



West African Bioethics Training Program

Community harms in Research in Africa

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Genomic research and Africa

- Genomic research is relatively new in Africa despite:
 - Role of Africa in human ancestry
 - Huge genomic, socio-economic, cultural (diet, religion, practices), climatic heterogeneity
 - Potential for huge contributions to understanding disease pathways, new approaches to treatment and prevention, drug discovery and pharmacogenomics
 - Widespread use and contribution of genomics research in developed countries





Genomic research and Africa

- Why should we conduct genomic research in Africa rather than use the valuable resources to implement known and effective strategies to combat prevalent public health problems:
 - Genomics research offer pathways to new solutions for Africa's old public health problems – HPV DNA testing is better than Pap smear in reducing mortality from cervical cancer - NEJM. 2009; 360: 1385-94
 - Results of genomics research in Africa informs understanding and application of research in other populations - Variation in APOL1 gene may contribute to high rates of kidney disease in African Americans Science. 2010; 329: 841-5





Genomic research and Africa

- Why should we conduct genomic research in Africa rather than use valuable resources on implementing known and effective strategies to combat prevalent public health problems:
 - Genomics research has potential to contribute to reduction in global health inequalities through “an enhanced translational genomics and population sciences agenda” CEBP 2011; 20: 2105 -14
 - Genomics research tends to be a catalyst for system-wide innovation, interest and investment in medical research in general





What is peculiar about Africa that is relevant to genomics research ethics

- Health indices, resources and access
 - Poor health indices
 - Poor health infrastructure
 - Limited access to good quality health care
- Patterns of diseases and health
 - Persistent communicable diseases
 - Rapidly progressing non-communicable diseases epidemic





What is peculiar about Africa that is relevant to genomics research ethics

- Socio-economic parameters
 - Poverty and rapid transformation in income levels
 - Urbanization – reduced physical activity, changing diet
 - Religion, culture and practices
- Education
 - Low levels of health professionals' knowledge about genomics
 - Low levels of general population's knowledge about health in general and genomics in particular





Why is ethics important in genomics research

- “Let us also remember that a slower progress in the conquest of disease would not threaten society, grievous as it is to those who have to deplore that their particular disease be not yet conquered, but that society would indeed be threatened by the erosion of those moral values whose loss, possibly caused by too ruthless a pursuit of scientific progress, would make its most dazzling triumphs not worth having.”

Hans Jonas

Philosophical reflections on experimenting with human subjects.

Daedalus, 1969; 98: 219-247



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Yoruba bo, won a ni ...

- Ile ti a fi ito mo, iji ni o wo
- In other words, research without ethics
 - “Is like a house built with saliva that soon melts away in the morning dew”





Characteristics of genomics research

- Requirement for large sample sizes which some feel tends to diminish the perceived “value” of the contributions of the individual
 - For example how do we compare the contributions of Raji – an 11 year old Yoruba boy with Burkitt’s lymphoma whose cells, in 1963, gave rise to the Raji cell line – the first continuous human cell line of hematopoietic origins with the anonymous Yoruba participant in the first phase of the International HapMap project whose genome was one of the first to be completely sequenced. Pulvertaft JV. Cytology of Burkitt's tumour (African lymphoma). Lancet 1: 238-240, 1964





Characteristics of genomics research

- Where am I? **Emi da?**
- Where are we? **Awa da?**

Asepo HapMap ti Gbogbo Agbaye

Ibuso | [Nipa Asepo](#) | [Esi](#) | [Itejade](#) | [Tutorial](#) |



Landmark or Region :

Reports & Analysis :

Data Source

HapMap Data Rel 24/phasell Nov08, on NCBI B36 assembly, dbSNP b126

Population descriptors: YRI: Yoruba in Ibadan, Nigeria, JPT: Japanese in Tokyo, Japan, CHB: Han Chinese in Beijing, China, CEU: CEPH (Utah residents with an

[中文](#) | [English](#) | [Français](#) | [日本語](#) | [Yoruba](#)

About the HapMap

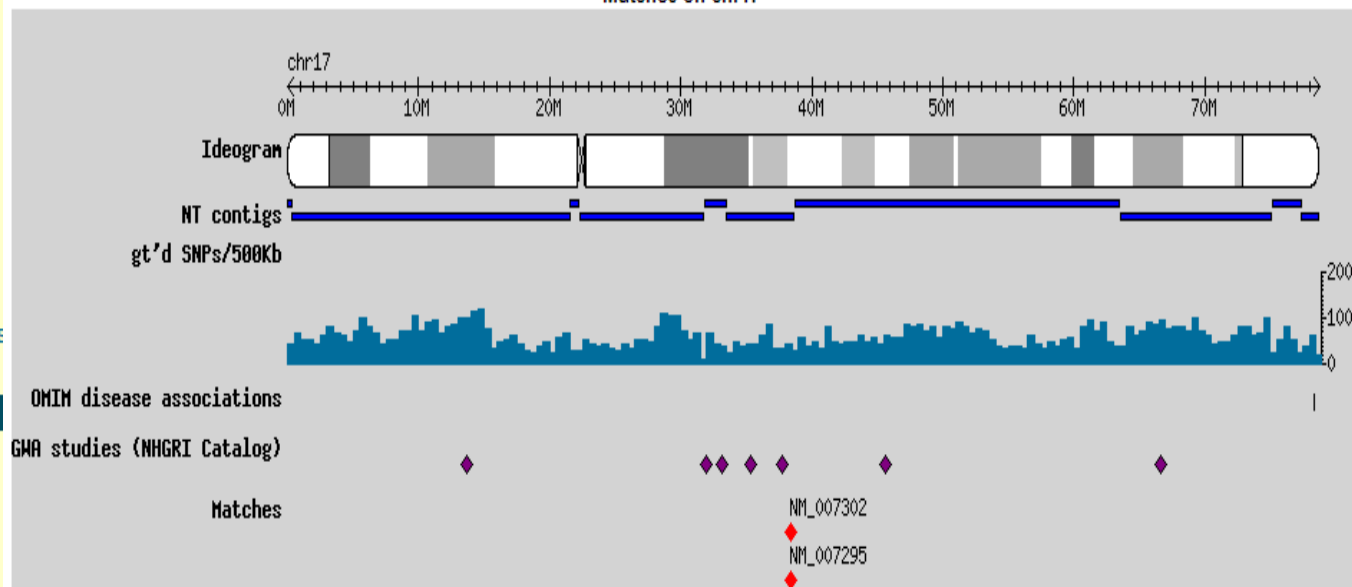
- Kinni HapMap?
- Orisun iwon-Jiini (Haplotypes)
- Anfani
- Awon Eya ti a ti se iwadi
- Majeobaje
- Iwe Idarapo mo iwadi
- Community Advisory Groups(CAG)
- Ilana Agbekale Esi Iwadi
- Ilana lilo Esi Iwadi
- Guidelines For Referring to HapMap Populations

Project Information

- [Ibuso](#)
- [HapMap Esi](#)
- [Olukowesi HapMap](#)
- [Alajoše HapMap](#)

The following 2 regions match your request.

Matches on chr17





Characteristics of genomics research

- Information on ethnicity that may
 - Raise specter of discrimination and stigmatization against individuals or communities
 - Engender a sense of pride and accomplishment
- The people of Aba-Alamu were proud of their contribution to the HapMap because
 - It reflects restored ethnic leadership and pride in education and science
 - They were contributing to de-stigmatization of Nigerians
 - They were contributing to the health and prosperity of African Americans
 - They were contributing meaningfully to global advancement in health and science



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Characteristics of genomics research

- Need for body fluids and tissues as substrates can raise significant concerns at the intersection between science, religion and culture. Illustrative experience of use of umbilical cord blood for research
 - We designed a study on the lead levels in the umbilical cord of newborn in Nigeria
 - Preliminary interaction with the community suggests that we will have significant challenges because of attitude to use of umbilical cord.
 - We designed a study of ELSI aspects of this research
 - Due to lack of funding our ELSI study was delayed so we proceeded with our original lead level in cord blood research



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Symbolism of the placenta with its umbilical cord blood in different cultures

Sociocultural meaning	Part of the world
Companion to child	Malaysia North Sulawesi
Protection and healing	Peru Bengal Costa Rica
Link child to community	Tahiti Bolivia Cambodia
Social identity of child	Java Trobriands, Ojibwa communities
Waste	North America





Opinion about the afterbirth

- *Lay opinion about the afterbirth*
 - *Umbilical cord or afterbirth is a dangerous thing to play with in Yoruba land, since it connects the child to the mother, Yoruba believe that how it is handled can change the destiny of a child.*
 - *That is what many pregnant women fear during childbirth and they are eager to collect the umbilical cord and after birth and give it to the father of the child (husbands).*
 - *Yoruba says “ki aye ma fi bi omo mu wa” – (May we not be vulnerable to our enemies through the umbilical cord)*
- *A traditional religion priest*
 - *burning the umbilical cord is best thing to do and it must done when people are not around, may be in the night at a location that is wet, so that that child life’s will be cool and prosperous.*
- *A Senior Nursing Officer*
 - *the importance of the afterbirth is that after a woman has had sex with a man and missed her period, God will put the placenta beside the fetus and this brings about the cordial relationship between mother and child that is responsible for the child’s breath and the child’s feedings*





Experience with cord blood research

- During the study, there was no single refusal to the request for umbilical cord blood for evaluation of lead level.
- All participants completed informed consent and kept a copy of the form
- Participants were given \$3 worth of multivitamins for participating in research
- Since conclusion of the research in 2006, there has been no request to withdraw sample
- People's actions may not often tally with prevalent norms
- Need for more studies and use of different techniques to explore the ethics of research in developing countries.
- We should expect that traditional attitudes and beliefs are prevalent but changing, often in unexpected ways.
- Ethical principles remain global but application is indeed local.



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Ethical aspects of genomics research

- Informed consent
- Sample export and ownership – Materials Transfer Agreements
- Ethical review process for multisite research
- Role of ethics review committees and
- Return of results
- Capacity development
- Protection of local scientists and communities





History of community harms

- Significant effort in research ethics has focused on individual's roles, responsibilities and likelihood of being harmed during participation in research
- Community harms are not infrequent but are often not recognized within the duration of the specific research
- Examples of community harm arising from research
 - Ashkenazi Jews in breast cancer research
 - Nigerians in Pfizer Trovan research
 - Havasupai in Arizona
 - African breast cancer patients and research results on patterns of hormone receptors





Definitions of communities

- Community delineates a wide variety of human associations, from tribes to municipalities to religious adherents to people who share similar diseases or outcomes.
 - “Community of African Breast Cancer Patients” is different from “Community of Havasupai Indians”
- A single set of regulations to fit all types of communities is doomed to failure
- A set of guidelines that may help researchers identify morally relevant characteristics is helpful





Definitions of communities

Community characteristic	Type of community						
	Aboriginal	Geographic/Political	Religious	Disease	Ethnic/Racial	Occupational	Virtual
Common culture and traditions, cannon of knowledge, and shared history	++	+	++	+/-	+	++	+
Comprehensiveness of culture	++	+/-	++	-	+	+/-	-
Health-related common culture	++	+	++	++	+	+/-	-



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Definitions of communities

Community characteristic	Type of community						
	Aboriginal	Geographic/Political	Religious	Disease	Ethnic/Racial	Occupational	Virtual
Legitimate political authority	++	++	+/-	-	-	+/-	-
Representative group/individuals	++	++	++	+	+	+/-	+/-
Mechanism for priority setting in health care	+	+	+/-	+	+/-	+/-	-

Weijer, C. and Emanuel, E. J. Protecting Communities in Biomedical Research. *Science*. 289; 2000:1142-1144



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Definitions of communities

Community characteristic	Type of community						
	Aboriginal	Geographic/Political	Religious	Disease	Ethnic/Racial	Occupational	Virtual
Geographic localization	+	++	+/-	+/-	+/-	-	-
Common economy/shared resources	++	++	+/-	+/-	+/-	-	-
Communication network	++	+	+	+/-	+/-	+	++
Self-identification as community	++	++	++	+/-	+	+/-	+



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How to avoid community harms

- Consultation in protocol development
- Information disclosure and informed consent
- Involvement in research conduct
- Access to data and samples
- Dissemination and publication of results





Linking protections to community and research characteristics

COMMUNITY CHARACTERISTICS REQUIRED FOR PARTICULAR PROTECTIONS

H, health-related common culture; LPA, legitimate political authority; Rep., representative group or individuals; PS, mechanism for priority setting in health care; GL, geographic localization; CE/SR, common economy or shared resources; CN, communication network; SI, self-identification as a community.

	Community characteristics							
Proposed protections	H	LPA	Rep.	PS	GL	CE/SR	CN	SI
Consultation in protocol development								
Respect for culture	✓							
Input on protocol			✓					





Linking protections to community and research characteristics

Consent		✓						
Consent required for protocol changes		✓		✓				
May withdraw consent		✓						
Involvement in research conduct								
Transfer of skills and expertise						✓		
Employment						✓		





Linking protections to community and research characteristics

Reimbursement for research costs						✓		
Informed about research progress			✓			✓		
Access to data and samples								
Consent for further use of samples	✓	✓						
Storage of data negotiated			✓					





Linking protections to community and research characteristics

Dissemination and publication							
Involvement in manuscript preparation			✓				
Draft report for comment						✓	
Acknowledgment							✓
Consent to identify		✓					
Final report			✓			✓	
Consent for researcher media interview		✓					

Table 2. Appropriate protections for communities depend on their characteristics. *Italics indicate community protections that require consent; nonitalics, protections that require only community consultation.*





How to avoid community harms

- Three general regimes of protection can be delineated, based on the specific protections appropriate to the distinct types of communities:
 - Community assent and consultation
 - Community consultation alone, and
 - No added protections





Questions

- How do community protections relate to individual informed consent, rights and responsibilities
- Is it more appropriate to conceive of a community as a vulnerable group protected by current regulations
- Might a community use added protections for research to legitimize the oppression of groups within the community
- Who counts as the community leader
- What if the community wants to suppress adverse or undesirable research findings



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