



**The Normative Framework for the Governance of
Collaborative Genomics Research in Kenya: A Critical
Appraisal**



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ABSTRACT

Introduction. Spectacular advances in technologies for mapping out the complete set of genes of individuals have ushered in the genomic era of science, and African populations are increasingly getting attention from international and local academic researchers who endeavour to chart out the genomes of African people.

However the advances in genomics and the increasing linkages of information on biological samples in tissue biobanks with databases through web enabled technologies challenge the adequacy of existing laws and ethical codes to protect the privacy, property, and autonomy rights of research participants.

Objectives. This study examines the capacity of the Kenyan normative frameworks to facilitate collaborative genomics research and protect the rights of research participants.

Methodology. The theoretical framework of legal and normative pluralism was applied to evaluate the international and national legal and ethical orders, relating to: privacy, confidentiality, informed consent, intellectual property rights and data sharing.

Results. The genomics research governance and regulatory space in Kenya is shaped by plural legal and ethical mechanisms, and is occupied by a constellation of actors including: regulatory authorities, governmental departments, research institutes, universities, research ethics committees and funding agencies.

While the constitution of Kenya has strengthened individual privacy rights, the legislative framework makes no reference to human genetic material and the special status of genetic information as acknowledged under international instruments.

The lack of data protection legislation means that the current practice by international collaborative research projects of maintaining genetic information on Kenyans in international databases has an uncertain legal basis. Uncertainty also exists as to the international data and tissue sharing arrangements entered into by various research groups operating in Kenya.

Conclusion and Recommendations. Genetic information requires special legislative protection. The genetic data obtained from Kenyans that are stored in overseas databases linked by the internet, enjoy little legal or ethical protection.

Kenya currently lacks a statutory framework on data protection as it relates to human genetic information; and there are lacunae in the law relating to privacy. The scope of the protection of property rights in respect of human biological samples is also not clear.

There is consequently need for a proper national policy with a focused statute to regulate human genomics research in Kenya to ensure better coherence, efficiency, consistency and protection of research participants. It is important and urgent that that a privacy and data protection law that secures the rights of Kenyans in relation to genetic information be elaborated.

The enforcement mechanism in a new governance framework should be strengthened, and the Research Ethics Committees should be given inspection capacities to enable them ensure genomics research is conducted in compliance with the approved protocols.