

# **Ethical Challenges in Genetic Research in Africa: Informed Consent and IRBs**



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# Globalization of the Genomic Enterprise

- Genomic revolution: greater understanding of human disease and its expression in populations throughout the world
- “10/90 Divide” in research and health expenditures
- Danger of reproducing and sustaining global disparities in the area of genomics and biotechnology
- Urgent need for capacity building in Africa, developing expertise in scientific, ethical, legal, and policy aspects of genomics and biotechnology



# Ethical Challenges: Genomic Research

- Capacity building--IRBs/ERCs
- Informed consent: individuals, family studies, community-based studies
- Protection of confidentiality (concerns about stigmatization)
- Benefit sharing (who benefits, bears the burden of genetic research)
- Commercialization of products
- Biobanks, access to/storage of samples

# Informed Consent and IRBs/ERCs

- International guidelines recognize ethical significance of informed consent for scientific research and need for ethical review of research protocols to insure protection of human subjects
- Studies show that IRBs spend most of their time considering issues associated with informed consent
- Majority of changes requested by IRBs relate to informed consent documents

# Genetics Research and Informed Consent

- Genetic research involving individuals has implications for privacy concerns, personal risk susceptibility.
- Genetic research involving family studies presents special issues surrounding informed consent practices.
- Beliefs about “genes” and “genetics” interface with notions of kinship and group identity, calling attention to complex issues surrounding individual consent and community approval in genetic research.

# Informed Consent to Genetic Research

- Who is “at risk” for potential harms associated with genetic research?
- The research participant? *And* his or her family? The larger community?
- Who should provide consent for different types of genetic research?
- What constitutes a “family” or a “community”?

# Informed Consent

- Bioethics practice based on western philosophical principle of respect for persons, strong emphasis on individual autonomy.
- Informed consent as ethical ideal.
- Informed consent as social process.
- Informed consent as praxis.

# INFORMED CONSENT

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- Consensus about core components of informed consent:
  - Provision of information
  - Comprehension
  - Voluntary participation
- Application may be problematic in genetics research, resource poor settings **and** in industrialized countries

# Challenges to Consent for Genetic Research

- Vulnerable population due to structural inequities: racism, poverty, low literacy rates, gender issues.
- IRB requirements for informed consent (e.g., written documentation) do not always mesh with local realities. Consent forms for research may be lengthy, confusing, difficult to understand.
- Language, genetic concepts difficult to communicate.
- Translation of consent forms from one language to another problematic.
- Who can give permission—consent for study?

# Results of Study on Informed Consent to Genetic Research: Nigeria/U.S.

- Surveyed 869 Yoruba and African American participants in genetics of hypertension, genetics of breast cancer research
- Great majority (90-99% each site) reported being told that participation was voluntary.
- Comprehension: participants' reporting research goal "to learn about genetic inheritance":
  - 31% Nigeria hypertension site (rural)
  - 70% Nigeria breast cancer site (urban)
  - 38% U.S. hypertension site (urban)

(Marshall, Adebamowo, Adeyemo, Rotimi)

# Results of Study on Informed Consent to Genetic Research: Nigeria/U.S.

- Married women reporting they needed to seek permission from their husband or partner before agreeing to participate in genetic research studies:
  - 47% Nigeria hypertension site (rural)
  - 19% Nigeria breast cancer site (urban)
  - No one in U.S. hypertension site (urban)
- No one in Nigeria asked “permission” from community elder to participate in genetic studies.

(Marshall, Adebamowo, Adeyemo, Rotimi)

***“It is not going to be dangerous once my husband did not say I should not do it.”*** Individual opinion has power over community opinion because one is not forced to do it. But if the community opinion (is to disapprove) then one may not open up to the questions the researcher will be asking. But individual opinion has power over community opinion.”

# Consent Challenges: Biobanks

- Future studies may not be identifiable at time of consent
- Research results may not have immediate clinical relevance for individual participants
- Research and information involves large samples, impact for a single sample not relevant
- DNA samples collected easily, minimal physical risk
- Research may require multiple requests for informed consent; this may be a burden for participants and researchers

## Informed consent challenges: future use of tissue samples

- How much information does someone need to make a decision about use of tissues in future research?
- What role, if any, should families have in making decisions about future research on tissue samples?
- What methods work best for obtaining consent for future studies?

# Approaches to consent for stored tissue samples

- “A system which required fresh consent would be extremely cumbersome and could inhibit research...blanket consent covering all forms of future medical research might be preferable.”  
(UNESCO 2001)
- Various models for “presumed consent,” with or without “opt-out”
- Some critics view these approaches as the “fiction of consent.”

## Consent for DNA use: Authorization Model

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- Individual choice about extent of involvement for future uses
- Use of identified biological materials for one particular study, no further contact
- Use of identified materials for one study, permission to re-contact
- Permission to use biological materials for any future study

# Conundrum of consent for stored tissue samples

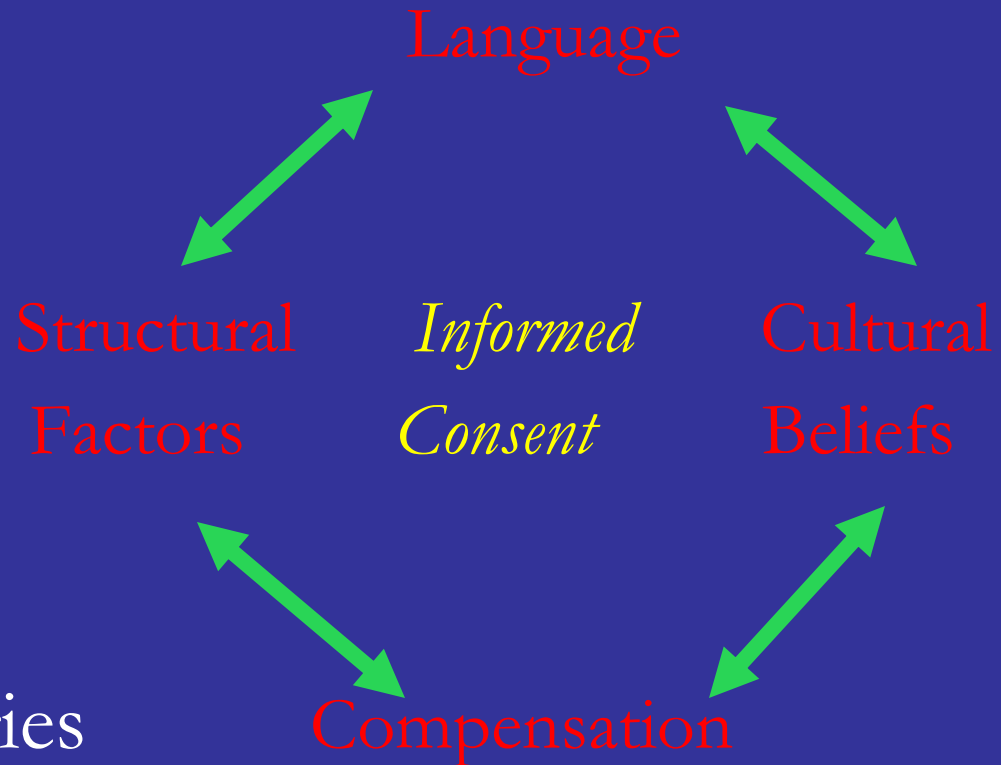
- “The value of recognizing that existing consent norms are incapable of accommodating much of the research associated with DNA data banks...forces policy makers and the public to confront the social tradeoffs inextricably linked to this work. If we...adhere to the well-established consent norms, a good deal of population research may not occur. On the other hand, if we abandon the current consent model, research participants will be giving up well established rights and a degree of control. By recognizing the choice, society can more clearly debate the benefits and risks of each course of action.”  
*(Caufield, Upshur, Daar 2003)*

# INFORMED CONSENT IN GENETIC RESEARCH: SOCIAL PROCESS

➤ Higher congruence between researcher/participant, greater likelihood for consent conditions.

➤ Greater dissonance, less likely to achieve consent conditions.

➤ Goal: develop strategies to diminish dissonance.



# Ethical Challenges: IRBs, Ethical Review Committees



- Institutional infrastructure
- Application of international ethical guidelines
- Education/training IRB members
- Politics of protocol approval
- Community representation on IRB committee

# Institutional Infrastructure

- Faculty, staff release time to work on ethics committee
- Support staff for committee
- Resources for supplies, xeroxing, etc.
- Resources for electronic communication, on-line access to protocols, etc.
- Availability of rooms for meetings

# Application of International Ethical Guidelines for Research

- Lack of sensitivity of international research collaborators to cultural context
- Need to accommodate consent requirements, sometimes requires changes in research design for genetic studies
- Disclosure of risks, comprehension
- Need for capacity-building, resources

# Education/training IRB members

- Understanding of ethical issues underlying design and implementation of research (including genetic studies)
- Knowledge of national and international ethical policies and guidelines, general and those specific to genetics research
- Competence for evaluating genetic and genomics research protocols (need to have IRB member who understands genetics issues)

# Politics of protocol approval

- Pressure to participate in international collaborative genetic research, overlook ethical concerns
- Pressure to obtain funding for genetic research initiatives, overlook ethical issues
- In some cases, junior faculty may fear sanctions from senior faculty if ethical questions are raised about genetics or other protocols
- Interpersonal professional dynamics, not relevant to protocol, can sometimes sabotage approval process

# Community representation on IRB committee

- Who is selected to represent community?
- What “community”?
- Knowledge of genetics, genetic research, implications for “community”?
- Conflicts of interest?
- Community representative may be intimidated by authority of professional faculty, may be uncomfortable raising questions

# Protecting Confidentiality: Informed Consent and IRBs

- Disclose strategies for protecting confidentiality in consent discussion (e.g. data storage, data reporting, etc.)
- **Individual** – research findings should be disclosed only to the individual NOT family members unless written permission is provided.
- **Family** – implications of genetic findings for family members (e.g., misidentified parentage and interpretation of elevated family risk).
- **Community** – mechanisms for community consultation if necessary, implications of findings for community (e.g., misrepresentation of results may contribute to stereotypes, racism)

# Protecting Participants and Communities in Genetic Research

- Establish an **independent scientific oversight body** if relevant
- Establish **community advisory board** when indicated
- Be honest with individuals, families, and communities about benefits and risks associated with study, benefits may not be immediately apparent
- Do not promise what you cannot deliver.
- Maintain continuous dialogue with participants regarding the goals, objectives and new project developments, devise mechanisms for contact.

# Future Challenges: Consent, IRBs, Genetic Research in Africa

- How are current guidelines being applied? Who is being served?
- Great need for empirical research:
  - Investigating existing informed consent practices.
  - Developing/testing new approaches to informed consent.
  - Evaluating IRB/ERC protocol review of consent.
  - Analyzing impact of structural inequities (global/local) on application of informed consent.
  - Need to pay attention to risk/benefits, protections against harm.

# Conclusions

- Africa---need to develop expertise internally to address science, technology, ethics, policy aspects of genomics.
- Capacity-building and leadership development programs to strengthen potential to participate in international policy and trade negotiations (e.g., trade-related intellectual property rights).
- Creation of effective, productive, and fair collaborative partnerships that foster growth and development in genomics (e.g., establishment of Centers of Excellence).
- Need for creative and innovative financing to build capacity and invest in promising areas of genomics for health problems in Africa.

# Conclusions

- The potential for the genomic revolution to change our lives is profound.
- Genetic investigators working within national borders and collaboratively, across borders, face a complex array of moral, social, political, and scientific problems in clinical and epidemiological research.
- Establishing a strong foundation for transnational cooperation facilitates resolution of dilemmas.