

ARISE task 2.1 – Kenya

Within the ARISE project, particularly in the framework of the task 2.1 “Governance, Ethics and Law” the analysis of the applicable rules to be considered and respected to conduct research activities was performed.

The analysis advises in planning and executing research activities to be performed within the ARISE project, such as questionnaire-based studies, retrospective and prospective clinical studies as well as research involving the secondary use of data (e.g. Electronic Patient Registry) and samples.

These studies might involve human subjects, including also vulnerable populations (such as children) and in many cases the studies might imply also the transfer of data and samples between non-European and European countries.

The table below includes relevant information on the applicable official documents, particularly laws, regulations, and guidelines, in Kenya, ruling the following items:

- Protection of personal data and confidentiality, including primary and secondary use of data
- Processing and protection of healthcare data, including also genetic data
- Handling of biological samples, including primary and secondary use of samples
- Requirements for minors and vulnerable populations

Title	Last update	Regulatory Authority releasing the document	Link
Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya	2004	National Council for Science and Technology	https://www.healthresearchweb.org/files/Kenya_Guidelines_Ethical_conduct_of_research_involving_human_subjects.pdf
National Guidelines for Research and Development of HIV/AIDS Vaccines	2005	Ministry of Health	https://www.academia.edu/35397601/Kenya_National_Guidelines_for_Research_and_Development_of_HIV_AIDS_Vaccines
Procedures and Guidelines for Research Authorization in Kenya	2009	National Council for Science and Technology	https://www.healthresearchweb.org/files/ResearchClearanceGuideline.pdf
The Constitution of Kenya	2010	The Republic of Kenya	http://kenyalaw.org/kl/index.php?id=398
HIV and AIDS Prevention and Control Act	Revised Edition 2012 [2006]	Parliament of Kenya	http://kenyalaw.org/kl/fileadmin/pdfdownloads/Acts/HIVandAIDSPreventionandControlAct_No14of2006.pdf
Public Health Act	Revised Edition 2012 [1986]	The Republic of Kenya	http://kenyalaw.org/kl/fileadmin/pdfdownloads/Acts/PublicHealthActCap242.pdf
Children Act	Revised Edition 2012 [2010]	Parliament of Kenya	http://kenyalaw.org:8181/exist/kenyalex/actview.xql?actid=No.%208%20of%202001



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Health Information System Policy	2014	The Republic of Kenya	http://publications.universalhealth2030.org/uploads/kenya_health_policy_2014_to_2030.pdf
Science, Technology and Innovation Act	Revised Edition 2014 [2013]	The Republic of Kenya	http://kenyalaw.org/8181/exist/kenyalex/actview.xhtml?actid=No.%2028%20of%202013
Kenya Information and Communications Act	Revised Edition 2015 [2012]	The Republic of Kenya	https://kfcg.co.ke/wp-content/uploads/2016/07/Kenya_Information_and_Communications_Act.pdf
Access to Information Act	2016	The Republic of Kenya	https://www.cuk.ac.ke/wp-content/uploads/2018/04/Access-to-Information-ActNo31.pdf
The Health Act	2017	Parliament of Kenya	http://kenyalaw.org/kl/fileadmin/pdfdownloads/Acts/HealthActNo.21of2017.pdf
Kenya Standards and Guidelines for mHealth Systems	2017	Ministry of Health	https://www.health.go.ke/wp-content/uploads/2020/02/Revised-Guidelines-For-Mhealth-Systems-May-Version.pdf
Data Protection Act	2019	Parliament of Kenya	http://kenyalaw.org/kl/fileadmin/pdfdownloads/Acts/2019/TheDataProtectionAct_No24of2019.pdf
National Ethics Review Committee Guidelines and Standard Operating Procedures (SOPs)	2019	Kenya Medical Research Institute (KEMRI), National Ethics Review Committee	https://www.kemri.org/scientific-ethics-review-unit-seru/#1596810021493-4fc360ab-3a94



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