REPUBLIC OF KENYA

National Commission for Science, Technology and Innovation

ADVISORY ON DEVELOPING A COMPREHENSIVE NATIONAL GENOMIC DATA POLICY



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Genomic research has transformative potential to accelerate innovations and advancements in Kenya's public health, precision medicine, agricultural resilience, and biodiversity management. However, the increasingly high-throughput generation and transboundary movement of genomic data introduce unprecedented risks to national biosecurity, national scientific advancement, individual privacy, and genetic sovereignty.

Genomic data governance presents unique challenges beyond conventional data governance because of the specific characteristics of genomic data, such as the volume of data carried by a single genome, the implications of genomic information for biological relatives and communities, and the potential for including or excluding whole populations in health research, advancements, and innovation.

Kenya's genomics research governance landscape is characterised by a constellation of institutions operating across intersecting but largely siloed mandates. The Science, Technology and Innovation Act (Cap. 511) vests NACOSTI with overarching responsibility for research licensing, ethics oversight and approval of research involving biological samples. The Environmental Management and Coordination Act and its 2025 Access and Benefit Sharing (ABS) Regulations task NEMA with governing access to genetic resources under the Nagoya Protocol. The Data Protection Act (Cap. 411C) mandates the Office of the Data Protection Commissioner to oversee personal data, while the Biosafety Act (Cap. 320) governs genetically modified organisms through the National Biosafety Authority. Other instruments affecting genomic data governance include the Health Act and the Digital Health Act. No single instrument or institution has responsibility for the full genomic data lifecycle.

In the past year, the National Commission for Science, Technology and Innovation has undertaken a national survey of institutions handling genomic data and convened several stakeholder consultative forums on genomic data governance in Kenya. The survey assessed genomic data governance in practice. Thirty-one (31) institutions, including universities, research institutions and hospitals in the public and private sectors, participated in the survey. These efforts led to the development of the June 2026 Policy Brief on Strengthening Genomic Data Governance in Kenya (NACOSTI Policy Brief No.1/ 2025-2026).

Despite the growth of the genomic research sector, research and stakeholder consultations have identified the following policy gaps:

- Unclear or inadequate data categorisation under the data protection law. The Data Protection Act, 2019 establishes principles for governing the collection, processing, and transfer of personal data, including sensitive health and genetic information. However, the Act does not expressly distinguish conventional medical data from genomic data or fully address the complexities associated with genomic information.
- Unregulated transboundary data transfers and biobanking. While both the Data Protection Act and the Science Technology and Innovation Act require approval for any data or material transfer beyond Kenya's borders, the requirements for Material Transfer Agreements (MTAs), Data Transfer Agreements (DTAs) may be bypassed, especially for digital sequence information (DSI) uploaded to international cloud repositories.
- Absence of standardised benefit-sharing mechanisms. Current frameworks lack clear provisions for intellectual property ownership, benefit sharing and

capacity building, including technology transfer linked to access and use of Kenyan genomic data. Without a national standard, scientists must negotiate these rights, exposing local researchers to exploitation.

- Bio-risk and dual-use research oversight. Genomic data relating to populations and pathogens presents heightened biorisk and dual-use concerns. The lack of a policy governing the biosafety and biosecurity of genomic data perpetuates these risks, as existing guidelines do not fully address potential dual-use biological risks linked to natural and synthesised pathogen genomes.

In view of the mandate of the State Department for Science, Research and Innovation as the policy and coordination lead in the science, research and innovation sectors, NACOSTI advises that the State Department prioritises the development of a National Genomic Data Policy to provide a comprehensive and coordinated governance framework for genomic research, including genomic data. The policy should address the full lifecycle of genomic data including collection, access, use, and sharing and seek to ensure fair access to the benefits of genomics.

The Commission remains committed to providing any further guidance on key elements of the policy and to participating in its development when called upon by the State Department. Realising the potential of scientific advancement that genomic data presents, while safeguarding privacy, biosecurity and national interests, requires a harmonised framework, mandatory compliance with data sharing standards and national systems for oversight and accountability.