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

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.

Outcomes to Date

- Assessment of 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 was done.
- A survey was conducted involving 187 genomic researchers, in-depth interviews with 15 genomic researchers and focus group discussions with 16 nurses involved in obtaining informed consent for genetic or genomic research. This aims to explore their knowledge, perceptions, and experience on ethical, legal, and social implication (ELSI) of research involving genomics and the collection, storage, and future use of human biological materials.
- Assessment of understanding of consent was done for 370 participants of three on-going genomic studies. In addition, 10 focus group discussions (FGD) were conducted with 80 parents, minors and young adults. Six of the 10 FGD involved parents/caregivers, two involved adolescents and two involved young adults. We aim to identify ELSI related knowledge, experiences, and perceptions of research participants including caregivers’ involvement in the informed consent process.
- Two surveys involving 122 parents and 90 adolescents have been conducted. In addition, eight focus group discussions were conducted involving 34 parents and 34 adolescents participating in the CafGEN study. We aim to explore parental and adolescent attitudes, preferences, and experiences in the return of individual genetic/genomic research results.
- 10 in-depth interviews have been conducted with 10 researchers conducting paediatric/adolescent genomic research. The aim is to explore experiences and perspectives of genomic researchers on the return of individual results in research involving minors as research participants.
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