Ethical and Social Issues in Informed Consent Processes in African Genomic Research

H3Africa
Human Heredity & Health in Africa

The Goal: To contribute to a better understanding of the ethical, legal, and social issues (ELSI) associated with various genomic research stakeholders in low resource settings.

The Problem

Genomic research raises a unique set of ethical, legal, and social challenges for further exploration to ensure that there is adequate protection of research participants, communities, and researchers. In Africa, challenges arise in determining the most appropriate approach for obtaining informed consent given the vulnerabilities arising from the complexity of genomic research; the high background poverty; low literacy levels; and linguistic/cultural differences between different populations in Africa. There are also concerns about research participants' ability to understand the concepts of genomic research, storage and future use of biological samples, and the potential risk of stigma or exploitation of study communities.

Project Strategy

- Explore culturally appropriate strategies of enhancing understanding during the consent and assent process in genetic/genomics research.
- Identify the best practices for improving understanding of the informed consent process leading to enhanced protection of the rights and welfare of participants.
- Employ mixed methods including surveys, direct observation of informed consent session, content analysis of consent documents, focus group discussions, and in-depth interviews with selected stakeholders.

Preliminary Outcomes

- Assessed the quality of 243 informed consent documents and 77 material transfer agreements for studies involving genetics, genomics, or the storage of samples for future use.
- Surveyed 187 genomic researchers to explore their knowledge, perceptions, and experience on ethical, legal, and social issues of research involving genomics and the collection, storage, and future use of human biological materials (HBM).
- Conducted in-depth interviews with 15 genomic researchers.
- Conducting a survey (n=98) and in-depth interviews with bioethicists (n=9) who are also members of Research Ethics Committees.
- Assessed understanding of informed consent of 363 participants of three active genomic studies.
- Conducted 10 focus group discussions (FGD) with 89 participants of three genomic studies including two FGD involving adolescents.

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