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Human Population Genetic Research: Innovation in the Face of Tradition and Remote Populations

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***Do present ethical guidelines
 adequately address respect for
 culture and tradition of
 indigenous peoples in population
 genomics research ?***



Objectives of population genomic research

1. Establish human origins.
2. Establish people migration patterns.
3. Contribute to public health monitoring (e.g.. susceptibility genes)
4. Provide foundation for personalized medicine, e.g.susceptibility genes, drug response genes (pharmacogenomics)
5. Establish forensic databases



Why is there much interest
 in involving indigenous peoples
 in genomic studies?

1. Less genetic variability (endogamy):
 Easier to establish gene associations
 with disease .
2. Bridge the genetic gap (remove the
 genetic divide).



Ethical Concerns

1. Social value: Do genomic studies have value for indigenous communities?
2. Balancing of risks and benefits:
 How will the research study benefit the people?
 What are the possible wrongs and harms to the people and their community?



Ethical Concerns

3. Informed consent
 - 3.1. Who will give the consent? Individual community, community representative?
 - 3.2. How is the "community representative" designated?
 - 3.3. How much understanding of genomics would allow indigenous people to recognize risks to tribal identity and pride, bodily integrity, individual and community privacy?





Ethical Concerns

4. Analysis, storage and ownership of tissue samples (also, biobanking)
 - Where? Access? Ownership? Re-use?
 - Who will be the signatories in a Material Transfer Agreement?
5. Researcher culture competence
 - How can one ensure that the researcher is familiar and respectful of the community tradition and culture?
6. Should genomic studies be limited (e.g., prevent research fatigue)? Who limits? How?



International/National Guidelines

- Guidelines for the Implementation of the 1997 UNESCO Universal Declaration on the Human genome and Human Rights (1999)
- UNESCO International Declaration on Human Genetic Data 2003
- CIOMS International Ethical Guidelines for Epidemiological Studies 2009
- Declaration of Helsinki 2013
- National Ethical Guidelines for Health Research 2011
- National Commission on Indigenous People (NCIP) AO 2012



UNESCO International Declaration of Human Genetic Data 1/2

- Article 4. (b) iv. Genetic data may have cultural significance for persons or groups.
- Article 6. (c) Ethics committees in the states involved should be consulted.
 - (d) Informed consent – identify risks
- Article 16. Change of purpose
- Article 18. States should regulate cross-border flow of human genetic data...



UNESCO International Declaration of Human Genetic Data, 2003 2/2

- Article 19: Sharing of Benefits
 - (i) special assistance to participants
 - (ii) access to medical care
 - (iii) Provision of new dx, tx, or drugs stemming from the research
 - (iv) support for health services
 - (v) capacity-building
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2009 CIOMS Guidelines for Epidemiologic Studies

- Guideline 4:** Individual informed consent
- Cultural considerations:
- individual consent only after obtaining permission from a community leader, a council of elders, ..
- ...Consultation with community members
- ... Community review of, and permission for, studies
- Guideline 24:** Use of stored biological samples and related data: confidentiality and informed consent



2013 Declaration of Helsinki

- 19.... All vulnerable groups and individuals should receive specifically considered protection.
- 20. ... justified if ... responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, the group should stand to benefit from the knowledge, practices or interventions that result from the research.



National Ethical Guidelines for Health Research 2011

Research with Indigenous People:

Problems posed when IP ethics is not represented, IP Norms and practices may be inconsistent with existing research ethics guidelines.

1. Presence of a community advocate or representative
2. Psychosocial and cultural needs of the community...

Indigenous People's Rights Act (IPRA) 1997



National Ethical Guidelines

Informed Consent:

Balance community approval and Individual consent

Competence of the Researcher

Inclusion of an appropriate social preparation phase of the study (respect for traditions), conduct of rituals,

Access and benefit sharing

Expertise of Ethics Committees

Presence of empowered community representatives



NCIP AO No. 1 Series 2012

The Indigenous Knowledge Systems and Practices (IKSPs) and Customary Laws (CLs) Research and Documentation Guidelines of 2012

- Protect and recognize rights of Indigenous Cultural Communities/ Indigenous Peoples to cultural integrity and to prescribe protection mechanisms at the international and national government level



NCIP AO No. 1 Series 2012

- Ensure and guarantee the exercise... of the right to allow or reject , through free and prior informed consent (FPIC), research and documentation of IKSPs and CLs and their derivatives
 - ensure that the ICCs/IPs benefit from the research output
- BUT There is no mention of GENOMIC RESEARCH except for flora and fauna bioprospecting.



Genomic Gaps in the Guidelines

1. Cultural Competence
 - Researcher and Ethics Review Committees
2. Understanding of Genomics
 - Indigenous community
3. Benefits to the indigenous community
4. Ownership of tissue samples and data
5. Storage and transfer of genetic material
6. Limits to genetic research activities among the indigenous people
7. Enforcement of Guidelines



Some Measures to Consider

1. Education of Researchers and ERC members on Indigenous culture and traditions
2. Education of IPs on genomics
3. Clarification of ownership and access issues in the MOAs with IPs.
4. National policy on population genomic research – who, with whom, how and whose
5. Inclusion of enforcement mechanisms in guidelines.





Thank you!!

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