

Developing a Framework to Guide Genomic Data Sharing and Reciprocal Benefits to
Developing Countries and Indigenous Peoples

A Colloquium

January 7-8, 2009
Georgetown University, Washington, DC

Hosted by
O'Neill Institute of National and Global Health Law
Georgetown University
and
Personalized Health Care Initiative
Department of Health and Human Services

Table of Contents

	Title
Page.....	1
Table of Contents.....	2
Acknowledgements.....	3
Thematic Analysis of Colloquium.....	4
Background White Paper.....	15
Glossary.....	34
Schedule of Colloquium.....	36
Biographical Sketches.....	38
Research Team.....	52

Acknowledgements

Dr. Charles H. Evans provided special guidance in the preparation and detailed editing of this report. The O'Neill Institute of National and Global Health Law Georgetown University wishes to thank the Personalized Health Care Initiative, Department of Health and Human Services for its partial financial support of the colloquium through P.O. #HHSP233200900062A.

Disclaimer

Opinions, interpretations, conclusions and recommendations are those of the authors and are not necessarily endorsed by the Department of Health and Human Services.

Thematic Analysis of Colloquium

The O’Neill Institute for National and Global Health Law invited twelve thought leaders with extensive experience in the conduct of biomedical research among indigenous peoples and developing countries to a colloquium at Georgetown University on January 7-8, 2009. The colloquium addressed a basic question: as genomic science develops across the world, how can the global community assure that indigenous nations and developing countries reciprocally benefit from their contributions to research? We invited thought leaders with broad experience with biomedical science research, public health, indigenous peoples and developing nations. On Day One of the colloquium, each thought leader gave a fifteen minute talk outlining key points on the colloquium’s basic question based on their individual experiences (see schedule and summary of individual contributions). Each thought leader spoke during one of three sessions, namely “Hearing Indigenous Perspectives”, “Hearing the Perspectives of Developing Countries” and “Implications for Genomics and Healthcare”. Group discussion of the talks occurred at the end of each specific section as well as the end of the day. Day Two opened the floor entirely for group discussion of the issues and next steps. Members of the O’Neill Personalized Medicine Workgroup observed the presentations and contributed to general discussion. This report offers a thematic analysis of the issues and recommendations of the two days’ work. The O’Neill Institute thanks all participants for spirited, detailed and respectful discussion. The O’Neill Institute also thanks the Personalized Healthcare Initiative, Department of Health and Human Services for providing partial support for the colloquium.

Results of the Colloquium

From the perspective of indigenous peoples and developing countries, the promises and perils of genomic science appear against a backdrop of global health disparity and political vulnerability. These conditions pose a dilemma for many communities when attempting to decide about participating in genomic research or any other biomedical research. Genomic research offers the possibility of improved technologies for managing the acute and chronic diseases that plague their members. Yet, the history of particularly biomedical research among people in indigenous and developing nations offers many examples of unethical practice, misuse of data and failed promises. This dilemma creates risks for communities who decide either to participate or not to participate in genomic science research. Like communities themselves, participants in the colloquium disagreed about the relative importance of the horns of the dilemma. Some argued that the history of poor scientific practice justifies refusal to join genomic research projects. Others argued that disease poses such great threats to the well-being of people in indigenous communities and developing nations that not participating in genomic research risks irrevocable harm. All agreed, however, that the dilemma potentially diminishes if the scientific community engages indigenous and developing communities in new ways - ways that employ genomic research as one tool for community development as well as a source of scientific information. Adopting these

new ways would also improve biomedical science by including continuous community engagement and progressive community empowerment as components of “rigorous scientific research”.

The Dilemma

Indigenous nations and developing countries share a history of underdevelopment and colonial exploitation that has often left their peoples politically and economically marginalized. People in these communities suffer disproportionately from both infectious diseases such as HIV/AIDS, malaria, and diarrhea and chronic illnesses such as diabetes and heart disease. Personalized medicine promises dramatic improvements in treatment for these illnesses through healthcare tailored to the genotype of individual patients. Yet, genomic science has just begun to collect the data necessary to support personalized medicine and requires some degree of participation by all the world’s people to succeed in its objectives, including people in indigenous and developing nations. The colloquium posed the question of how to assure that people in indigenous and developing nations realize benefit from their participation in genomic research.

Spokespersons from indigenous communities asserted, however, that genomic investigators should not presume that all communities would agree to participate in the research. Indeed, indigenous organizations such as the United Nations Working Group on Indigenous Peoples and many indigenous communities have already decided not to participate in genomic research citing negative experiences with earlier projects such as the Human Genome Diversity Project (HGDP), the National Geographic Genographic Project, and others (see also the background paper for the colloquium). From this perspective, the struggle of indigenous peoples worldwide to achieve recognition of their sovereignty and rights of self-determination informs the discussion about biomedical research, particularly when scientific investigators act in untruthful, clandestine and other unethical ways. Insisting that investigators respect the sovereignty of indigenous nations helps protect community members from the social disruption, cultural theft and shame that potentially follow from scientific abuse.

Select examples of scientific misconduct in genomics research

- Arizona Court of Appeals. Havasupai Tribe v. Arizona Board of Regents. (Arizona Court of Appeals, 2008)
- Tribe blasts 'exploitation' of blood samples. (Dalton, 2002)
- Safari Research in Mexico (Seguin et al., 2008)

Others, particularly spokespersons for developing countries, acknowledged the importance of sovereignty and colonial history but expressed great concern that people from their communities could easily miss benefitting from advances in personalized medicine as they had missed so many other technological “revolutions”. Indeed, a “genomic gap” already exists between Africa and the developed world that may be impossible to close. The global community faces a challenge to not let Africa fall farther behind in genomic science. Mexico offers an important case study because, as a developing country with many indigenous communities, it has faced the questions of scientific practice and health disparity in the design and implementation of its National Institute of Genomic Medicine (INMEGEN) (Seguin B., et al, 2008).

Resolving the dilemma

As the colloquium participants discussed these points and evaluated their implications for genomic science and healthcare, conversation began to focus on fundamental importance of engaging indigenous and developing communities in the discussion about and process of genomic research. Four topics emerged from the discussion, including:

- consulting with communities
- complexities of consent
- training members of local communities in science and healthcare, and
- training scientists in how to work with indigenous and developing communities.

The urgent necessity of training members of indigenous and developing communities to function as interlocutors between the scientific and local communities ran as a common thread through the discussion about each of these topics. This approach eventually identified genomics research as a potential entry point into the social development of local communities in indigenous nations and developing countries.

Consulting with local communities: Canadian case law requires consultation with indigenous peoples about issues involving them and their well-being. It further requires providing good reasons for not following their advice. The Canadian Institutes of Health Research (CIHR) has engaged in extended consultations and deliberations with Canadian indigenous communities to develop guidelines that protect indigenous participants and promote research (CIHR, 2007). Such consultations acknowledge the basic sovereignty and right of self-determination of indigenous peoples as expressed in documents such as the General Assembly Resolution 61/295, United Nations Declaration on the Rights of Indigenous Peoples (UN Declaration). Consultation marks a first step in but does not necessarily imply consent to participate in research.

Consulting with Indigenous Canadians about Research

CIHR established the Aboriginal Ethics Working Group (AEWG) in March 2004 as part of a broader national endeavor to develop the “Guidelines for Health Research Involving Aboriginal People”. The AEWG met to deliberate, discuss and draft the Guidelines over the course of two years. A series of commissioned background papers and contributions from the Aboriginal Capacity and Developmental Research Environments (ACADRE) network informed the deliberations of the AEWG.

The ACADRE network is a unique university-based resource with links to academic research communities and partnerships with regional First Nation, Inuit and Métis communities. Early ACADRE activities focused on work with communities to translate traditional values and ethics into guidance for health researchers.

The CIHR Ethics Office along with the National Council on Ethics in Human Research conducted workshops and consultations with Aboriginal communities, researchers and members of research ethics boards to obtain feedback on the draft Guidelines. CIHR and its partners electronically posted the document to enable widespread access and awareness, and to solicit comments prior to final revision. The Guidelines were then edited by CIHR Ethics Office, in consultation with Health Canada and Justice Canada, to optimize internal consistency, and to ensure that the Guidelines reflected CIHR's mandate (CIHR, 2007).

Complexities of Consent: Requiring free, prior and informed consent in matters pertaining to the well-being of indigenous communities constitutes one of four basic principles structuring the UN Declaration of the Rights of Indigenous Peoples (UN, 2007). Working with local communities to obtain consent, however, raises complexities not encountered in conventional biomedical research protocols. The CIHR guidelines recognize that group consent precedes individual consent among indigenous peoples because they are communitarian. Although individuals may refuse to participate in research, scientists may not even approach individuals without first receiving the community's consent in some instances. In other instances such as obtaining consent from married women as described in the textbox about INMEGEN, individual rights of consent or refusal remain inviolate. In the case of Mexico, INMEGEN sought consent at three levels including the individual, local community and the state.

How the National Institute of Genomic Medicine of Mexico Obtains Consent in Genomic Research

The government of Mexico established the National Institute of Genomic Medicine (INMEGEN) in 2004. INMEGEN's large-scale Mexican Genome Variability Project has included two phases to date. Phase 1 focused on genotyping the Mestizo population across the country including border states who provide many migrants to the USA. Phase 2 focused on genotyping indigenous people. In both phases INMEGEN worked with the Departments of Health in each Mexican state as well as local leaders from participating communities to enable state and local review of the research plans and procedures. INMEGEN implemented a broad, community-based consent process based on 12 questions and answers mounted on public posters, three weeks of public education in each state, and community meetings that enabled local media and community members to ask questions. Before sample collection, each participant had an individual session with an investigator to address any additional questions and sign the consent form with two witnesses of the local community. The consent form, based on the current Federal Laws in Mexico, included the eight guidelines from the International HapMap Project Ethical, Legal and Social Issues Program and reflected the 12-question format of the public campaign. INMEGEN trained local university students to collect samples at the university-based collection stations on behalf of the state governments. Phase 2 posed special challenges because indigenous people speak 65 separate languages, rarely speak Spanish and often lack basic science education. INMEGEN adapted its consent process when working with indigenous communities, including explaining the project in local languages, translating the consent posters into local languages, and consulting with local chiefs to obtain community consent. INMEGEN did not agree to allow men to grant consent for women. People from two indigenous communities joined the university students as trained sample collectors. Some communities obtained healthcare services in exchange for their participation in the project (Seguin et al., 2008; Lara-Alvarez et al, 2007).

Train community members as scientists and healthcare workers: Grassroots research conducted by members of local communities themselves on topics of their own choosing constitutes the gold standard for research in indigenous and developing nations. This approach offers many social and scientific benefits. Training and employing community members as researchers or healthcare workers builds human capital with the potential for yielding general improvements in the local standard of living. Community investigators also make possible “morally valid” consent; that is, consent based on cross-cultural translation of science and local traditions. Examples exist of locally-run Institutional Review Boards such as among the Navajo (University of Arizona, 2008) and the Alaska Native Medical Center (see <http://www.anmc.org/>). Multicultural members of local communities function as “champions” for science as well as protectors of their community. Community investigators help assure that research focuses on topics relevant to local communities, prepare communities for scientific advances and facilitate the adaptation of local culture and customs to changing circumstances. Communities not interested in training as scientists should also be able to benefit from genomic research. The Amish provide a strong example of a community fully interested in participating in genomic research (Ruder, 2004), but not necessarily interested in training as scientists.

The Native American Research Center for Health Initiative

The NARCH initiative is an effort coordinated through the National Institutes of Health and the Indian Health Service to build the research capacity of Federally-recognized Tribes, Tribal Organizations (including Tribal Colleges) and Tribally authorized Indian Health Boards. Specifically, these groups have the opportunity to form partnerships with research institutions and to apply for funding to create a Native American Research Center for Health (NARCH) (IHS, 2008).

The NARCH initiative is founded on the principle that research is most relevant to the needs of Tribes when conceptualized and carried out by members of the organizations themselves. Through providing funding that supports partnerships NARCH seeks to:

- To develop a cadre of AI/AN scientists and health professionals
- To reduce distrust of research by AI/AN communities
- To reduce health disparities (HHS, 2008)

To date, the NARCH initiative is entering its seventh year and fifth funding cycle. The emphasis of the program is to provide funding to AI/AN Tribes or Tribally based organizations in partnerships to conduct high quality biomedical, behavioral and health services research. For FY 2007, NARCH grantees received awards ranging from \$100,000 to over \$1,000,000, for a total budget of more than \$7 million (IHS, 2008). The budget for FY09 is expected to be a minimum of \$3 million (HHS, 2008).

Teach scientists how to work with indigenous and developing nations: The controversies over genomic research and expectations for consultation with local communities justify training scientists in how to conduct research in indigenous and developing communities. Successful cross-cultural interactions depend on people understanding that they see other cultures through their own cultural perspective and bring their own culture to the negotiating table. Colloquium participants made recommendations for training scientists in many specific topics, such as:

1. Respecting the different values held by different groups
2. Understanding the paramount importance of tribal sovereignty and the complexities of consent
3. Engaging in real consultation with communities
4. Recognizing differences between heritage and citizenship for indigenous nations
5. Implementing the methods and value of grassroots and participatory action research, and
6. Incorporating methods and requirements for interdisciplinary community development into research awards.

Capacity Development in Indigenous health research: An Australia Approach

In Australia over the last decade, the National Health and Medical Research Council (NHMRC) has developed a four prong approach to the investment in Indigenous health research as a means of contributing to improving the poor health status which is experienced. With Indigenous health research goals and intentions embedded in the strategic plan, the NHMRC has developed a strong work plan to:

- Provide guidance to the broader research community to focus activity on national priorities, through the development and dissemination of the *Roadmap for Aboriginal and Torres Strait Islander health research*.
- Develop high level ethical & research processes to govern the conduct of research which involves and/or impacts on Indigenous people, including Ethical Guidelines (which have evolved since 1992), and an established *Criteria for Aboriginal and Torres Strait Islander Health Research* which is a part of the national peer-review assessment processes for research grant applications;
- Improve participation of Aboriginal and Torres Strait Islander people in the policy and decision making processes of the NHMRC as the peak national health research body. This entails representation on committees (policy and peer-review), and as members of staff.
- Build capacity of Aboriginal and Torres Strait Islander people to undertake research relevant to their communities, with significant emphasis placed on Indigenous capacity building through the above mentioned Criteria.

Make genomics an “entry point” for community development: The processes of consultation, consent, and training in genomic science and personalized medicine potentially yield many secondary benefits for local communities, including stimulation of multiple paths for community development. Colloquium participants made several suggestions for realizing this potential along the broad path of genomics and personalized medicine, including:

1. Ensure that local communities “own” the results of genomic research by controlling the biological samples and developing the expertise to use the data for local needs and development,
2. Match benefits for local communities to the challenges of specific project steps,
3. Develop the infrastructure for what local communities define as next steps,
4. Identify achievable entry points for communities to adapt genomics to their local needs such as computerized bioinformatics and information management, and
5. Place the highest priority on improving the healthcare of local communities.

Potential Next Steps for the Colloquium

The colloquium identified potential next steps in several categories of action, including:

1. Formalize an organization to support a long term effort:
 - a. Establish a steering committee with a broad range of stakeholders
 - b. Create a secretariat to manage daily operations and promote ongoing work
 - c. Develop a strategic plan to establish a sense of direction and clarify our identity
2. Develop resource materials, including:
 - a. A template for engaging communities for adaptation and refinement by local people
 - b. A standard language that clarifies the story about genomics
 - c. Fact sheets about genomics and personalized medicine
 - d. A list of credible sources about genomics and personalized medicine
 - e. Powerpoint presentation(s) about the colloquium’s work available on the web for download.
3. Develop an information campaign about the issues:
 - a. Develop listservs for technical and public audiences
 - b. Develop webpages for participants and the public with links to stakeholder groups
4. Launch a diplomatic effort to inform global agencies about the issues:
 - a. Develop a list of target agencies in order of priority
 - b. Organize and schedule a series of targeted workshops on relevant, specific topics
 - c. Investigate approaches to the Obama administration through O’Neill contacts (Tim Westmoreland)
 - d. Send a delegation to the next meeting of the UN Permanent Forum on Indigenous Peoples in New York, NY in May 2009.
5. Support internal country discussions and policy initiatives about the issues.

Thematic Analysis References

Alaska Native Medical Center [ANMC]. 2006. [cited on 2008 Dec 16] Available from:<http://www.anmc.org/>

Arizona Court of Appeals. Havasupai Tribe v. Arizona Board of Regents. 2008. [cited 2008 Dec 4]. Available from:
<http://www.cofad1.state.az.us/opinionfiles/CV/CV070454.pdf>.

Canadian Institutes of Health Research [CIHR] CIHR guidelines for health research involving aboriginal people. 2007 May. [cited 2009 Jan 22]. Available online:
<http://www.cihr-irsc.gc.ca/e/29134.html>

Dalton, R. Tribe blasts 'exploitation' of blood samples. Nature Vol 420, Nov 2002

Department of Health and Human Services [HHS]. Indian Health Service Native American Research Centers for Health (NARCH) grants announcement type: new and competing continuations funding announcement number: HHS-2009-IHS-NARCHV-0001. 2008

Hardy BJ, Seguin B, Goodsaid F et al. The next steps for genomic medicine: challenges and opportunities for the developing world. Nat Rev Genet 2008; 9 Suppl 1:S23-7.

Indian Health Service [IHS]. Native American Research Centers for Health, 5th Round (NARCH V). 2008. [cited 2009 Jan 22]. Available from:
<http://www.ihs.gov/medicalprograms/research/narch-V.cfm>

Jimenez-Sanchez G. Developing a platform for genomic medicine in Mexico. Science 2003; 300 (5617):295-6.

Jimenez-Sanchez G, Silva-Zolezzi I, Hidalgo A et al. Genomic medicine in Mexico: initial steps and the road ahead. Genome Res 2008; 18 (8):1191-8.

Lara-Alvarez C, Hidalgo-Miranda A, Silva-Zolezzi I, Balam E, Del Bosque Plata L, March S, Barrientos E, Jimenez-Sanchez G. Ethical, legal and social aspects of the Mexican genomic variability. Project poster presentation at HUGO. 2007

National Health and Medical Research Council [NHMRC]. 2002. The NHMRC road map: a strategic framework for improving aboriginal and Torres Strait islander health through research and final report of community consultations on the NHMRC road map. [cited 2009 Feb 17]. Available online at: <http://www.nhmrc.gov.au/publications/synopses/files/r28.pdf>

National Health and Medical Research Council [NHMRC]. 2003. Values and ethics: guidelines for ethical conduct in aboriginal and Torres Strait

islander health research. [cited 2009 Feb 17]. Available online at:
http://www.nhmrc.gov.au/health_ethics/human/conduct/guidelines/_files/e52.pdf

Ruder K. Genomics in Amish country. Genomic news network. 2004 Jul 23. [cited on 2009 Feb 1] Available from:
<http://www.genomenewsnetwork.org/articles/2004/07/23/sids.php>

Seguin B, Hardy B, Singer PA, Daar, AS. Genomics, public health and developing countries: the case of the Mexican National Institute of Genomic Medicine (INMEGEN). Nat Rev. 2008 October: S5-S8.

United Nations [UN]. Declaration on the Rights of Indigenous Peoples. 2007 Sep 13. [cited 2009 Jan 22] Available from:
<http://www.un.org/esa/socdev/unpfii/en/drip.html>

University of Arizona. Process of conducting research on the Navajo nation. 2008 Oct. [cited on 2009 Jan 30] Available from:
<http://cals.arizona.edu/pubs/natresources/az1472.pdf>

White Paper

Prepared by the research team as background to the colloquium

Introduction

This paper presents the results of background research conducted in preparation for a colloquium on approaches to data sharing and assurance of reciprocal benefits with developing countries and indigenous peoples in genomic research held on January 7-8, 2009 at Georgetown University. The colloquium included representative thought leaders from developing countries, indigenous peoples, genomic science, genomic medicine and global health and constituted the first step in a long term effort to stimulate a global conversation about the implications of genomic science for indigenous peoples and developing countries. As genomic science develops momentum throughout the world, strong arguments exist for assuring its benefits reach peoples in developing countries and indigenous nations. These arguments are particularly persuasive given that genomic science will not reach its full potential in improving the health of the world's people without participation of developing and indigenous peoples as sources of genetic information and as participants in basic and clinical research projects. Projects such as the HapMap project (IHC, 2003), the National Geographic's Human Genome project (NGHG, 2005), biodiversity sampling and pandemic flu strain sharing offer examples from which to learn. Yet, advancing the reciprocal benefits that genomic science can provide also requires hearing the voices and examining the circumstances of developing countries and indigenous peoples. This project will mobilize past experiences with contemporary perspectives to ensure that all people throughout the world reap the benefits of genomic science.

Based on case studies of three developing countries that have launched major genomic science projects, Seguin et al. (2008) identify five factors of a "Roadmap" necessary to assure that developing countries receive benefits from genomic science including political will, local health benefits, institutional leadership, genomic sovereignty, and knowledge-based economy. When successfully implemented, the "Roadmap" for genomic science contributes to "the establishment and potential future success of" genomic science initiatives. Although indigenous peoples worldwide enjoy varying degrees of sovereignty, they almost always live as encapsulated nations in a larger state, dominated by non-indigenous majorities. Thus, they rarely stand structurally placed to accrue benefits from genomic science as described by Seguin et al. (2008). Examining the similarities and differences about the implications of genomic research for the world's developing countries, and indigenous peoples potentially offers a path toward a generalized, global framework for assuring the benefits of genomic science for all.

Indigenous peoples share two factors of the Roadmap, namely concerns for genomic sovereignty and achieving local benefits from genomic science.

1. Genomic sovereignty: Indigenous peoples clearly understand possession and use of their members' genomic information as a question of sovereignty;
2. Local benefits: Thanks to experience with genetic research on diabetes (Ferreira and Lang, 2006) indigenous people will highly value but raise straight questions about benefits to them from genomic science.

These similarities notwithstanding, important differences exist.

1. Political will: the political wills of the national government and of an indigenous government or leadership could easily diverge on genomic science;
2. Institutional leadership: Leaders of different tribal governments or local indigenous communities will undoubtedly vary in their attitudes toward and willingness to participate in genomic science projects. Indigenous people will distrust any public relations campaign about genomic science as pure hype designed to use them for other peoples' benefit.
3. Genomic sovereignty: Intellectual property laws about ownership of discoveries in genomic science will not necessarily ensure return to people who only provide samples.
4. Knowledge-based economy: One cannot assume any benefits of a general knowledge-based economy for encapsulated populations with dependent economies.

With these introductory points, the colloquium set the stage for discussion of four basic questions, namely:

1. What are the similarities and differences in assuring return on contributions to genomic science for developing countries, and indigenous people?
2. What conditions and approaches are necessary to assure benefits of participation in genomic science projects for indigenous people and developing countries, specifically:
 - a. What specific conditions should exist before requesting participation of indigenous peoples and developing countries in genomic science projects (e.g. genetic sovereignty, local self-determination of participation)?
 - b. If no specific benefits from genomic science could easily accrue to indigenous people or developing countries, what other types of (healthcare) benefits should be returned in their stead?
3. What barriers prevent indigenous people from directly participating in genomic science?
4. What principles and mechanisms should define, implement and evaluate the impact of a global framework for guiding introduction and assuring benefits of genomic science for developing countries and indigenous peoples.

Project Design and Methods

This project, "Developing a Framework to Guide Genomic Data Sharing and Reciprocal Benefits to Developing Countries and Indigenous Peoples," was launched on January 7-8, 2009 with a colloquium of invited thought leaders from developing countries, indigenous peoples, genomic science, genomic medicine and global health, including:

Dr. Doris Cook —Ethics Office of Canadian Institutes of Health Research
Dr. Theresa Cullen—United States Indian Health Service
Ms. Jacinta Elston—Medicine, Health, and Molecular Sciences, James Cook University
Ms. Tonya Gonnella Frichner—United Nations Permanent Forum on Indigenous Issues
Dr. James Galloway—United States Public Health Service
Dr. Bette Keltner Jacobs—School of Nursing and Health Studies, Georgetown University
Dr. Gerardo Jimenez-Sanchez —National Genomic Medicine Institute of Mexico
Dr. Ted Mala —Southcentral Foundation
Dr. Clifton A. Poodry—National Institute of General Medical Sciences
Dr. Charles Rotimi—NIH Center for Research on Genomics and Global Health
Rev. Rodrigue Takoudjou, SJ—Department of Pharmacology, Georgetown University
Dr. Ian Wronski—Medicine, Health and Molecular Sciences, James Cook University

The colloquium began with groups of short presentations from each participant on the general topics of “Hearing the Indigenous Perspective”, “Hearing the Perspectives of Developing Countries” and “Implications for Healthcare and Genomic Science”. An open discussion followed the talks on each topic. After hearing and initially discussing the ideas of all participants, the colloquium closed the first day by “Identifying Key Issues” that had emerged from its work. This discussion set the stage for “Tackling the Issues”, the colloquium’s work for the second day. The colloquium closed with a discussion of “Next Steps” to take in the project. The conversations during the colloquium were recorded and transcribed for later use by all participants.

Report: The O’Neill Institute prepared and submitted a colloquium report titled “Thematic Analysis of Colloquium” in partial fulfillment of its obligation to the Personalized Healthcare Initiative, Department of Health and Human Services who helped support the colloquium. The O’Neill Institute sent drafts of the colloquium report to all participants for review, comment and revision. The final report reflected the perspectives of all participants who have received a copy for their own records.

Researchers from the O’Neill Institute and the Personalized Healthcare Initiative began investigating the open literature to better understand the context and content of the colloquium before the colloquium. Without in any way attempting to preempt discussion during the colloquium, we sought to identify common concerns about genomic science, clarify lessons learned from past experience and briefly compare formal codes, guidelines and protocols that have been developed to regulate research and healthcare related to genomic science among indigenous people and developing countries. This background paper explains the results of our work.

Common Concerns about Genomic Science among Indigenous Peoples

The first publication of the human genome sequence in 2001 marked the dawn of the “Post-Genome Era” and led to a new public awareness of genetics and genomics (Lander at al., 2001; Venter et al., 2001). The data generated by these projects were the DNA sequence of a handful of individuals, as they were not designed to capture the diversity of the human genome. Concurrently with sequencing projects, efforts were underway to

capture this diversity by sampling the DNA of many people from distinct geographic locations. The approaches to ethical, legal and social implications (ELSI) of these projects differed, as did their success at interacting with indigenous peoples and residents of developing countries. In some cases, genomic scientists and local communities have effectively collaborated. In others, work has yet to commence. We can learn important lessons from these past experiences (Cavalli-Sforza, 2005).

Case Study 1: The Human Genome Diversity Project

In 1991, as the Human Genome Project began sequencing the human genome, a group of geneticists hypothesized that there was great value in cataloging the genetic variations existing in human populations around the world (Cavalli-Sforza et al., 1991). This idea was the inception of the HGDP. Over the next two years meetings were held to plan this undertaking, including a workshop at the National Institutes of Health on ethical issues and funding (Greely, 2001). In 1993, the Human Genome Diversity Project was launched with the stated mission “to arrive at a much more precise definition of the origins of different world populations by integrating genetic knowledge, derived by applying the new techniques for studying genes, with knowledge of history, anthropology and language.” The proposed plan was to compile genetic information, in addition to biological samples from “populations that are representative of all of the world's peoples.” The aims and protocols of the HGDP were articulated in a meeting summary along with ethical guidelines to address concerns of cultural sensitivity informed consent, intellectual property and racism (Bodmer et al, 1993). The project encountered harsh criticism from organizations speaking out on behalf of many communities, such as Indigenous Peoples Council on Biocolonialism (IPCB, 1995), the Rural Advancement Foundation International (RAFI, 1994). The objections grew from multiple aspects of the HGDP: the assumption of extinction for some groups of indigenous peoples without concomitant assistance to these groups, the potential for discrimination, the lack of control of access to genetic information, the issue of individual and community informed consent, the possibility of biological weapons targeted at indigenous peoples, and the conflict between theories of human migration and the cosmologies of indigenous peoples.

In 1997, the HGDP released a model ethical protocol for collecting DNA samples (Weiss et al., 1997). The National Research Council also undertook an ethical review in 1997 which concluded that there existed “numerous ethical, legal, and human-rights challenges in the prosecution of a global effort and offers possible guidelines to the resolution of some, albeit not all, of the challenges that the committee identifies” (NRC, 1997). The efforts of the HGDP to engage with the targeted populations have not succeeded and the HGDP website reports that no samples have been collected under the auspices of the project in North America, since its last update in August of 2006 (Bodmer et al., 1993). What does this case teach us about conducting genomic science?

Preservation of Self: DNA as a Cultural Identity

Indigenous people share common concerns about the conduct and implications of genetic research in their communities. The most frequent samples used in biological research come from blood, oral/buccal swabs, and hair fragments (Turman, 2001). These samples may continuously regenerate within the body and therefore seem to not be permanently 'lost' from the participant. Such a view depends on the assumption that all participants share a similar concept of the body. Dr. Frank Dukepoo, a Hopi Indian and geneticist, explains that "to us, any part of ourselves is sacred. Scientists say it's just DNA. For an Indian, it is not just DNA, it's part of a person, it is sacred, with deep religious significance. It is a part of the essence of a person" (Petit, 1998). Recognizing that the samples are not merely data, but a valued, sacred, and significant component of a cultural identity is a first step towards identifying mutually satisfactory approaches to further research.

Given the sacrosanct nature of the samples, one approach to DNA research with indigenous communities is regarding the samples as "on loan" to researchers. This reaffirms the indigenous peoples' outright ownership of the biological information (Arbour and Cook, 2006). The researcher is not, under any circumstance, permitted to use the samples for any other study at any time without further specific consent. Recognizing samples in this context would be a critical first step towards discussions of reciprocal benefits and detailing guidelines for additional research.

Who grants consent, the Individual or the Community?

Professor Henry T. Greeley of Stanford Law School notes pursuing DNA samples from indigenous communities is "no more a helicopter science. You can't just fly in, jump out in your white coats, gather some samples and leave" (Petit, 1998). The need to obtain consent for each specific research aim is further complicated by the organizational structures of the indigenous communities. For example, an individual member of the Mohawk community clearly has the right to loan his or her biological samples to researchers. However, that individual may live on a Mohawk reservation, which may identify with a larger Mohawk national community, which in turn is a part of the League of Iroquois and broader still the National Congress of American Indians (Underkuffler, 2007). These self-defined authorities frequently overlap and indigenous governing bodies are rarely acknowledged formally in developed nations (Rosenthal, 2006).

Unclear hierarchical authority within and among indigenous communities has complicated even good-faith efforts made by researchers to obtain proper consent for genetic studies. In 2000, the Australian biotech company Autogen received permission from the Tongan government to collect biological samples from the archipelago's original inhabitants (Schuklenk and Kleinsmidt, 2006). The intent of the research was to investigate diabetes, which was rampant throughout the community. Individual consent from participants was planned, but due to very public objections from community leaders reflecting the views of a minority subset of the prospective participants, all plans were

cancelled for any collection of samples or research with the samples (Schuklenk and Kleinsmidt, 2006).

Representative organizations can be instrumental in drafting general guidelines that are culturally sensitive to Aboriginal communities. The Canadian Institute for Health Research's Guidelines for Health Research Involving Aboriginal People is one promising example of collaboration between government and regional representatives, in this case with First Nation, Inuit, and Métis communities (CIHR, 2007). Regarding community and individual consent, Article 4 of the guidelines states that researchers "should consult community leaders to obtain their consent before approaching community members individually. Once community consent has been obtained, the researcher will still need the free, prior and informed consent of the individual participants" (CIHR, 2007). Though representative leadership is useful in relaying general cultural concerns, consent should ultimately remain on an individual participant level. Participatory research methods are also frequently advocated as a collaborative approach that continuously reaffirms community consent for varying studies based on the same data.

Does genomic science threaten indigenous cosmology or sovereignty?

Indigenous populations are potentially a very valuable source of DNA information. The biological samples are valuable in terms of potential advances in the field of health (including the monetary benefits of patenting), but also valuable in studying the history of populations across the globe. Both of these areas of study present obstacles and risks to indigenous populations, requiring strict and specific guidelines for conducting responsible research. Genetic studies are already offering alternative explanations for human migration patterns over centuries (Daniel, 2001). Some people fear that DNA studies may contradict specific indigenous cultural histories, which could undermine arguments for sovereignty and other legal claims (Harmon, 2006).

Case Study 2: The National Geographic Genographic Project

The Genographic Project, sponsored by IBM and the National Geographic Society, began collecting DNA samples in the spring of 2005 (Behar et al., 2007). This project has a much more circumscribed mission than that of the HGDP. As stated, the "Genographic Project is seeking to chart new knowledge about the migratory history of the human species by using sophisticated laboratory and computer analysis of DNA contributed by hundreds of thousands of people from around the world" (NGGP, 2008). It is clearly stated that this research is focused on human migration and ancestry, the data will be made publicly available, and no cell lines will be created. Furthermore, the project is "nonprofit, nongovernmental, nonpolitical, and noncommercial," and clearly states that no patents will be filed using information gathered by the project. With a decade of experience since the HGDP, the Genographic Project has extensive ELSI information on its website and has created the Genographic Legacy Fund to support education and cultural conservation efforts in communities of indigenous peoples and in developing nations.

Many indigenous people share the excitement for scientific advances from genetic research; however, there are sensitive cultural and political considerations that must be explored further. Council members from the Georgetown tribe in Alaska note the potential for the DNA information to link them with other tribes throughout the continental United States (Harmon, 2006). This could increase solidarity and unite communities facing similar issues with non-indigenous governing bodies. The worry that the research will be used to discredit tribal histories contrasts with the view that research could unite indigenous communities. Dr. Linita Manu'atu, a Tongan senior lecturer at Auckland University of Technology, reaffirms that "for Tongans, we were created in Tonga. We have gods, our own gods, which we created the same as the people of Israel. We have our own stories, but we are being told they're not good enough" (Harvey, 2005). More directly, genomic studies of indigenous populations have been described as "race-based research" which is "highly political" (Harvey, 2005). The stated aims of the research outline a desire to understand how all human beings are related. For some but not all indigenous spokespersons, the conclusions of these investigations have potentially severe consequences for indigenous communities. In addition, a precedent of less-than-honest genetic research by non-indigenous scientists has fostered doubt in the integrity of future studies.

Case Study 3: The International HapMap Project

The International HapMap Project (IHC, 2003) has the goal of developing a map of the human genome, complete with variations that occur in different populations, for the purposes of supporting genome-wide association studies that are the standard investigational protocol to look at common, complex human diseases, such as diabetes and cardiovascular disorders. The HapMap Project also declared its intention to publicly release data in an expedient fashion for use by the larger research community. From the outset, this project focused on ELSI issues that plagued the HGDP and published this framework in *Nature Reviews Genetics* 2004 (Foster, 2004). It incorporated Community Advisory Groups as liaisons between studied populations and the institutional bio-banking specimens and planned community tailored compensation for study participants. Samples for the HapMap Project have been collected from four populations, people of European ancestry in Utah, the Yoruba people of Ibadan, Nigeria, Japanese people from the Tokyo area and Han Chinese from Beijing. The communities from Utah, Tokyo and Beijing are being sampled by researchers from their own country. Interaction with the Yoruban people occurs through an existing collaboration between Howard University and the University of Ibadan. This collaborative group had built a trust with the Yoruba prior to the HapMap Project. In discussions with the National Human Genome Research Institute, several leaders of the Native American health research community expressed a lack of interest in participating in the project. The reasons cited were concerns that the data would be used for population-history studies and comparisons between indigenous populations (Foster, 2004). The leadership of NHGRI, being sensitive to the autonomy of tribes, did not push further.

Distrust in Integrity of Scientific Community

Distrust in the integrity of genetic research has consistently been reinforced through histories of errant misuse of biological samples, as well as institutionalized oppression of indigenous communities. John Liddle, Director of the Central Australian Aboriginal Congress, reaffirms these strong sentiments, articulating that “over the last 200 years, non-Aboriginal people have taken our land, language, culture, health- even our children. Now they want to take the genetic material which makes us Aboriginal people as well” (RAFI, 1994). The list of examples is extensive both in terms of scope of the research conducted without consent, and the length of time the loaned samples have been preserved and studied.

Case Study 4: Misuse of biological samples from the Havasupai Indians

As recently as November 2008, Havasupai Indians were granted permission through the Arizona Court of Appeals to proceed with legal action related to misuse of biological samples taken by Arizona State University and the University of Arizona. Over 200 genetic samples were consensually loaned for diabetes research in the early 1990s. Within two years, researchers published that diabetes was growing too rapidly within the community to be associated with genetics (Havasupai Tribe v. Arizona Board of Regents, 2008). Years after these published findings, the samples were then used without the consent of the Havasupai to investigate schizophrenia, inbreeding, and population migrations (Davenport 2008).

Case Study 5: Misuse of biological samples from the Nuu-chah-nulth

Unethical use of biological samples is not limited to our most recent advances in genetics. Over 25 years ago more than 800 genetic samples were taken from the Nuu-chah-nulth tribe by researchers at the University of British Columbia. The consent was given by the Nuu-chah-nulth to investigate rheumatoid arthritis, which significantly affects their community. These samples have since been used and shared for a variety of different studies, without consent, among many different collaborators throughout the world (Dalton, 2002). Dr. Shiela van Holst Pellekaan, a molecular anthropologist from the University of New South Wales in Sydney, concludes “there have been many instances where information has been given to researchers in an attitude of trust (and an implied, though often not stated) belief that the trust will not be violated. However, because there has often been a fundamental failure on the part of researchers to disclose the full intention of the research project, particularly with regard to publication, the researched have felt betrayed by people who have taken information away, obtained higher degrees from the work, published ...and never returned to the communities concerned” (Pellekaan, 2000).

Lessons Learned from Past Experience

What are the key lessons learned from the range and development of formal codes, guidelines and protocols for conducting genomic research among indigenous people. Genomic surveys ask questions about the biological basis of communities and human history. For this reason, the recent history of genomic research among indigenous peoples and developing countries everywhere on the globe instructs us that researchers

and communities must cultivate trust prior to the initiation of research. Cultivating trust requires

- Communicating project goals to both communities and individuals
- Disclosing and discussing alterations in the initial purposes of a research project as they occur
- Obtaining secondary consent when proposing new uses of collected data and samples

Researchers must actively work to promote mutual understanding of intentions and consequences of research through ongoing dialog between researcher and community. Experience also shows that open-ended studies create more apprehension than focused ones. We must also recognize that the legacy of past projects affects the success of current and future projects.

Survey of Existing Guidelines for Genomic Research with Indigenous Populations

A matrix of existing guidelines for genomic research with indigenous populations presented below (Table I) has been constructed based on the principles outlined by Sharp and Foster (2002) in *An Analysis of Research Guidelines on the Collection and Use of Human Biological Materials from American Indian and Alaska Native Communities*. The table reports and compares the different guidelines/principles currently used by various international organizations. The categories included in the matrix are divided into five complimentary principles: community consultation, sample collection and informed consent, use and storage of biological materials, prioritization of research uses and post-research obligations. Guidelines are individually coded according to the complementary principles based on their inclusion or exclusion of fifteen sub-principles. One axis of the matrix is the fifteen sub-principles. The other axis of the matrix represents individual sets of guidelines listed by organization and year of publication. This work builds on the previous analysis by Sharp and Foster (2002) by applying the existing framework to more recent guidelines for ethical research with indigenous populations. The selection criteria for guidelines is limited to those created by English speaking countries or international bodies which explicitly address genomic research or generally address health research with indigenous populations. A matrix key has been created to provide the guideline name with full citation information for each set of guidelines.

Preliminary observations

- The matrix demonstrates the evolution of research guidelines over time. As late as the mid-1990s guidelines rarely recommended community consultation. Today all of the recent guidelines published by state-run organizations explain the need for individual and community approval on issues such as secondary uses of data and withdrawal of samples.
- The matrix underscores the importance of explicitly consulting communities and individuals in efforts to conduct research with indigenous populations.
- Guidelines have evolved from showing little emphasis on the enumeration of reciprocal benefits to the point where all guidelines require benefit sharing with

contributing populations. An increasing number also take a clear position on how to benefit contributing populations when research leads to commercial applications.

- The overall trend shown in the matrix is a movement towards guidelines that prescribe mutually beneficial and deeply collaborative research partnerships, many of which can be categorized within the framework of participatory research.
- The CIHR guidelines (2007) present the most comprehensive contribution on this issue according to our analysis. The guidelines touch on all fifteen of the coded sub-principles and capture the intended spirit of these principles in a comprehensive and concise manner.

Table I: Survey of Guidelines for Genomic Research with Indigenous Populations

	HUGO Council (1996)	UNESCO (1997)	HGDP (1997)	AIATSIS (2000)	IHS (2001)	AMA (2002)	WHO (2002)	NHMRC (2003)	UNESCO (2003)	NIGMS (2004)	UNESCO (2005)	CIHR (2007)
Community Consultation												
In protocol development			y	y		y	y	y		y	y	y
Before collection of samples	y		y	y	y	y	y	y	y	y		y
Embodies respect for cultural differences	y	y	y	y	y		y	y	y	y	y	y
Formal community approval required			y		y	y	y	y		y		y
Sample Collection and Informed Consent												
Done in a culturally sensitive manner		y	y	y	y		y	y	y	y	y	y
Discussion of a collective harm (e.g. group discr) as part of inform consent process		y	y	y	y		y	y	y	y	y	y
Use and Storage of Biological Materials												
Potential uses defined prior to sample collection				y	y	y	y	y	y	y		y
Provision for withdrawal of samples (IW or CW)			IW,CW	IW,CW		IW	CW	IW,CW	IW	IW,CW	IW	IW,CW
Discussion of secondary uses with contributors (DI or DC)			y	DI			DC		DI	DI,DC		DI,DC
Secondary uses require community approval					y	y	y	y	y	y		y

Prioritization of Research Uses												
Should benefit contributing population	y	y	y	y	y		y	y	y		y	y
Clear position on commercial applications	y	y	y	y			y				y	y
Post-research obligations												
Ongoing research updates to participating communities	y		y	y		y	y	y	y	y	y	y
Community review of study findings before release			y	y	y		y	y	y	y		y
Need to develop local capacities		y	y					y			y	y

Y signifies that the sub-principle is included in the indicated guideline(s).

Matrix Key

HUGO Council (1996): Human Genome Organisation, Ethical, Legal, and Social Issues Committee Statement on the Principled Conduct of Genetic Research. HUGO Ethical, Legal, and Social Issues Committee Report to HUGO Council Bethesda, March 21, 1996.

UNESCO (1997): United Nations Educational, Scientific and Cultural Organization, Universal Declaration on the Human Genome and Human Rights, November 11, 1997.

HGDP (1997): Human Genome Diversity Project, North American Regional Committee, Model Ethical Protocol for Collecting DNA Samples, 1997.

AIATSIS (2000): The Australian Institute of Aboriginal and Torres Strait Islander Studies, Guidelines for Ethical Research in Indigenous Studies, May 2000.

IHS (2001): Indian Health Service, IHS Guidelines for Implementing and Complying with IHS Policy on Specimens, March 31, 2001.

AMA (2002): American Medical Association, Code of Medical Ethics: E-2.079 Safeguards in the Use of DNA Databanks in Genomic Research, 2001.

WHO (2002): World Health Organization, Indigenous Peoples and Participatory Health Research, 2002.

NHMRC (2003): National Health and Medical Research Council, Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research, 2003.

UNESCO (2003): United Nations Educational, Scientific and Cultural Organization, International Declaration on Human Genetic Data. Resolution adopted on the Report of Commission III at the 20th plenary meeting, 16 October 2003.

NIGMS (2004): National Institute of General Medical Sciences, Policy for the Responsible Collection, Storage and Research Use of Samples from Named Populations for the NIGMS Human Genetic Cell Repository, August 25, 2004.

UNESCO (2005): United Nations Educational, Scientific and Cultural Organization, Preliminary Draft Declaration on Universal Norms on Bioethics, Feb. 9, 2005.

CIHR (2007): Canadian Institutes of Health Research, CIHR Guidelines for Health Research Involving Aboriginal People, May 2007.

Appendix - Examples from Biodiversity

Current and past experience in biodiversity research provides an example of existing frameworks in data sharing and reciprocal benefits outside of the realm of human genetics. The International Cooperative Biodiversity Groups and the Convention on Biological Diversity both address the issues of data sharing and reciprocal benefits around international research involving genetic material, generally interpreted as non-human genetic material.

International Cooperative Biodiversity Groups

The International Cooperative Biodiversity Groups (ICBG) program (FIC, 1992) was developed and initiated in 1992 as a collaborative effort of the National Institutes of Health (NIH), the National Science Foundation (NSF) and the U.S. Agency for International Development (USAID) to improve human health through drug discovery, conservation of biodiversity and research on sustainable economic activities for the environment, health, equity and democracy. Funding for this program is managed by the NIH Fogarty International Center and is currently supported by the NIH, NSF and the Department of Energy.

In order to be eligible for funding in the ICBG program, the following objectives must be part of the research proposal (HHS, 2008):

1. Discover and promote development of plants, animals, and micro-organisms and their molecular constituents toward human health therapeutic agents. While not required, an ICBG project may also incorporate microbial research toward energy applications,
2. Undertake biodiversity inventory, and promote conservation and bioresource planning and policy in collaborating countries,
3. Train U.S. and developing country research scientists and transfer research tools related to the scope of the work of this funding opportunity announcement to collaborating research institutions in the developing world, and
4. Establish models for ethical and practical scientific collaboration with biogenetic resources.

In addition, applicants must establish a plan to address issues relating to genetic resources access, intellectual property and benefit-sharing. The ICBG program does not define what may be appropriate in general, but instead requires that investigators work closely with host countries and collaborators to determine the appropriate intellectual property and benefit-sharing for the specific community with which they will work. Award grantees are required to submit their collected bioinventory and drug discovery data to a Global Data Center. This data is considered proprietary, confidential and the property of the grantees and their collaborators.

This program has supported the discovery of over 5,000 plant, animal and fungus species around the world and is currently building research capacity in over 20 institutions. The ICBG funded project working models for intellectual property, benefit-sharing and technology transfer have provided useful information around policy discussions.

Convention on Biological Diversity

The Convention on Biological Diversity is a multilateral treaty that was adopted at the 1992 Earth Summit in Rio de Janeiro (Earth Summit, 1992). It established three main goals:

1. The conservation of biological diversity,
2. The sustainable use of the components of biodiversity, and
3. The fair and equitable sharing of the benefits from the use of genetic resources.

One of the cross-cutting themes of the Convention is access to and sharing of the benefits of genetic resources. The usage of plant genetic resources to develop pharmaceutical products without fair benefits to the source country is an example of what drives this focus, particularly considering that much of the world's biodiversity exists in developing countries. The treaty recognizes that countries have sovereignty over their genetic resources, and therefore access to such biological resources must have "prior informed consent" from the host country, carried out on "mutually agreed terms". The treaty further recognizes that any genetic resources that are used in commercial applications gives the host country right to benefits in a variety of forms, for example cash, equipment, shares of profits or training for national researchers. These benefits sharing arrangements are established separately by individual countries.

Another cross-cutting theme of the Convention is traditional knowledge. Similar to physical genetic resources, the Convention recognizes the close ties of indigenous people to biological resources and the need to ensure benefits from the use of that traditional knowledge. Members of the Convention have agreed to "to respect, preserve and maintain" and encourage benefits sharing from the usage of traditional knowledge.

Lessons Learned

- Host country ownership of plant and animal genetic material is recognized and accepted by participants of the program and/or treaty.
- Prior consent is necessary to access a country's genetic resources and the manner in which access is given must be agreed upon in advance.
- Reciprocal benefits for access to plant and animal genetic material are appropriate and/or necessary.
- Training of national students/researchers is a recommended and/or necessary immediate reciprocal benefit for the host country.
- The Treaty recognizes that compensation is necessary for commercial applications of a host country's genetic resources.
- In general, reciprocal benefits and intellectual property around genetic resources is determined on a country by country basis.

Conclusions

The ICBG program and the Convention on Biodiversity provide examples of efforts to ensure reciprocal benefits to indigenous people and developing countries regarding access to their genetic resources. Both operate on a system that encourages individual agreements with host countries to determine the benefits that are most appropriate for

their local populations. Given that these general lessons are in place for plant and animal genetic resources, are they appropriate to extend to human genetic resources?

References

- Australian Institute of Aboriginal and Torres Strait Islander Studies [AIATSIS]. Guidelines for ethical research in indigenous studies. 2000 May. [cited 2008 Dec 17]. Available from: http://www.aiatsis.gov.au/research_program/?a=2290
- American Medical Association [AMA]. Code of Medical Ethics of the American Medical Association: E-2.079 Safeguards in the Use of DNA Databanks in Genomic Research. 2002. [cited 2008 Dec 17]. Available from: http://books.google.com/books?id=wKsZgYRHkxQC&pg=PA35&lpg=PA35&dq=Safeguards+in+the+Use+of+DNA+Databanks+in+Genomic+Research&source=bl&ots=rrfHKbtGFZ&sig=cxmi1o2T0zTambIkMWN5uLDs8u0&hl=en&sa=X&oi=book_result&resnum=3&ct=result
- Arbour L, Cook D. DNA on Loan: Issues to Consider when Carrying Out Genetic Research with Aboriginal Families and Communities. *Community Genetics*, 2006
- Arizona Court of Appeals. Havasupai Tribe v. Arizona Board of Regents. 2008. [cited 2008 Dec 4]. Available from: <http://www.cofad1.state.az.us/opinionfiles/CV/CV070454.pdf>.
- Bodmer J, Bodmer W, Cavalli-Sforza LL et al. Summary document incorporating the HGDP outline and development, proposed guidelines, and report of the International Planning Workshop. Porte Conte, Sardinia, June 9-12, 1993. [cited 2008 Dec 11]. Available from: <http://www.stanford.edu/group/morrinst/hgdp/summary93.html>
- Cavalli-Sforza L. The Human Genome Diversity Project: past, present and future. *Nature Reviews Genetics* 2005; 6 (4):333-40.
- Cavalli-Sforza LL, Wilson AC, Cantor CR et al. Call for a worldwide survey of human genetic diversity: a vanishing opportunity for the Human Genome Project. *Genomics* 1991; 11 (2):490-1.
- Canadian Institutes of Health Research [CIHR] CIHR guidelines for health research involving aboriginal people. 2007 May. [cited 2008 Dec 2]. Available from: <http://www.cihr-irsc.gc.ca/e/29134.html>
- Dalton, R. Tribe blasts 'exploitation' of blood samples. *Nature* Vol 420, Nov 2002
- Daniel Jr., R. The First Americans: The pleistocene colonization of the new world. [Review], *Journal of Field Archaeology* Vol 28, 2001

Davenport, P. Court revises Arizona tribe's lawsuit over research. *Contra Coast Times* [Internet]. 2008 Dec. [cited 2008 Dec 29]. Available from: http://www.contracostatimes.com/nationandworld/ci_11101736

Department of Health and Human Services [HHS]. International Cooperative Biodiversity Groups. 2008 Sep 9. [cited 2008 Dec 15] Available from: <http://grants.nih.gov/grants/guide/rfa-files/RFA-TW-08-010.html>

Earth Summit. UN Conference on Environment and Development. 1992. [cited 2008 Dec 15] Available from: <http://www.un.org/geninfo/bp/enviro.html>

Ferreira, ML and Lang, GC editors. *Indigenous peoples and diabetes: community empowerment and wellness*. Carolina Academic Press 2006.

Fogarty International Center for Advanced Studies in Health Science [FIC]. International Cooperative Biodiversity Groups. 1992. [cited 2008 Dec 9] Available from: http://www.fic.nih.gov/programs/research_grants/icbg/

Foster MW. Integrating ethics and science in the International HapMap Project. *Nature Reviews Genetics* 2004; 5 (6):467-75.

Greely HT. Human genome diversity: what about the other human genome project? *Nat Reviews Genetics* 2001; 2 (3):222-7.

Harmon, A. DNA Gatherers hit snag: tribes don't trust them. *New York Times*. Dec 10, 2006

Harry D. The human genome diversity project and its implications for indigenous peoples. 1995. [cited 2008 Dec 11] Available from: http://www.ipcb.org/publications/briefing_papers/files/hgdp.html

Harvey, C. Stirring up the gene pool. *New Zealand Herald*. Jul 29, 2005

Human Genome Diversity Project, North American Regional Committee [HGDP]. Model ethical protocol for collecting DNA samples. 1997. [cited 11 Dec 2008] Available from: http://www.ncbi.nlm.nih.gov/pubmed/12627556?ordinalpos=19&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DefaultReportPanel.Pubmed_RVDocSum.

Human Genome Organization [HUGO]. Statement on the principled conduct of genetics research. 1996 Mar 21. [cited 2008 Dec 9] Available from: <http://www.eubios.info/HUGO.htm>.

Indian Health Service [IHS]. IHS guidelines for implementing and complying with IHS policy on specimens. 2001 Mar 31. [cited 2008 Dec 11] Available from: <http://www.aatchb.org/epi/docs/ResearchEthics/T3-Specimen.pdf>

International HapMap Consortium [IHC]. The International HapMap Project. *Nature* 2003; 426 (6968):789-96.

Lander ES, Linton LM, Birren B et al. Initial sequencing and analysis of the human genome. 2001. *Nature*; 409 (6822):860-921.

National Research Council. Evaluating human genetic diversity, Series Evaluating Human Genetic Diversity. Washington, DC: National Academy; 1997.

National Geographic Genographic Project [NGGP]. A landmark study of the human journey. [cited 2008 Dec 10] Available from: <https://genographic.nationalgeographic.com/genographic/index.html>

National Health and Medical Research Council [NHMRC]. Values and ethics: guidelines for ethical conduct in aboriginal and torres strait islander health research. 2003. [cited 2008 Dec 16]. Available from: http://www.nhmrc.gov.au/health_ethics/human/conduct/guidelines/_files/e52.pdf.

National Institute of General Medical Sciences [NIGMS]. Policy for the responsible collection, storage and research use of samples from named populations for the NIGMS human genetic cell repository. 2004 Aug 25. [cited 2008 Dec 12] Available from: <http://ccr.coriell.org/Sections/Support/NIGMS/CollPolicy.aspx?PgId=220>.

Pellekaan S. Genetic research: what does this mean for Indigenous Australian communities?. *Australian Aboriginal Studies*. Mar 2000 65-75

Petit C. Trying to study tribes while respecting their cultures. *San Francisco Gate*. Feb 19, 1998

Rural Advancement Foundation International [RAFI, now ETC Group]. The Patenting of human genetic material. 1994. [cited on 2008 Dec 16] Available from: http://www.etcgroup.org/en/materials/publications.html?pub_id=501z

Rosenthal, JP. Politics, culture, and governance in the development of prior informed consent in indigenous communities. *Current Anthropology*. Vol 47:1 2006 Feb.

Schuklenk U, Kleinsmidt A. North-south benefit sharing arrangements in bioprospecting and genetic research: A Critical Ethical and Legal Analysis. *Developing World Bioethics* 2006 Vol 6: 3. 2006

Seguin B, Hardy B, Singer P, Daar, A. Genomic science and developing countries: creating a room of their own. *Nature Reviews Genetics* Jun 2008: 487-493.

Sharp R, Foster M. An analysis of research guidelines on the collection and use of human biological materials from American Indian and Alaska Native communities. 2002. *Jurimetrics* 42:165-186.

Turman K. Understanding DNA evidence: a guide for victim service providers. United States Department of Justice. 2001. [cited on 2008 Dec 11]. Available from: http://www.ojp.usdoj.gov/ovc/publications/bulletins/dna_4_2001/NCJ85690.txt

Underkuffler L. Human genetics studies: the case for group rights. *The Journal of Law, Medicine & Ethics* Fall 2007

United Nations Educational, Scientific and Cultural Organization [UNESCO]. Universal declaration on the human genome and human rights. 1997 Nov 11. [cited 2008 Dec 15] Available from: http://portal.unesco.org/shs/en/ev.phpURL_ID=1881&URL_DO=DO_TOPIC&URL_SECTION=201.html.

United Nations Educational, Scientific and Cultural Organization [UNESCO]. International declaration on human genetic data. 2003 Oct 16. [cited 2008 Dec 15]. Available from: http://portal.unesco.org/en/ev.phpURL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=201.html

United Nations Educational, Scientific and Cultural Organization [UNESCO]. Preliminary draft declaration on universal norms on bioethics. 2005 Feb 9. [cited 2008 Dec 15] Available from: http://portal.unesco.org/shs/en/files/7359/11087373831Preliminary_Draft_EN.pdf/Preliminary_Draft_EN.pdf.

Venter J, Adams M, Myers E et al. The sequence of the human genome. *Science* 2001; 291 (5507):1304-51.

Weijer C, Goldsand G, Emanuel E. Protecting communities in research: current guidelines and limits of extrapolation. *Nature Genetics* 1999 Nov; 23(3): 275-280

Weiss K, Cavalli-Sforza L, Dunston G et al. Proposed model ethical protocol for collecting DNA samples. *Houst Law Review* 1997; 33 (5):1431-74.

World Health Organization [WHO]. Indigenous peoples and participatory health research. 2002. [cited on 2008 Dec 17] Available online at: http://www.who.int/ethics/Indigenous_peoples/en/index.html

Glossary of Terms

Communitarian: Unlike classical liberalism, which construes communities as originating from the voluntary acts of pre-community individuals, “communitarian” groups emphasize the role of the community in defining and shaping individuals. In the context of this report, it refers to the tendency of many local people in Indigenous nations and developing countries to require consultation and consent with community representatives before approaching individuals about participating in research projects.

Community Investigators: people who conduct and/or assist in conducting research about their own communities. See also “grassroots research”.

Developing Countries: No single criterion exists for unambiguously distinguishing “developed” from “developing” countries. Common practice labels Japan in Asia, Canada and the United States in North America, Australia and New Zealand in Oceania, and Europe as “developed” regions or areas because of their high Gross National Products, high level of per capita income or high level of industrialization. Countries that combine these kinds of measures in various ways warrant designation as “developing”. (Soubbotina, T, *Beyond Economic Growth: Meeting the Challenges of Economic Growth*, Washington, DC: World Bank, 2000)

Free, Prior and Informed Consent: The underlying principles of free, prior and informed consent can be summarized as follows: (i) information about and consultation on any proposed initiative and its likely impacts; (ii) meaningful participation of indigenous peoples; and, (iii) representative institutions. (Secretariat of the Permanent Forum on Indigenous Issues, Jan. 2005)

Genetic Sovereignty: in the context of global research about genomics, genetic sovereignty refers to the capacity of a people, country or nation to own, control access to and use of samples, data and knowledge of human, plant or animal genes.

Genomic medicine, science and research: the adjective “genomic” modifies medicine, science and research concerning interactions of human genes with each other and an individual’s environment. Genomics involves the scientific study of complex diseases such as heart disease, asthma, diabetes and cancer because they are caused more by a combination of genetic and environmental factors. Genomics offers new possibilities for therapies and treatment of some diseases, as well as new diagnostic methods. The major tools and methods related to genomics studies are bioinformatics, genetic analysis, measurement of gene expression, and determination of gene function (NHGRI, Frequently Asked Questions about Genetic and Genomic Science, <http://www.genome.gov/19016904>). See also, (Genomics and World Health: Report of the Advisory Committee on Health research, Geneva, WHO (2002)) and (WHA 57.13: Genomics and World Health, Fifty Seventh World Health Assembly Resolution; 22 May 2004)

Genotype: The genetic identity of an individual that does not show as outward characteristics. (NHGRI Talking Glossary, Available from: <http://www.genome.gov/glossary.cfm?key=genotype>)

Grassroots Research: quantitative and qualitative approaches to research that engage members of local communities in the identification of topics, conduct and/or analysis of research. Also known as “participatory action research”, this approach usually but not always focuses on “applied” research about topics of immediate concern to local communities.

“helicopter research”/ “safari research”: a term that refers disparagingly to research projects that drop into communities, collect data and leave without establishing any short or long term relationship with local people.

Indigenous Communities, Nations and Peoples: Indigenous communities, peoples and indigenous nations are those who, having a historical continuity with societies prior to the invasion and pre-colonial societies that developed in their territories, consider themselves different from other sectors of society now prevailing in those territories or parts thereof. They currently comprise non-dominant sectors of the society and are determined to preserve, develop and transmit to future generations their ancestral territories and ethnic identity as a foundation for their continued existence as a people, according to their own cultural patterns, social institutions and legal systems. (UN Permanent Forum on Indigenous Issues, <http://www.un.org/spanish/indigenas/2003> Available from: http://siteresources.worldbank.org/BOLIVIA/Resources/Bolivia_CSA_ANNEX_2.1_Def_of_Indig_Peoples.pdf)

Multicultural: Of or relating to or including several cultures (Webster’s Online Dictionary, Available from: <http://www.websters-onlinedictionary.org/definition/multicultural>)

Personalized Medicine: The use of individual molecular (often genetic) information to prevent disease, choose medicines and make other critical decisions about health. (Biotechnology Industry Organization, Science for Life, 2009, Available from: http://www.bio.org/speeches/pubs/er/glossary_p.asp)

Self-Determination: The principle of self-determination refers to the right of a people to determine its own political destiny. (Encyclopedia of American Foreign Policy, 2002, Available from: (http://findarticles.com/p/articles/mi_gx5215/is_2002/ai_n19132482)

Sovereignty: is the right or capacity of countries to determine their own affairs. More specifically, it is the right of the supreme political authority - usually a government - to unqualified and unrivalled authority over its people and land. Sovereignty and the concept of the nation state are closely related. It is argued that globalization is eroding the world of sovereign states, and that many national decisions are now influenced by global forces. This issue is also referred to as global democracy deficit. (WHO, Available from: <https://www.who.int/trade/glossary/story082/en/index.html>)

Colloquium Schedule

Wednesday, January 7, 2009

8:30 BREAKFAST

Welcome and introductions

9:00 Howard Federoff, Executive Vice President, GUMC

9:10 Bette Jacobs, Dean, School of Nursing and Health Studies

9:20 Greg Downing, Director, Personalized Healthcare Initiative, HHS

Hearing Indigenous Perspectives

9:30 Tonya Gonnella Frichner

9:45 Jacinta Elston

10:00 Doris Cook

10:15 Katherine Gottlieb

10:30 Bette Jacobs

10:45 BREAK

11:00 Open Discussion

Hearing Perspectives of Developing Countries

11:30 Gerardo Jimenez-Sanchez

11:45 Charles Rotimi

12:00 Rodrigue Takoudjou

12 :15 LUNCH

1:15 Open Discussion

Implications for Healthcare and Genomic Science

1:45 Jim Galloway

2:00 Theresa Cullen

2:15 Ian Wronski

2:30 Clifton Poodry

2:45 BREAK

3:00 Open Discussion

Identifying Key Issues

3:30 Open discussion

7:00 DINNER

Thursday, January 8, 2009

8:30 BREAKFAST

Tackling the Issues

9:00 Review previous day's discussions

9:15 Open discussion

10:30 BREAK

10:45 Continue open discussion

12:00 LUNCH

1:00 Next Steps

2:00 End colloquium

Colloquium Presenters
Biographical Sketches

Doris Cook, Ph.D., M.P.H.

Doris Cook has done extensive work in developing research ethics protocols for health research projects involving Canada's First Nations peoples. Between 2003 and 2007, she was the Manager, Aboriginal Ethics Policy Development in the Ethics Office, CIHR where she coordinated the development of the new Aboriginal research guidelines. Prior to the assignment with the CIHR, she spent 10 years in the Policy Division at Health Canada where she was the lead analyst on files such as ethics, genetics and assisted human reproduction. She was part of the Canadian delegation that negotiated UNESCO's Declaration on the Human Genome and Human Rights and represented Canada at the Council of Europe's Standing Committee on Ethics. She has recently provided advice and assistance on the development of draft guidelines on access and benefit sharing for accessing Aboriginal traditional knowledge associated with genetic resources in Canada. She is also involved in ethics review at the community level in her First Nation community. Doris is a member of the Akwesasne Mohawk Nation, a territory that comprises parts of the state of New York and the two Canadian provinces of Ontario and Quebec.

Theresa Cullen, M.D., M.S.

Theresa Ann Cullen, M.D., M.S., is the Chief Information Officer (CIO) and Director of the Office of Information Technology for the Indian Health Service (IHS), an agency within the Department of Health and Human Services. As CIO, Dr. Cullen oversees a diverse range of agency functions in information systems planning, development, and management. Dr. Cullen is a commissioned officer in the U.S. Public Health Service and holds the rank of Captain.

Dr. Cullen began her IHS career in 1984 as a General Medical Officer at the IHS Hospital in San Carlos, Arizona, where she served as the Maternal Child Health Coordinator, EMS Coordinator, and the Health Promotion/Disease Prevention Coordinator. From 1986 to 1988, she served as the Tucson Program Area Maternal Child Health Coordinator and Area HIV Coordinator at the Sells IHS Hospital in Sells, Arizona. Dr. Cullen returned to the IHS following post graduate work, as a General Medical Officer and Clinical Director at the Sells IHS Hospital from 1991 to 1999. She directed the Department of Clinical Services, oversaw health care to the Tohono O'odham population, provided administrative oversight to field and school clinics, and managed clinical performance improvement activities. From 1999 to July 2006, Dr. Cullen served the IHS as the OIT Senior Medical Informatics Consultant in Tucson, Arizona. In this position, she served as the RPMS Program Manager, Physician/Clinical Advisor, and the IHS lead on interagency agreements with National Aeronautics and Space Administration and the Administration for Children and Families.

Among Dr. Cullen's numerous honors are the Meritorious Service Medal; Outstanding Service Medal; Achievement Medal; Commendation Medal; Unit Citation Medal; Davies Award for Public Health from the Healthcare Information and Management Systems Society; HHS Secretary's Award for Distinguished Service for the Intradepartmental Team for the FY03 Accelerated Financial Audit and Reporting and the Agency for Healthcare and Research Quality Health Information Technology Group-2004; and the IHS Director's Award. Dr. Cullen has also authored numerous publications during her career.

After receiving a bachelor of philosophy and biology degree from Johnston College in Redlands, California, in 1978, Dr. Cullen earned a doctor of medicine degree from the University of Arizona, College of Medicine, in Tucson, Arizona. In 2001, she earned a master of science degree in administrative medicine and population health from the University of Wisconsin in Madison, Wisconsin. Dr. Cullen is Board Certified in Family Practice and has a certification in Addiction Medicine from the American Society of Addiction Medicine.

Jacinta Elston, M.S.

Associate Professor Jacinta Elston, an Aboriginal and South Sea Islander woman from north Queensland in Australia is a descendent of the Kalkadoon people of north-west Queensland. She is a master's graduate with Public Health and Tropical Medicine qualifications from the Faculty of Medicine, Health and Molecular Sciences at James Cook University. Her Masters was received in 1998 and her Diploma in 1994.

Prof Elston Chairs the James Cook University Medical School's Aboriginal and Torres Strait Islander Student Selection Committee, and is a current member of the Research Committee of the National Health and Medical Research Council (Australia), having previously served on the NHMRC's Research Agenda Working Group for Aboriginal and Torres Strait Islander people. Jacinta is also an independent ministerial appointee to the National Breast and Ovarian Cancer Centre, and has served on the National Aboriginal and Torres Strait Islander Health Council.

Prof Elston holds the position of Associate Dean Indigenous Health, in the Faculty of Medicine, Health and Molecular Sciences at James Cook University in Townsville., Australia.

Tonya Gonnella Frichner, J.D.

Ms. Gonnella Frichner, Esq., Snipe Clan, Onondaga Nation, Haudenosaunee, Iroquois Confederacy, is President and founder of the American Indian Law Alliance in New York, a lawyer and activist, whose academic and professional life has been devoted to the pursuit of human rights for Indigenous peoples. Recently, she was brought forward by Indigenous nations, peoples, and communities and appointed as the North American

Regional Representative to the United Nations Permanent Forum on Indigenous Issues (2008-2011) by the President of the United Nations Economic and Social Council.

She earned a Bachelor of Science Degree, magna cum laude, from St. John's University in NYC, and her Juris Doctor from the City of New York Law School at Queens College, where she is a member of the Board of Visitors. Ms. Gonnella Frichner also sits on the Board of Directors and serves as legal counsel to the Iroquois Nationals lacrosse team, international competitors at the World Cup level representing the Haudenosaunee Confederacy. She also serves as an Adjunct Professor of American Indian history, law, and human rights.

In 1987, shortly after graduation from law school, she served as a delegate for and was of legal counsel to the Haudenosaunee at the UN Sub-Commission on the Human Rights/Working Group on Indigenous Populations in Geneva, Switzerland. Since that time, Ms. Gonnella Frichner has actively participated in international forums for Indigenous peoples. She has worked closely with elders from the Haudenosaunee Confederacy (especially the Onondaga nation) and the Lakota Nation (through the Teton Sioux Nation Treaty Council). Her most recent efforts were focused on the process of the establishment of the Permanent Forum On Indigenous Issues, and the negotiation processes concerning adoption of the "UN Declaration on the Rights of Indigenous Peoples" and the proposed OAS "Declaration on the Rights of Indigenous Peoples."

For her work with Indigenous peoples, Ms. Gonnella Frichner has been honored with (to name just a few) the Harriet Tubman Humanitarian Achievement Award, the Female Role Model of the Year (one of 10) of the Ms. Foundation for Women, the Thunderbird Indian of the Year Award, Ellis Island Medal of Honor, and the NY County Lawyers Association Award for Outstanding Public Service. Most recently, she was a recipient of the Alston Bannerman Fellowship. She sits on several boards, including the Seventh Generation Fund and the Boarding School Healing Project.

James M. Galloway, M.D.

Dr. Galloway was appointed to the position of RHA on March 6th, 2007 by the Assistant Secretary of Health (ASH) and is the lead federal physician, the principal federal public health official and the senior USPHS officer for Region V, which encompasses the states of Illinois, Indiana, Michigan, Minnesota, Ohio and Wisconsin. Dr. Galloway serves as the Department's principal representative for public health in the field for this region. Dr. Galloway provides advice on matters of health care and public health and participates in policy development and implementation at the regional and national levels. As the Regional Health Administrator, Dr. Galloway's leadership responsibilities include disease prevention, health promotion, women's and minority health, the reduction of health disparities, the fight against HIV/AIDS, the Medical Reserve Corps, pandemic influenza and emergency planning. He is actively involved in the push for enhanced access to quality health care.

Dr. Galloway was also appointed by the Assistant Secretary for Preparedness and Response as the Senior Federal Official for Pandemic Influenza and Bioterrorism for Region C (covering 12 states of the Midwest and west). Dr. Galloway is now an Adjunct Professor at Northwestern College of Medicine. He was previously assigned to the University of Arizona where he remains an Associate Professor of Clinical Medicine in the College of Medicine as well as an Associate Professor of Public Health in the College of Public Health. As Director of the Native American Cardiology Program prior to coming to Chicago, Dr. Galloway organized and provided direct cardiac care to Native Americans in Arizona, Nevada, Utah, California and New Mexico. He was the senior cardiologist nationally for the Indian Health Service and the director of the National Native American CVD Prevention Program.

Dr. Galloway works with the American College of Cardiology in its efforts with the American Diabetes Association in the “Make The Link” Program, an educational and public health approach focusing on the link between diabetes and heart disease. For this work, Dr. Galloway received the national American Diabetes Association’s 2003 C. Everett Koop Award for Health Promotion and Awareness on behalf of the American College of Cardiology. He is also involved in a number of Tribally requested research initiatives, including the Strong Heart Study and the SANDS (Stop Atherosclerosis in Native Diabetics) Study and is a founder and active leader in the ‘Pathways Into Health’ tribal, academic and federal and tribal collaboration for the development and education of American Indian and Alaska Native health care professionals utilizing the strengths of distance learning, cultural integration and interprofessional education. He is also a co-founder and leader in the large collaborative entitled “Building A Healthier Chicago,” an urban wellness intervention being developed as a national model.

Bette Keltner Jacobs, Ph.D.

Bette Jacobs has served as dean of Georgetown University School of Nursing & Health Studies (NHS) since 1999.

During her tenure, Jacobs has overseen a substantial growth in the school’s research portfolio, the recruitment of high profile scholars, and the continued development of four vibrant academic departments in Health Systems Administration, Human Science, International Health, and Nursing.

Jacobs has led the school through significant improvements in key facilities, including the full restoration of St. Mary’s Hall, the NHS home on Georgetown University’s campus; the addition of the O’Neill Family Foundation Clinical Simulation Center; and the opening of the Discovery Center. In 2006, NHS and Georgetown University Law Center announced their co-founding of the Linda and Timothy O’Neill Institute for National and Global Health Law.

In addition, Jacobs continues to publish in her field, which involves children with disabilities, maternal health, healthy equity, and health among American Indian communities. She is currently among a group of researchers on a five-year R01 grant

from the National Institute of Child Health and Human Development to study, “Preventing Child Neglect in High Risk Mothers.”

From 1997-2000, Jacobs was president of the National Alaska Native American Indian Nurses Association. She remains active in many professional organizations, including the American Association of Mental Retardation, American Nurses Association, American Academy of Nurses, National Alaska Native American Indian Nurse Association, American Public Health Association, National Council of University Research Administrators, Society for the Advancement of Chicanos and Native Americans in Science, and National Coalition of Ethnic Minority Nurse Associations (treasurer). In 2007, she also became of a member of an advisory council of the Reading Is Fundamental (RIF) Multicultural Literacy Campaign. She is a Fellow of the American Academy of Nursing (FAAN).

Gerardo Jimenez-Sanchez, M.D., Ph.D.

Dr. Gerardo Jimenez-Sanchez was born in Mexico City in 1965. He obtained his Medical Doctor degree from the National Autonomous University of Mexico (UNAM). He did his residency in Pediatrics at the National Institute of Pediatrics and earned his Ph.D. degree in Human Genetics and Molecular Biology from the Johns Hopkins University in Baltimore, MD, USA. He received his diploma in business administration from the IPADE Business School.

Dr. Jimenez-Sanchez is Director General of the National Institute of Genomic Medicine of Mexico, Professor of Genomic Medicine at the National Autonomous University of Mexico and Investigator of the Mexican Health Foundation. He is affiliate member to the Institute of McKusick-Nathans Institute of Genetic Medicine at the Johns Hopkins University. In August 2003, he was elected Founder President for the Mexican Society of Genomic Medicine and served as President of the I and II National Congresses of Genomic Medicine in 2004 and 2006.

Dr. Jimenez-Sanchez is a founder member of the National Commission for the Human Genome in Mexico and member of the Mexican Academy of Pediatrics, the Mexican Society of Pediatrics, the Mexican Association of Human Genetics, and the Mexican Society of Biochemistry. In 2007, became member of the Board of Directors, P3G (Public Population Projects in Genetics) International Consortium, Canada. In 2007, he was elected Chairman of the Working Party on Biotechnology at the Organization for Economic Co-operation and Development (OECD).

He is the leading investigator in the Mexican Genomic Diversity Project and the Mexican Medical Resequencing Initiative. His current research focuses on the study of human disease causing genes, production of animal models for the study of human diseases and the development of genomic medicine in Mexico. He is Course Director in following graduate courses: “Introduction to Genomic Medicine”, “Genomic Applications to Clinical Pediatrics” and “Genomics in Internal Medicine”, first of its kind in Latin

America. Dr. Jimenez-Sanchez' work has resulted in the publication of articles and chapters in specialized journals and books. He received the Research in Pediatrics Award of the Society for Pediatric Research in 1999. Along with his colleagues David Valle and Barton Childs, he produced the first medical analysis of the human genome, published with the first draft of the human genome in *Nature* in 2001. He received the National Award in Clinical Investigation "Dr. Miguel Otero" from the Government of Mexico. In April of 2003, he was appointed Silanes Professor in Genomic Medicine. In 2004, he received the Golden Masters Award from the International Forum of Business Administration.

Ted Mala, M.D., M.P.H.

Dr. Mala received his Doctor of Medicine and Surgery (MD) from the Autonomous University of Guadalajara in 1976 and a Master's Degree of Public Health (MPH) from Harvard University in 1980. He has actively pursued his career in Public Health and Health Administration both in Alaska as well as internationally in the circumpolar countries.

As the first Secretary General of the International Union of Circumpolar Health, he worked extensively in northern countries which resulted in his founding the Circumpolar Health Institute at the University of Alaska at Anchorage. During that time, he was awarded a NIH Fogarty US-USSR Fellowship to work in the Siberian Branch of the Academy of Medical Sciences at Novosibirsk. In the year 2000, he was elected a member of the Russian Siberian Academy of Polar Medicine.

In 1990, he joined the Cabinet of Alaska Governor Walter J. Hickel to become the first Alaska Native Commissioner of Health and Social Services. The Department had two thousand employees and a billion dollar budget. It included seven divisions: social services, juvenile corrections, public health and mental health as well as public assistance, medical assistance and substance abuse prevention.

In 2001, Dr. Mala was elected President of the national Association of American Indian Physicians and in 2008 was elected by his peers as "Indian Physician of the Year". He also served on the Council of Public Representatives of the National Institutes of Health in 2002 and continues to serve as an advisor on Native American issues to various NIH Institutes and Centers as well as a grant reviewer.

Currently Dr. Mala has been at Southcentral Foundation for the past decade serving as Director of Traditional Healing at the Alaska Native Medical Center and Director of Tribal Relations at SCF. SCF is the Alaska Native health corporation that serves the Anchorage area as well as 55 villages. He assists the President of SCF in tribal negotiations as well as representing Native American concerns at NIH.

As an Alaska Native Inupiat Eskimo enrolled in the Village of Buckland as well as the Northwest Arctic Native Association (NANA) in Kotzebue, he integrates those values with his Russian heritage to assist other Native people to "walk in two worlds with one

spirit". He lectures on circumpolar medicine as well as the role of Native Americans in health research. His father was Ray Mala, the first Native American film star whose credits included the Oscar winning film "Eskimo" (1932). He has two children who are in California working in the film and television industry.

He is a frequent visitor to Hawaii collaborating with the Department of Native Hawaiian Health at the John A. Burns School of Medicine at Honolulu.

Clifton A. Poodry, Ph.D.

Clifton A. Poodry is the Director of the Minority Opportunities in Research (MORE) Division at the National Institute for General Medical Sciences (NIGMS), NIH. He is responsible for developing and implementing NIGMS policies and plans for minority research and research training programs. He also serves as a liaison between NIGMS and NIH, other federal agencies and the scientific community.

Prior to assuming this position in April of 1994, Dr. Poodry had been a Professor of Biology at the University of California, Santa Cruz where he also served in several administrative capacities. As a professor, Dr. Poodry was involved with minority student development through the NIH sponsored Minority Biomedical Research Support (MBRS) and Minority Access to Research Careers (MARC) Programs. Over the years, he also served on the NIH review committees for both programs.

As a Program Director for Developmental Biology at the National Science Foundation, Poodry developed the minority supplement initiative that was copied widely at NSF and later at NIH.

Dr. Poodry is a native of Tonawanda Seneca Indian Reservation in Western New York. He earned both a B.A. and an M.A. in Biology at the State University of New York at Buffalo, and received a Ph.D. in Biology from Case Western Reserve University. He was the 1995 recipient of the Ely S. Parker Award from the American Indian Science and Engineering Society for contributions in science and service to the American Indian community. In 1999 he received an Honorary Doctor of Science Degree from the State University of New York.

Charles Rotimi, Ph.D., M.P.H.

Dr. Rotimi is the Director of the Center for Research on Genomics and Global Health (CRGGH), whose mission is to advance research into the role of culture, lifestyle, genetics and genomics in health disparities. Dr. Rotimi develops genetic epidemiology models and conducts population genetics research that explores the patterns and determinants of common complex diseases in the African diaspora and other human populations.

A key focus of Dr. Rotimi's research is understanding the triangular relationship between obesity, hypertension, and diabetes, which together account for more than 80% of the

health disparity between African Americans and European Americans. Genetic epidemiology models developed by his group are helping to address whether high disease rates are the result of exposure to environmental risk factors, genetic susceptibility, or an interaction between the two.

Dr. Rotimi has been extensively involved in a number of genetic epidemiology projects that are being conducted in several African countries and in the United States. These projects have included the Africa America Diabetes Mellitus (AADM) study, the Howard University Family Study, the Genetics of Obesity in Blacks Study, and the Engagement of African Communities for the International HapMap Project.

Dr. Rotimi's group is engaged in the first genome-wide scan of an African American cohort, with the goal of identifying genes associated with obesity, hypertension, diabetes, and metabolic syndrome. More than 2,000 participants from multigenerational African American families are enrolled in this large-scale genetic epidemiology study. In collaboration with investigators at the Coriell Institute for Biomedical Research, this research will explore how the genome-wide association study (GWAS) approach can inform complex disease mapping in a genetically admixed population such as African Americans.

Dr. Rotimi's group is also participating in the Black Women's Health Study, a national longitudinal study begun in 1995 to determine the underlying cause of selected illnesses in black women. It includes 59,000 women aged 21 to 69 at the time of enrollment. Over 25,000 DNA samples have been processed to date, and the data derived from these samples are being used in a number of scientific investigations, including those examining the genetic bases of cancer, diabetes and lupus.

Since much of his research activities are focused on vulnerable populations, Dr. Rotimi is collaborating with investigators at Case Western Reserve University and the University of Ibadan in Nigeria to study issues related to informed consent in genetics studies. These efforts are investigating whether subjects in genetics studies perceive their participation as voluntary, and whether consented individuals understand the purpose of the genetic studies in which they are participating.

Rodrigue Takoudjou, SJ

Rodrigue Takoudjou, SJ is a priest of the Jesuit Order in the Catholic Church. Fr. Takoudjou was born on October 23, 1973 in Ndoungué – Cameroon. Rodrigue completed his elementary and secondary studies in Cameroon and obtained a BS in chemistry from the “University of Yaounde I”. Rodrigue also has a BA in philosophy from the “Faculté de Philosophie St Pierre Canisius” in Kinshasa – Congo, and a BA in theology from the “Universidad Pontificia Comillas” in Madrid – Spain. Rodrigue received a MS in Physiology and Biophysics from Georgetown University and is currently a PhD candidate in pharmacology at the same institution. Fr. Takoudjou taught physics and chemistry to 8th grade students in Chad for two years, and did intensive work with traditional healers of the same country. Fr. Takoudjou was initiated to the therapeutic

virtues of more than 50 tropical plants, which he subsequently used to treat many patients. Fr. Takoudjou gave lectures on Introduction to pharmacology at the Jesuit medical school “Le Bon Samaritain” in Chad during the summer of 2007, and is assigned to conduct research and teachings at the same institution after the completion of his Studies in the United States.

Ian Wronski, M.B.B.S., D.T.M. & H., M.P.H., M.S.

Professor Wronski’s career focus has been on the development of health workforce and health infrastructure in northern Australia and the broader western Pacific and south-east Asian regions, within university, health system and Aboriginal Medical Service settings.

He has been President and Chair of key national advocacy organizations including the Australian College of Rural and Remote Medicine and the Australian Council of Pro Vice-Chancellors and Deans of Health Sciences. In addition, he was the first Medical Director of the Kimberley Aboriginal Medical Services Ltd, and in conjunction with Gracelyn Smallwood, was the principal author of the Interim Set of Goals and Target in Aboriginal and Torres Strait Islander Health. He was a practicing procedural clinician in the Kimberley region until 1992.

He has been responsible for the introduction of a suite of health professional programs at James Cook University at undergraduate and postgraduate levels that target workforce shortages in Indigenous, rural and remote communities including medicine (the first new medical school established in Australia in 25 years), nursing, pharmacy, occupational therapy, medical laboratory science, sport and exercise science, clinical exercise physiology, physiotherapy, speech pathology, veterinary science and dentistry.

There has been concomitant development of research activities focusing on tropical health and medicine, tropical veterinary science, Indigenous health and the health of underserved populations: Development of research expertise and capacity in immunogenetics, cellular immunology and neurobiology. Established research programs include tropical microbiology, parasitology, tropical veterinary science, zoonoses, comparative genomics, tropical public health and Indigenous health; Development of an Australian Institute of Tropical Health and Medicine to address tropical health and biosecurity issues; Development of Public Health and Tropical Medicine at James Cook University as part of the Federal government’s Public Health Education and Research Program. This public health program provides Australia's only medical training program in Tropical Medicine and has developed postgraduate training in disaster and refugee medicine.

In parallel, he has played an active role in the development of health workforce strategies for underserved populations through: involvement in key national committees on the medical, nursing, allied health and Indigenous health workforce; participation in the development of national goals and targets for Indigenous health; professional organisations such as, Chair of the Australian Council of Pro-Vice Chancellors and Deans of Health Sciences (2005 - present), President of the Australian College of Rural

and Remote Medicine (2000 - 2003), education committees of the Faculty of Public Health Medicine, and Council of the Australasian College of Tropical Medicine; convening the “Tropical Triangle” alliance of health and medical educational organisations in North Queensland, Fiji, Papua New Guinea, and Timor-Leste.

**O'Neill Institute Personalized Medicine Workgroup
Biographical Sketches**

Julie A. DeLoia, Ph.D.

Dr. Julie DeLoia is currently an Associate Professor in the Department of Human Sciences and Associate Dean of Academic Affairs for the School of Nursing & Health Studies. She earned her PhD in Human Genetics from the Johns Hopkins University. Following a post-doctoral fellowship at the University of Pennsylvania in developmental genetics, she spent a summer at the Max-Planck Institute in Freiburg, Germany as a visiting scientist and before joining the faculty of the University of Pittsburgh School of Medicine in 1992, where she earned tenure. She has authored 45 manuscripts, has been awarded both federal and non-federal funding and has served on multiple NIH study sections. Her work with revising the medical school curriculum in Genetics and Genomics earned her the Kenneth E. Schuit Dean's Master Educator Award in 2006 and induction into the inaugural class of Academy of Master Educators. From 2002 through 2007, she served as the Director of Research for the Ovarian Cancer Center of the University of Pittsburgh. She joined the faculty and administration of the School of Nursing & Health Studies in August of 2007. Dr. DeLoia's current research focus is on the genetic variables that contribute to chemotherapy effectiveness in ovarian cancer patients.

Gregory J. Downing, D.O., Ph.D.

Dr. Downing was appointed in March 2006 as Program Director for the United States Department of Health and Human Services (HHS) Secretary Michael O. Leavitt's priority initiative for Personalized Medicine. In this role, he coordinates trans-HHS agency programs for the analysis, planning and implementation of policies and systems to facilitate adoption of Personalized Health Care practices.

Prior to his move to HHS, Dr. Downing served at the National Institutes of Health since 1993 in research, policy, and program management roles. Dr. Downing earned his medical degree from Michigan State University and his Ph.D. in pharmacology from the University Kansas. He completed his residency in pediatrics and fellowship in neonatology before joining the faculty of the University of Missouri-Kansas City in the Department of Neonatology at The Children's Mercy Hospital. Dr. Downing is certified by the American Board of Pediatrics in pediatrics and neonatology—perinatal medicine.

Jeff Collmann, Ph.D.

Dr. Collmann, Center Director and Associate Professor, Disease Prevention and Health Outcomes, O'Neill Institute for National and Global Health law, School of Nursing and Health Studies, Georgetown University, obtained his Ph.D in Social Anthropology from the University of Adelaide, Adelaide, South Australia. His research focuses on understanding the effect of bureaucracy and other complex forms of organization on everyday life. The results of his research on social change among Australian Aborigines

have been published in numerous articles and as a book, *Fringedwellers and Welfare: the Aboriginal response to bureaucracy*. He completed a Postdoctoral Fellowship in Clinical Medical Ethics, Department of Philosophy, University of Tennessee. He teaches courses at Georgetown University in the anthropology of biodefense, infectious disease and Australian culture.

Charles H. Evans, Jr., M.D., Ph.D.

Dr. Evans, professor and chair of the Department of Human Science at Georgetown University School of Nursing & Health Studies received his B.S. in biology from Union College (NY), and his M.D. and Ph.D. degrees from the University of Virginia. His advanced training in pediatrics was at the University of Virginia Medical Center. Following his postgraduate training he was appointed to the National Institutes of Health intramural staff as a principal investigator. From 1975-1998 as a physician scientist he served as Chief of the Tumor Biology Section at the National Cancer Institute and as a Captain in the U.S. Public Health Service Commissioned Officers Corps at the National Institutes of Health in Bethesda, MD. Dr. Evans research interests are carcinogenesis (the etiology of cancer), the normal immune system defenses to the development of cancer, and methodology in clinical trials with small numbers of participants, e.g. space medicine and astronaut healthcare, and mentoring in adolescence. While at NIH he discovered the ability of cytokines to directly prevent carcinogenesis and was the first to isolate a direct acting anticarcinogenic cytokine for which he was awarded four U.S. Patents. From 1998 to 2002 he served as Head of the Health Sciences Section, as Sr. Adviser for Biomedical and Clinical Research and as Scholar in Residence in the Institute of Medicine at the National Academy of Sciences.

Kevin T. Fitzgerald, S.J., Ph.D.

Kevin FitzGerald is Dr. David P. Lauler Chair in Catholic Health Care Ethics at Georgetown University. Previously at Loyola University in Chicago, he is also a Research Associate Professor of Oncology at Georgetown. He frequently testifies before Congress, and is a nationally recognized authority on genetics and medical ethics. He has advised the American Association for the Advancement of Science, the William G. McGowan Charitable Fund, Inc, DuPont, March of Dimes and the U.S. Council of Catholic Bishops. He currently serves as a member of the Secretary's Advisory Committee on Genetics, Health and Society (SAGHS), in the Department of Health and Human Services, USA. Dr. FitzGerald received dual Ph.D.s in bioethics and in molecular genetics from Georgetown and a Master of Divinity from the Jesuit School of Theology in Berkeley, CA.

Jessica J. Nadler, Ph.D.

Jessica Nadler is an American Association for the Advancement of Science Policy Fellow (2008-09) placed in the Personalized Health Care Initiative at the US Department of Health & Human Services. She earned her Bachelor's degree in Biology from the University of Pennsylvania and her Doctorate from the Department of Genetics at the

University of Washington, Seattle. She was a postdoctoral fellow in the Department of Genetics at the University of North Carolina at Chapel Hill.

Jennifer Weisman, Ph.D.

Jennifer Weisman is currently an American Association for the Advancement of Science (AAAS) Science & Technology Policy Fellow at the Department of Health & Human Services, working on the Secretary's Personalized Health Care Initiative. She spent her first year of the fellowship at the National Institutes of Health working on the Director's Initiative to enhance peer review. Jennifer completed a National Academies Christine Mirzayan science policy fellowship directly prior to starting her AAAS fellowship. She was a fellow at the Koshland Science Museum, where she performed evaluations of the new infectious diseases exhibit and designed public programs for the museum. Jennifer was previously a Giannini Family Foundation postdoctoral fellow at the University of California, San Francisco. As a postdoc, she worked on the discovery of new therapeutics to treat malaria, and was also a volunteer at the Exploratorium science museum and a teaching partnership participant in public schools in San Francisco. Jennifer received her B.S. degree in Chemistry from the College of William and Mary and her Ph.D. in Physical Chemistry from the University of California, Berkeley. Her doctoral research focused on the identification and study of compounds responsible for the diffuse interstellar bands using quantum computational chemistry.

Kimberly Bassett

Kimberly Bassett has worked as a Research Assistant with the O'Neill Institute in Georgetown's Department of International Health since August 2007. Her current projects with O'Neill include global health governance and genomic research with indigenous and developing country populations. Kimberly has also collaborated on various projects at the World Bank, including a review of a grant from the Bill and Melinda Gates Foundation for the elimination of lymphatic filariasis and an evaluation for the Bank's Independent Evaluation Group of the Stop TB Partnership. Her main areas of interest include maternal-child health and infectious diseases in the global context .

Ms. Bassett graduated in May of 2007 with a B.S. in International Health from the Georgetown University School of Nursing & Health Studies. While an undergraduate, Kimberly spent time working with community health organizations in the Washington, D.C. area as well as with an Aboriginal clinic in Perth, Australia.

Jason S Roffenbender, M.S.

Jason Roffenbender has worked as a Research Assistant at the O'Neill Institute since the Fall of 2008. His current projects include HIV/AIDS nurse workforce capacity building programs in Sub-Saharan Africa, and genomic research with indigenous and developing country populations. He earned a B.A. in Philosophy from the University of Virginia and a M.S. in Physiology and Biophysics from Georgetown University.

Kate Cherry

Kate Cherry has been a Research Assistant at the O'Neill Institute since the Fall of 2007. In this capacity, Ms. Cherry's research has focused on the current status and ethical implications of personalized medicine for the future of health care. Kate was also the Assistant Conference Manager for the O'Neill Institute's forum on Ethics and Personalized Medicine.

Ms. Cherry earned a B.A. in Public Policy Studies from Duke University, and has worked at non-profit organizations focused on economic development for low income populations and international sport development. Ms. Cherry's passion for health issues comes primarily from her experiences as a health educator in Malawi and Honduras. While at Duke, she was an active member of the University's Center for Race Relations, a tutor and mentor in Durham Public Schools, and the co-director of a gender relations improvement initiative.

Research Team

O'Neill Institute of National and Global Health Law, Georgetown University

Kimberly Bassett
Katherine Cherry
Jason Roffenbender, M.S.

Personalized Health Care Initiative, Department of Health and Human Services

Jennifer Weisman, Ph.D.
Jessica Nadler, Ph.D.

Principal Investigator

Jeff Collmann, Ph.D.
Center Director
O'Neill Institute of National and Global Health Law
Georgetown University