential risks and a plan for addressing them. An outside researcher may co-present with a colleague working in the community where possible.

Research processes that work in one community may not fit the oversight needs of another.

The community is attending to many priorities outside of accommodating researchers.

GLOSSARY AND EVALUATION

Glossary

The following provide basic information on terms used in this report as described on the [Office of Research Protections](#) (OHRP) website.

Institutional Review Board (IRB)

Board (IRB): An IRB is a group of individuals that performs ethical review of proposed research. IRBs registered with the Office of Human Research Protection must approve proposed non-exempt research before human subjects work may begin. IRBs exist at academic and other institutions where research with human participants is being conducted and federal or state funding is received, such as re-

search grants.

Federal Wide Assurance (FWA)

(FWA): Registering an IRB is related, but not the same as obtaining a FWA. An institution must have a FWA in order to receive support from Health and Human Services for research involving hu-

man subjects. The FWA designates at least one IRB registered with the OHRP.

See “[Registering an IRB and Obtaining an FWA: What to do in what order](#)” for more information.

Informed Consent: A process that (1) provides research participants with information needed to make an informed decision; (2) facilitates understanding of the information disclosed; and (3) promotes voluntariness of the decision about whether or not to participate in the research.



TUIREW evaluation and survey responses

A post-workshop online survey was administered to TUIREW participants. We received a total of 14 responses from Urban Indian Organizations (1), Tribe or Tribal Organizations (3), and University or Academic Research Institutions (10). All that responded found the workshop “very” or “somewhat” worthwhile, but two were unsure whether they would attend a future meeting on this topic.

Suggestions for additional workshop topics included:

- Developing review procedures for “non-research” work (i.e.: needs assessments, evaluations,)
- Info on data ownership, Memo-

- randum of Understanding
- Models that bridge gap between tribal and research cultures
- T/UI perspectives on IRB process; gaps in IRB systems; ways of implementing at T/UI (community) level

“I walked about thinking of the purpose of review boards, and how we can ensure that they are fulfilling that purpose.”

-Urban Indian Organization

“There is a huge gap between Tribal communities and the field of research/science. Tribes need protections in place. The young Native men and women who have gone into sciences are the bridge between these two worlds.”

-Tribe or Tribal Organization

“Diversity, diversity, diversity! Would love to hear more about what communities are doing—just a few hints [at this workshop], but it sounds really interesting.”

-University or Academic Research Institution

PRESENTATIONS

Ralph Forquera

Executive Director, Seattle Indian Health Board (SIHB)

Mr. Forquera described some of the core issues that mobilize him to advocate for urban Indian health care and research. Urban Indians are no longer under jurisdiction of tribes and have been discriminated against in recent years.

For example, he mentioned that in some meetings the members of each tribe applaud their own, but when an urban tribal member introduces himself everyone is silent. We've created a sense of division. *"Why don't we applaud ALL Indians?"* How can we do things better to make others feel welcome and included? Non-federally recognized

tribes and urban centers are not eligible for Indian Health Service direct resources, which also creates a sense of being an outsider.

Affairs cards often present the incorrect blood quantum, providing a false impression of tribal heritage, and multiple tribal affiliations are

"We need to come together to celebrate all Indians and create change."

It is important to remember that many urban Indians came from reservations or relocated from other Indian communities. Many are of mixed race and even with multiple tribal affiliations. Bureau of Indian

not recognized.

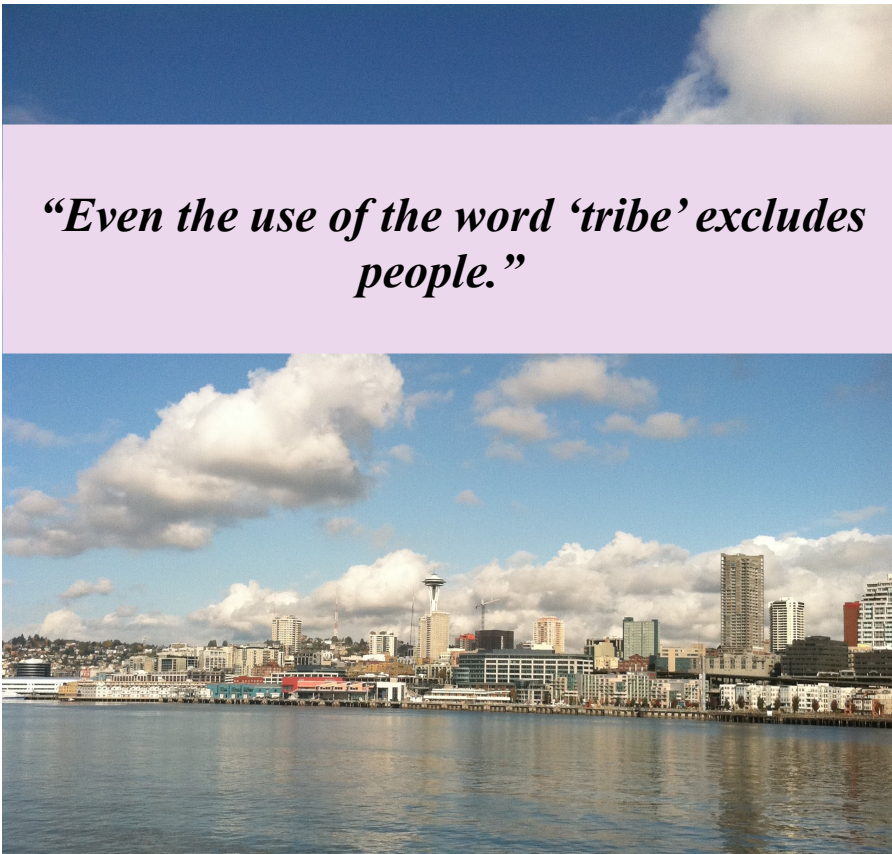
The Urban Indian Health Institute (<http://www.uihi.org/>) was created to (1) make this population visible and (2) collect data that can be used to bring health care and resources to urban Indian communities.

An Institutional Review Board (IRB) must meet federal requirements for membership, criteria for review, etc. We developed the *Privacy Board* to address urban research issues and to protect the interests of SIHB members and clients.

When SIHB does research or collects data, they are interacting with many cultural groups and try to be sensitive to differences and respectful of all.

While recognizing the potential harm associated with research, Mr. Forquera expressed excitement about improving systems that could return benefits to Indian people. *"UW and WSU are at the cutting edge of facilitating conversations of this nature."*

"Even the use of the word 'tribe' excludes people."



PRESENTATIONS

Tom Weiser/Clarice Charging

Co-chair IRB/Coordinator IRB, NW Portland Area Indian Health Service

The Northwest Portland Area Indian Health Board (www.npaihb.org) is a non-profit advisory organization serving 43 federally recognized tribes of OR, WA, and ID.

The NPAIHB convenes Delegates appointed by member Tribes quarterly to direct and oversee activities in areas of Indian health, legislation, health promotion and disease prevention, and data surveillance and research. They also provide research infrastructure through their Epidemiology Center.

The Portland area Indian Health Service (IHS) offers research review as a service to the tribes. They

hold a Federal Wide Assurance agreement with most of the tribes, which allows them to be a designated regulatory body for human subjects research where multiple IRBs are involved. Investigators can submit protocols to all required IRBs simultaneously to minimize review time. Whereas federal regulations focus on protection of indi-

viduals, this IRB also looks at how tribal communities might be affected by the research.

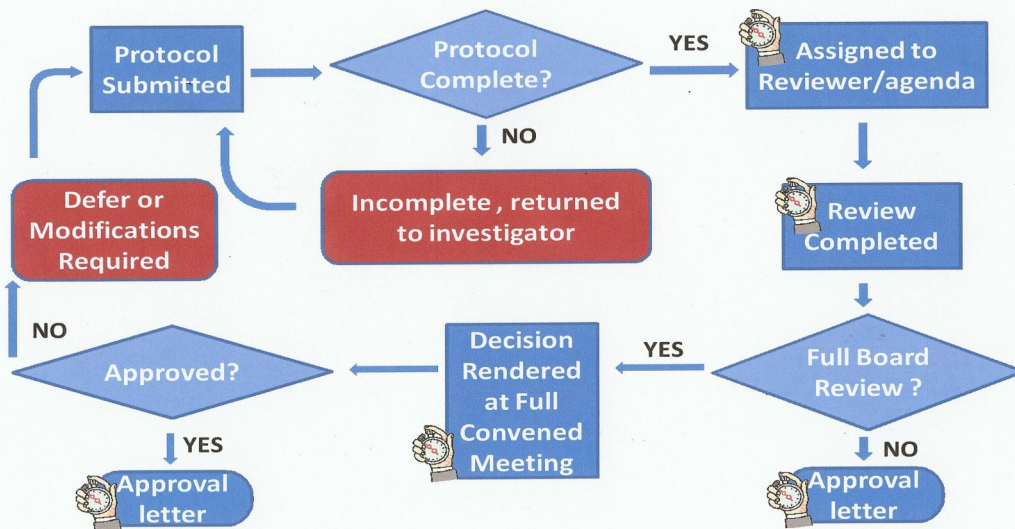
The Portland Area IHS IRB uses a fully electronic submission system—*IRB Net* (training.irbnet.org/training) to track the approval process. The sys-

tem allows users to follow the application steps. For example, an investigator can log on to IRBNet to view the anticipated timeline for a protocol assignment. Protocol submission checklists vary depending on review assignment (ie: new application, modification, continuing review, publication/revision, or response/follow-up). Expedited pro-

protocols are reviewed by two representatives, while full board reviews occur monthly and require a quorum of IRB members. Expedited reviews don't have a deadline, but they can take longer based on the workload of the IRB staff and members. The majority of protocols involve biobehavioral, social science, or epidemiology studies.

“We don’t like to see consent forms that look like a legal document designed to protect the university”

Portland Area IHS IRB Review Process



PRESENTATIONS

Susan Brown Trinidad, MA

Research Scientist, UW Department of Bioethics and Humanities/CGHE



“Consent is a process, not a form”

Ms. Trinidad, a qualitative researcher and member of a UW IRB committee, presented historical and current events that have shaped the federal regulatory systems. She also discussed basic elements of IRB roles/structures.

Past research abuses have drawn public outcry and demand for federal oversight. *The Doctors Trial* drew international attention to research that had been conducted on prisoners of war and concentration camp inmates during WWII. The trial led to *The Nuremberg Code* (1947) as part of a legal judgment against physicians convicted of crimes against humanity for their part in experiments on prisoners of war and concentration camp inmates. The Code states that “voluntary consent of the human subject is essential”, and has since been an ethical model for basic humanitarian considerations in the conduct of research.

The *Tuskegee Syphilis Experiments* were part of a 40 year-long study that documented progression of untreated syphilis in >400 poor African American men in Mason County, GA. Funded and conducted by the US Public Health Service,

the study did not inform men that they were part of a research program and treatment was withheld to follow progression of the disease. After the story broke in 1974, a set of moral principles was published for protection of human subjects in the *Belmont Report*: respect for persons, beneficence, justice, and non-maleficence. These principles form the basis of US regulations for the protection of human volunteers in research.

The third *case* described a recent settlement that included the return of data and samples to the Havasupai Tribe. Researchers gained tribal

“researchers have a social contract, a responsibility, that goes beyond what is covered in consent forms”

- UW faculty

permission to study association of gene variants with type 2 diabetes among members of this small tribe living at the base of the Grand Canyon. The tribe later learned that samples and data had been used for other studies that they did not authorize, including subjects they found objectionable. Scientific community discourse often focused on whether a broad consent form covered additional types of research, but the tribe contends that, based on their interactions with the researchers, they believed samples would only be used for diabetes work.

Institutional Review Boards (IRBs)

- Protect study participants; enforce regulations
- Committees: at least five members including a scientist, a non-scientist, a non-affiliated community representative
- Review: risk/benefit ratio; plans to minimize risk; protection of participant privacy; informed consent; participant recruitment; conflicts of interest
- Certain circumstances: IRBs may waive written consent (ie: if questions about illegal activities) or the requirement for informed consent (ie: emergency interventions)

PRESENTATIONS

Ron Whitener

Executive Director, UW Native American Law Center/CGHE

Ron Whitener, a member of the Squaxin Island Tribe in south Puget Sound, discussed a model for developing T/UI review systems.

Through a National Human Genome Research Institute-funded Challenge Grant, Mr. Whitener and CGHE faculty, Helene Starks, conducted a study with a small WA

State tribe to elicit community priorities for health interventions and research, and assess tribal member attitudes and willingness to participate in research.

With guidance from tribal leadership and community advisors, the goal is to create a research oversight and regulatory process. A toolkit is under development that documents steps in processes for the community health prioritization and the deliberation for identifying and choosing regulatory options. A systematic index of tribal research

codes and policies will be included in the toolkit to provide practical resources for other communities to replicate building a research review and oversight protocol adapted to the local population needs. Mr. Whitener is currently working with

the Urban Indian Health Institute to develop a kit relevant to urban settings.

In addition to building a review system, the project hired two Research Assistants (RAs) and trained them in research methods and analysis. This provided employment for local community members, as well as

which health issues were of the greatest concern. These informal discussions took place wherever adult community members naturally gathered, such as Women's circles and Elders' luncheons, as opposed to scheduling formal interviews or focus groups.

Members most often mentioned

matters such as employment opportunity, cultural teachings, treaty rights, and traditional fishing and hunting as health-related issues.

The project also gathered views on research participation. Tribal members scored their willingness to participate in an hypothetical behavioral health study comparing a group that would receive free treatment (support group sessions) with one that just

received brochures and informational materials. Another vignette described a genetic study examining whether certain genes contributed to health; participation involved interviews about health and donating blood for research.

Take home points:

- Recognize that there is increased participation when community Research Assistants are employed to do the research
- Communities can create temporary non-profits to deal with research projects or initiatives linked to local health priorities
- Communities could benefit from developing locally relevant human subjects training for tribal members
- Try to make the review process protective and meaningful, but not too complicated. Systems that are overly demanding hinder research that communities want to move forward on.



skill development that could be applied to other initiatives within the community beyond the project.

The RAs held a series of "community conversations" with tribal members to better understand

SMALL GROUP DISCUSSIONS

Informed Consent Scenarios

Four small group round-tables discussed different hypothetical informed consent scenarios. To enrich the diversity of experiences, each group included a mix of university staff or faculty, IRB representatives, Native researchers, students, tribal community members, tribal college staff, and urban Indian organization representatives. The following are summaries of the discussions. Included are issues of concern that were raised by TUIREW participants, as well as suggestions and strategies.

The **1st scenario** described a study to assess prescription drug abuse in small rural tribal communities and an urban Indian center. The research team included mental health and substance abuse specialists from each of the communities. Interview questions asked about illegal use of prescription drugs. The communities were supportive of the study which addresses a critical health priority, and interested in results to better understand the scope of the issue. Group discussions covered topics of content for the consent form, which groups should review the form, modes of delivery to ensure understanding of potential risks, and study protocol.

Suggestions:

- “The list includes government agencies. Turn to community groups, non-profits, Elders, tribal council. They’ll tell you about what will work.”
- If an urban center, important to

involve people on the front line in that community, such as medical clinic or treatment center.

- Include details on where interview will take place, who will be conducting it, and how the space will be made safe to answer sensitive questions. But not too much information.

“Everything is identifiable in small communities”

- Describe how the data will be kept safe (ie: won’t be shared with law enforcement).
- Include examples of sensitive questions so people get an idea of what the interview will be like.
- Keep language accessible—avoid acronyms; explain things like “recreational drug use” in laymen terms. If working with kids, be straight forward, but use language they understand (ie: What is “opioid”?)
- Problem focused research can be painful. Include something that explains how the information will be de-identified, and that it will be published outside of community.

Issues of concern:

- “This is a very sensitive topic. You have to be careful in a small community, using trusted members on the research team might not be the best choice. It’s going to be impossible to guarantee confidentiality.”
- Recruiting through clinic can be confused as part of health care. Make sure people aware that you are recruiting for research, not providing a clinical service. Participation is voluntary.
- “I think of IRB as my friend, keeps a researcher from overlooking important parts of the consent process. The community oversight systems do the same, but I have trouble with how different requirements and timelines don’t mesh.”
- A consent form is a document, which may act as a contract on paper. This doesn’t address the process of insuring that people really know what they are getting involved in.

“Agencies like recognition for the research. Tribes want to see what you’re doing before they’ll put their name on it”

SMALL GROUP DISCUSSIONS

Informed Consent Scenarios

Strategies:

- We (the IRB) always work with researchers before the Board review. We talk with them to guide areas of their protocol that need revision—back and forth a few times to get it right.
- Records that identify participants can be a big risk to individuals and the community. A lot needs to be thought through carefully including whether oral consent would be better. Could seek waiver of written consent if that is the only identifying record.
- Literacy levels and consent language can make communication of important information difficult. Alternatives to written forms: video, story-book, play, visuals.

The **2nd scenario** explored whether community co-researchers should identify themselves when involved in project dissemination (ie: through articles, presentations, media, etc). As part of a long-standing partnership, former study participants gradually took on new roles as community co-researchers that included assisting in participant recruitment, facilitating focus groups, and analyzing data.

In this scenario, co-researchers are interested in actively authoring manuscripts, and reports for tribal council and peer audiences. The community partners

are also working on creating products that showcase project outcomes in ways that are more accessible to community members, such as a digital story about their experiences as co-investigators.

Discussion questions: (1) *Does naming community members as co-authors violate participant protection standards? Would naming in Acknowledgement section be more appropriate?* (2) *Naming individual community members as co-authors may have the unintended consequence of identifying their community as having been part of research. Is this a problem? If so, could it be dealt with?*

The group first discussed assumptions regarding “community representation”.

- Someone working with a community may not be a member of that tribe or organization.
- Naming certain people will identify their affiliation, among those that are familiar with them.
- Family can be identified. Tribal government may be on board but not the families; The body

“These questions go beyond the purview of an IRB”

that governs the community and makes decisions may be at odds with what community members want.

“Approval is needed, but no hard and fast rule on what approval means”

- “Are the results stigmatizing, neutral, or positive? How do the results affect the group?”

Aspects of an individual wearing the hat of a community member and a co-investigator when disseminating research were also explored.

- “As a Native researcher I have to ask myself, ‘Do I identify myself by my tribal affiliation?’ I am not the expert of everything.”
- If the community doesn’t want to be identified then that’s that. The co-author is merely one person on the research team. If the decision is split down the middle, then the most conservative and protective route needs to be taken.
- “We don’t all want to be named. Humility plays a part.”

• Co-authors might include their tribal affiliation as a point of pride, and because it is culturally expected. This does not always mean that the community they affiliate with was involved in the study.

SMALL GROUP DISCUSSIONS

Informed Consent Scenarios

- Is it assumed that tribal individuals represent the community? Can they represent themselves?

Some suggestions:

- Co-authorship does not explicitly have to name the community.
- A general acknowledgement of involvement might be used, “Many members gave generously of their time...”
- “I had a co-author, she wanted to be named. The editors didn’t want her to because she would be identified as an individual. She signed a release.”
- “It depends...Every case is individual. There is no black and white.”

In the **3rd scenario**, a group discussed confidentiality in research with small communities. Co-researchers play a role in projects due to their familiarity with people and health systems. Even with required training and signed agreements, co-researcher access to data on individuals (ie: survey responses) can be perceived as threatening anonymity or privacy. Issues of confidentiality can also surface among focus group participants with shared history and social networks. Despite review of informed consent forms that emphasize “What is shared in this room, stays in this room”, sensitive information exposed in research settings can

make people vulnerable to social stigmatization or gossip

Discussion questions: *What models exist for training community-co-researchers to maintain confidential information? Are there additional measures to insure confidentiality of sensitive information?*

Suggestions:

- Trainings required or available—Health Insurance Portability and Accountability Act (HIPAA) on how protected health information can be used and disclosed; Indian Health Service has online training; National Congress of American Indians offers CBPR training for tribes.
- Train researchers on traditions of the community, and on how to ask a question and establish a “safe zone”.
- Have the focus group participants set their own ground rules.
- Present at different community events (ie: BBQs, dinners, Elders’ luncheon, council meetings) about research benefits and risks, and about the meaning of consent.
- Self-selected focus group participants can insure trust if members already have a relationship (ie: friends, family). This includes not sharing things they don’t want others to know.

Issues of concern and strategies:

- Focus groups are made up of individuals that have self-selected to speak about a topic. It is a limited perspective that may not truly be representative [of the community].
- Gossip is how communication works in communities. It can’t really be “controlled”. May help to talk about long-term impact of sharing identifiable information. Define what is sensitive (ie: illegal drug or alcohol use of underage people).

Take home points:

- **No consensus on process. Needs to be worked out on case-by-case basis**
- **Be sensitive to existing protocols established for local geography, and population**
- **On-going consultation with people at varied levels (ie: governing body, Elders, community leaders) is critical**

SMALL GROUP DISCUSSIONS

Is there room for process alignment?

The small group discussion on day two focused on alignment of research review processes between institutions, across community and academic IRBs, or between urban and tribal community systems.

Discussion question: *As researchers identify intricacies of working with T/UIs (ie: timelines for project approval, variation in local systems for community participation, additional review processes for publications and presentations of research results, time for building relationships) while meeting demands of academic environments and funding agencies, some have questioned whether working with Native populations is plausible. Can we find a balance that respects and meets the needs of both researchers and T/UI groups?*

Discussion highlights:

- Larger institutions should prioritize relationships with tribes and urban groups. Have a liaison with ongoing relationships extending beyond a particular research project.

- Include urban Indians in outreach efforts.
- Pressure congress, funding organizations, advisory boards,

- Encourage tribes to...”have awareness of what is coming into and out of your community”.

- Identify resources for tribes to address some of these research ethics issues internally.

- Create a consortium of tribes to pursue guidelines and help get things done in a timely manner.

- Systematic external and internal processes means not having to reinvent the wheel.

- Create capacity to grow Native researchers.

- Be sure all are aware of different timelines and demands (ie: funding agency, university, tribal or urban community leadership, review committees).

- “It’s like if you invited yourself to dinner at my house, but wanted to come at only a certain time, and choose the menu and when you will leave.” There is a need to address ongoing ignorance. The more clear we can be on the T/UI side the more the agencies can adjust.

“tribes and universities have very different perspectives, and bringing together will take lots of work”

-university staff or faculty

“I’ve got 20 years in health education, and clinic administration. I haven’t seen big improvements. It’s apparent we need research to know what works in western or traditional medicine. This conference has been a practical engagement in the process...ideas about a toolkit. Dream big, like funding agencies that are culturally competent!”

-T/UI

“The better the relationship, the better it will be for you.”

-T/UI

and universities to expand mission statements and define “good health” to also include “good information”.

- A permission checklist for researchers that defines respectful ways to approach a community, and includes the necessary paperwork.
- Share progress reports with the community.

For questions or comments regarding the
Tribal and Urban Indian Research Ethics
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A copy of the TUIREW report can be
found on the Center for Genomics and
Healthcare Equality website:

<http://depts.washington.edu/cghe/>

Appendix

Federal human subjects research regulations:

Human Subjects Research Code of Federal Regulations (45 CFR 46)

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

Waiver of Documentation of Consent (45 CFR 46.117(c) 1 OR 45 CFR 46.117(c) 2)

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.117>

Waiver of Consent (45 CFR 46.116(c) OR 45 CFR 46.116(d))

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116>

Research ethics resources:

Tribal Research Assessment Checklist (Northern Plains Tribal Epidemiology Center)

www.aatchb.org/epi/docs/ResearchEthics/T1-TRAC.doc

Tribal Codes/Protocols Pertaining to Research (University of AZ Native Peoples Tech Assistance Off)

www.nptao.arizona.edu/research/tribalCodes.cfm#suspended

Model Tribal Research Code (American Indian Law Center, Albuquerque, NM)

www.nptao.arizona.edu/research/NPTAOResearchProtocolsWebPage/AIILawCenterModelCode.pdf

National Congress of American Indians Policy Research Center

www.ncaiprc.org

Urban Indian Health Institute

www.uihi.org