Citation: Mohammadzadeh, A., Farjaminejad, S., Patel, P., Ahmad, R., Nanyonga, S., Stavropoulou, C. & Kozlakidis, Z. (2025). Biobanking in Sub-Saharan Africa: A Review of Data Protection Frameworks. Biopreservation and Biobanking, 23(3), pp. 177-185. doi: 10.1089/bio.2024.0086

Biopreservation
and Biobanking

Biopreservation and Biobanking

BIOBANKING IN SUB-SAHARAN AFRICA: A REVIEW OF DATA PROTECTION FRAMEWORKS

Journal:	*Biopreservation and Biobanking*
Manuscript ID	BIO-2024-0086
Manuscript Type:	Original Article
Date Submitted by the Author:	18-Jun-2024
Complete List of Authors:	Mohammadzadeh, Anoosh; City University of London, School of Health Sciences Farjaminejad, Samira; City University of London, School of Health Sciences Patel, Poonam; City University of London, School of Health Sciences Ahmad, Raheelah ; City University of London Stavropoulou, Charitini ; City University of London Nanyonga, Sandra; Fondation Universite Cote d Azur Kozlakidis, Zisis; International Agency for Research on Cancer, Laboratory Service and Biobank Group
Keyword:	Data management, Biobank
Manuscript Keywords (Search Terms):	sub-Saharan Africa, biobanking, data protection, regulatory frameworks, Africa

BIOBANKING IN SUB-SAHARAN AFRICA: A REVIEW OF DATA PROTECTION FRAMEWORKS

Anoosh Mohammadzadeh[1], Samira Farjaminejad[1], Poonam Patel[1], Sandra Nanyonga[2], Raheelah Ahmad[1], Charitini Stavropoulou[1], Zisis Kozlakidis[3*]

1. School of Health Sciences, City University of London, London, UK
2. Université Côte d'Azur, Nice, France
3. International Agency for Research on Cancer, World Health Organization, Lyon, France

*Corresponding author:
Zisis Kozlakidis, PhD
International Agency for Research on Cancer
World Health Organization
25 Avenue Tony Garnier
69366 Lyon CEDEX 07, France
Phone: +33 472 738 411
Email: kozlakidisz@who.int

Running title: Data protection and biobanks in sub-Saharan Africa

Keywords: Africa; biobanking; data protection; regulatory; sub-Saharan Africa

ABSTRACT

Introduction: Biobanks are a foundational infrastructure supporting research at scale and contributing to the scientific progress. The increasing collection of human samples and associated data presents challenges both in terms of physical storage and handling as well as digital. In north America and Europe (health) data protection frameworks have been in place for several years, regulating the use of collected personal data, including healthcare data, as those typically used by human biobanks. Yet, regulatory frameworks for biobanking, particularly in low- and middle-income settings, are highly fragmented and a little is known in this area.

Objectives: This review focuses on identifying the health-related data protection frameworks in Sub-Saharan African countries, as they are relevant to biobanking.

Methods: We used complementary literature review approaches to ensure the completeness of our results: for biobanking identified as ‘African’, as well as for ‘disease-based’, ‘country-based’, and artificial intelligence-based approaches.

Results: In total, 56 articles were identified and reviewed in full, 31 health-related acts and frameworks relevant to biobanking, and 24 general data protection acts and frameworks, from 37 countries. In some countries, such as Kenya and Zambia, these acts were implemented, in some others they were not. In most cases, as these regulatory frameworks have been recently created and implemented, there is little or no data relating to the impact of their implementation.

Conclusion: Our findings confirm that regulatory frameworks for biobanking in Sub-Saharan Africa are still in a consistent period of emergence, in an effort by national governments to address the existing fragmented landscape and support the development of research.

Introduction

Human biobanks established themselves as an indispensable part of the research infrastructure ecosystems during the early 2000s, supporting the first large-scale, international genomics projects. They have since grown in number and scope, and become ubiquitous in high-income settings, where the majority of -omics based research has been conducted. (1) However, there is a marked imbalance in the distribution of research infrastructures, including biobanks, between low- and middle-income countries (LMIC) and high-income countries. (2) In turn this contributes negatively to the inclusion of LMIC populations in international research initiatives. Several initiatives are in place to mitigate this challenge, as for example, the Biobank and Population Cohort Network (BCNet) coordinated by the International Agency for Research on Cancer, the executive research agency of the World Health Organization for cancer (IARC/WHO). (3) BCNet was created in 2013 with the expressed aim to bring together biobanking activities in LMICs and through training and educational support, harmonize standard operating protocols to international standards and thus provide the foundation for LMIC biobank participation in international research opportunities. (4, 5)

Within the LMIC context, biobanking has the potential to significantly impact the biomedical research capacity and ultimately healthcare delivery, (6) as by establishing biobanks, scientists can gain access to diverse biological samples, which can lead to a better understanding of regional health challenges and the development of tailored treatments. Additionally, biobanks can act as central research support hubs facilitating collaborations between local researchers and international institutions, fostering knowledge exchange and capacity building. (7) The COVID-19 pandemic highlighted the need for research systems across the globe to respond quickly to healthcare emergencies. A series of publications, with the inclusion of BCNet participating institutions, helped outline the pressures and challenges that biobanking faced during that time within different contexts, including in LMICs. (8-10)

Health systems in sub-Saharan Africa attracted particular attention, as they are often characterized as ‘fragile systems’, i.e. systems that have previously struggled to respond to the effects of health emergencies and pandemics, such as the Ebola outbreak of 2014 in West Africa (11) or ongoing pressures from non-communicable diseases such as cancer. (12) As such many aspects that can contribute to overall health resilience have come into a sharp focus for this region. One such aspect is the development of infrastructures, e.g., biobanks, -omics centers of excellence, disease registries and others, that can service both healthcare needs (especially at times of national emergency, such as the pandemic) as well as research needs (in times of relatively predictable healthcare needs) and scale up/down their activities as needed.

The state of such infrastructures in sub-Saharan Africa has been described in detail in several publications (12, 13), as well as the challenges for their creation and integration to existing research structures. (14-16) However, the description of the aspects relating to the data governance and data handling in LMIC biobanks are less well characterized with only a few studies focusing on this aspect (17, 18). As each biological sample stored in biobanks can be analyzed by different precision methodologies, the acquisition of data from biobanks is anticipated to increase significantly, generating the need for establishing standards applicable to big data (19), as well as defining appropriate data governance frameworks at national and regional levels (20-22).

Previous work by IARC/WHO through BCNet reviewed the regulatory frameworks of some sub-Saharan African countries (23), as a primer of the larger study presented here. The findings showed a highly fragmented field of regulatory frameworks across the African continent, yet one that was emerging simultaneously in different countries and further catalyzed by the COVID-19 pandemic. As such it became necessary to conduct an in-depth study on the regulatory frameworks for health-related data protection in sub-Saharan African countries as they relate to biobanking. These frameworks were investigated as a regional whole and not within the confines of an extant network as was done previously.

Methodology

This literature review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) method (24). Databases in English (Pubmed, Google and Google Scholar) were searched using the keywords ("sub-Saharan Africa") AND ("biobank") OR ("biobanking") AND ("healthcare data protection") OR ("privacy policy") OR ("patient confidentiality") OR ("ethical considerations") for papers from database inception to October 2023. This provided a starting point for the literature review providing a wide range of 4802 identified manuscripts.

The search was further refined as follows with the input of the City University of London Library:

a) Looking at an African Continent Approach, as there are multi-national projects specifically mentioning challenges and opportunities posed by the regulatory frameworks.
Databases: all the databases on the Ovid Online platform (CityLibrary Journals@Ovid, Journals from Ovid, AMED, EBM Reviews, Embase, Global Health, HMIC, MIDIRS, Ovid Emcare, Ovid Nursing Database, Social Policy and Practice, Medline).
Keywords:
1. data protection/privacy policy/confidentiality/ethical regulations/ethical considerations/ biobank.
2. sub-Saharan Africa/ Africa/ African countries/ African continent
3. 1+2

b) Disease-based Approach, as some infectious diseases in the region (AIDS, Ebola, and Malaria) have specific funding streams, surveillance mechanisms, biobanks and in some cases, frameworks.
Database: all the databases on the Ovid Online platform (as in a) above)
Keywords:
1. data protection, privacy policy, confidentiality, ethical regulations, ethical considerations, biobank.
2. Sub-Saharan Africa/ Africa/ African countries/ African continent
3. Aids/ Ebola/ malaria
4. 1+2+3

c) Country-Based Approach. All the sub-Saharan African countries searched one by one for the relevant acts and frameworks.
Keywords:

1. data protection, privacy policy, confidentiality, ethical regulations, ethical considerations, biobank.
2. (name of each country)
3. 1+2

d) Artificial Intelligence (AI) approach. AI was used to identify additional manuscript. We searched with OpenAI on Bing Chat (25) for the "framework for data protection and biobanking in sub-Saharan African countries".

Following the above searches, forward and backward citation tracking was performed on those results. Additionally, the names of the frameworks and acts mentioned in these findings were used as clues to identify more results from the original pool of 4802 manuscripts. At the next stage, Bing Chat was used again for searching for additional results using name of each country individually.

These different search approaches were necessary, as there are several frameworks that have been published, but not yet implemented, and as such their mention in the international scientific literature is severely limited.

Following the removal of duplicates, and the exclusion of articles because of: (1) Irrelevant topic; (2) Inaccessible full text; (3) Retracted articles, 344 articles were reviewed for their title and abstract, and finally 56 studies were identified for full text review and included in the current review (summarized in Supplementary information). The review of the articles took place by three independent researchers (AM, SF and PP) and any contradicting opinions were resolved by a third independent reviewer (ZK, RA and CA).

Results

This review identified 56 articles (listed in Supplemental Material A), within those any act, legislation, framework, or law regarding privacy or data protection that was mentioned and is relevant to biobanking has been included. In total 31 health-related, and 24 general data protection acts and frameworks were identified which are relevant for biobanking in sub-Saharan African countries. In some countries these acts are still awaiting approvement by the authorities and some have been awaiting implementation. By October 2023, 36 African countries had data protection laws and/or regulations. Sixteen countries had signed the African Union Convention on Cyber Security and Personal Data Protection and thirteen had ratified it. These laws which cover general data protection rules and some regulations for data security in IT industry, or cybersecurity were found in the texts and through the literature search more easily than the ones that were health related. The guidelines by the Human Heredity and Health in Africa (H3Africa) initiative (26) have formed the foundation for several of these acts, and some countries have adapted their acts or frameworks to align with the H3Africa recommendations (27-29).

South Africa is well resourced in respect to the number of acts and guidelines in health research data protection, followed by Nigeria, Tanzania, Uganda, and Kenya in no particular order. Tables 1 and 2 below summarize the data protection acts or guidelines. Table 1 contains the acts which are directly health or health research related, and the Table 2 contains the general data protection acts, which are partly applicable to the health and health research sector though not explicitly so. Both Tables are supplemented with the specific section that would apply to biobanking operations, when there is a specific mention regarding the collection of data associated to physical samples.

While this is all the data that could be identified for the existence of legal and regulatory frameworks for health-related data protection in sub-Saharan African countries as they relate to biobanking, information regarding their implementation was not found in all cases. In most countries these acts took some years to prepare and even more years to be assented. (30, 31) In some cases, the acts were not implemented immediately when they were voted by parliament or signed by the president, but a slower implementation was proposed (32).

The relevant sections of the identified frameworks usually had the following headings: introduction to regulatory authorities, guidelines about researching on animals and humans, key norms and standards, norms of data and biological materials, considerations about research methods and contexts, ethics in research, research ethics committee’s introduction and roles and infrastructure.

Discussion

It is appreciated that there are specific differences between laws, regulations, and recommendations. Laws are legally binding rules established by governing bodies that must be followed and enforced within a jurisdiction. They are typically passed by legislative bodies and carry legal consequences for non-compliance. Regulations are specific rules or requirements issued by governmental agencies to implement and enforce laws. They provide detailed guidance on how laws are to be applied in practice. Recommendations, on the other hand, are non-binding suggestions or advice provided by authorities or expert bodies to inform best practices or behaviors without legal mandates or enforcement mechanisms. This review has been maximally inclusive of all the above, as was considered important to display the entirety of the emerging data protection frameworks for healthcare as they relate to biobanking in sub-Saharan Africa. As can be seen in the Tables 1 and 2 most of these instruments have been produced in the last decade. As the field continues to grow and develop the expectation is to witness the creation of the full complement of legal and regulatory instruments, as well as their implementation in practice.

Digital maturity: A common occurrence identified through the literature search is that each country has used its own Data Protection Act to produce associated health or research related ethical guidance. This is important because it demonstrates the indirect impact of these regulations on ethics and is comparable to the impact of data protection regulations elsewhere in the world, e.g., the General Data Protection Regulation (GDPR) in the European Union, which had indirect impacts on ethical guidelines, particularly in fields of healthcare, research and biobanking, where sensitive data, including genetic information, is involved. (33-36) Having said that, the consistent promotion and integration of digital health activities, inclusive of research activities, within the African continent in the last two decades has led to an increasingly public and accurate digital health maturity assessment. For example, the World Health Organization (WHO) regional and national offices, together with the Gates Foundation, GAVI, the Vaccine Alliance, and other partners contribute to the assessment and annual publication of the Health Information Systems Assessment (HIS), additionally publishing the relative HIS maturity for each one of the African countries, as part of the Global Digital Health Index (37). Importantly, this Index demonstrates a consistent digital maturity within the African continent, and that is certainly reflected on the numbers of legislations and guidelines identified in the present report- it is inevitable that an increased digital maturity creates a bottom-up pressure on specifying operational frameworks including for research data held within biobank infrastructures. As a validation of our findings, we have also compared the identified material against the DLA Piper Global Data Protection Map (a private, international law firm that collates global data protection legislation into a single point od reference). We had a complete concurrence with the associated findings. Moreover, using the Global Data Protection Map, the progress towards digital maturity is evident, as well are the gaps where still a few countries remain with complete absence of any such relevant legislation and/or guidelines (38).

Geographical determinants: From a geographical perspective, the development of these frameworks reflects regional groupings, as shown in the map on Figure 1. Western African countries have used the Economic Community of West African States (ECOWAS) forum as the central lever aiding the development of the data protection frameworks. This is not surprising as ECOWAS has been promoting common mechanisms across its fifteen member states in many fields of activity, including the economy and healthcare. One of the most prominent such activities of latter years has been the regional one health coordination mechanism. (39) Thus, this regional forum provides a fertile ground for coordinated regulatory emergence and harmonization and has the potential to strengthen further the regional biobanking activities, as for example through the ECOWAS biobank hosted in Côte d'Ivoire. (40)

It must be noted at this point that privacy, data protection and data localization are "borrowed concepts", i.e., Western notions that have been introduced into Africa, and not necessarily entirely aligned with local views. For example, the African Charter on Human and People's Right (African Charter) (41) did not include a privacy provision. Thus, there have been several academic and legal discussions as to how fundamental this right may be at the regional context (42). The Malabo Convention (43) was adopted in 2014 by the African Union (AU), as a first whole-continent attempt to harmonize data protection, driven by the need for enhanced cyber security. While the convention itself has only been partially adopted across the continent, it has had two significant impacts in the fields of health research and biobanking: firstly, it alludes to a privacy right, and secondly, it has allowed governments to reflect on data protection policies nationally, acting as a catalyst for their subsequent development. Specifically, Southern African countries have followed the early example of South Africa in terms of creating comprehensive frameworks, and in a similar manner, Eastern African countries are developing with Kenya and Tanzania currently having the more mature systems. The notable gap is in the central African section where there is a complete lack of such legislation, reflecting the disruptive and continuing political instability.

Research initiatives: An interesting point is the impact of the H3Africa initiative on the creation of regulatory frameworks for biobanking and data protection across the African continent, which was established in 2012 and has benefited by and interacted with the above-mentioned contexts. H3Africa highlighted the importance of establishing ethical guidelines and legal frameworks to govern the collection, storage, and sharing of genetic and health data in research settings early on through four sets of activities: i) it emphasized the necessity of upholding high ethical standards in genomic research, including obtaining informed consent, respecting privacy and confidentiality, and ensuring community engagement and benefit sharing. These principles have indeed informed the development of regulatory frameworks for biobanking and data protection. ii) H3Africa prioritized capacity building in bioethics and regulatory affairs to strengthen the ability of African countries to develop and implement appropriate regulatory frameworks. This was done often in collaboration with national or other international initiatives, e.g., BCNet. iii) It fostered collaboration and knowledge exchange among African countries and international partners and iv) it advocated for the integration of ethical considerations into national policies and legislation governing biobanking and data protection.

The above activities had two consequences that are now visible through the emerging legislative frameworks: they led to an increased recognition of the importance of protecting research participants' rights and interests, as well as promoting trust and transparency in genomic research initiatives, and secondly, they have resulted to similarities that can be seen in these acts from different countries, though falling short of a harmonized landscape.

Cultural determinants, Trust and Transparency: Finally, another issue that was frequently highlighted by the literature as a reason for the creation of such legal frameworks was the mistrust that exists for the scientific cooperation with international partners. The negative history of past misguided attempts at using physical samples and associated healthcare data in some parts of the continent and has described previously (44, 45) is still resonating with legislating bodies. While this has a positive implication of perhaps accelerating the creation and implementation of these frameworks, at the same time it may also have a negative consequence for biobanking which requires partnership and data transfer in its core and may thus require some time to overcome the existing historical legacy.

Additionally, the cultural understanding of data privacy is an important parameter in the development of legal frameworks. Specifically, Ubuntu, is an African philosophy emphasizing community, interconnectedness, and mutual respect, offers a unique perspective on privacy. It views privacy not as an individual right but as a communal value, where personal information is respected and protected within the context of maintaining harmony and trust within the community. In Ubuntu, privacy is balanced with the collective well-being, ensuring that while individuals' dignity and personal boundaries are honored, the needs and health of the community are also considered. Thus, the legal frameworks developed in sub-Saharan Africa for biobanking should be viewed through this cultural lens (46, 47).

Limitations

In general, finding the acts in the sub-Saharan African context was a challenging task. Some acts could not be found online, some were not in the English language, and some were not publicly accessible. Despite efforts to comprehensively search for relevant studies, it is possible that some relevant regulations may be missed. In addition to this, while there was data describing these documents, in many cases no exact data can be found about the implementation of the acts. As such caution should be given to the interpretation of the national efforts, as they can be at very distinct phases of implementation, ranging from a consultation/preparatory phase to a formal regulatory framework that has been approved, yet its status can range from being non-implemented to fully implemented. Moreover, regulations may exist in local languages that was thus difficult to identify with the current search methodology.

Conclusions

Our findings confirm that for health-related data protection frameworks in sub-Saharan African countries as they relate to biobanking continue to emerge and spread across the continent at different speeds, responding to the calls for stronger regulation to support research in this region. However, they are fragmented and largely in-development. Most of the acts in place are broad guidelines without extensive details, which then require an interpretative step to aid implementation. Notably the regional initiatives, such as the one championed by ECOWAS, have the potential for accelerating this process and can lead through an indirect harmonization towards feasible scientific co-operation among the countries in the region and further afield.

Acknowledgements:

The authors would like to thank the Library of City University of London for their extensive input in constructing the parallel literature research strategies. Additionally, the authors would like to thank Prof Gordon Akanzuwine Awandare, Director of the West African Center for Cell Biology of Infectious Pathogens (WACCBIP), University of Ghana, Ghana; Dr Carmen Swanepoel, Principal Medical Scientist/Lecturer: Division of Haematology /Department of Pathology at the National Health Laboratory Service/University of Stellenbosch, South Africac; and Marianne K Henderson, Division of Cancer Epidemiology and Genetics – NCI, USA, for their input and discussions during the conduct of the research.

Funding:

Dr Kozlakidis was funded in part by the National Cancer Institute (NCI, USA), Center for Global Health Award #66415_Activities for Biobanking and Cohort Building Network (BCNet).

Disclaimer:

Where authors are identified as personnel of the International Agency for Research on Cancer/WHO, the authors alone are responsible for the views expressed in this article and they do not necessarily represent the decisions, policy or views of the International Agency for Research on Cancer/WHO.

REFERENCES

1. Vaught J, Lockhart NC. The evolution of biobanking best practices. Clinica chimica acta. 2012 Oct 9;413(19-20):1569-75.
2. Sargsyan K, Huppertz B, Gramatiuk S, editors. Biobanks in Low-and Middle-Income Countries: Relevance, Setup and Management. Springer International Publishing; 2022 Mar 15.
3. Henderson MK, Kozlakidis Z. ISBER and the biobanking and cohort network (BCNet): A strengthened partnership. Biopreservation and Biobanking. 2018 Oct 1;16(5):393-4.
4. Zawati MN, Tassé AM, Mendy M, Caboux E, Lang M, Biobank and Cohort Building Network Members. Barriers and opportunities in consent and access procedures in low-and middle-income country biobanks: meeting notes from the BCNet training and general assembly. Biopreservation and biobanking. 2018 Jun 1;16(3):171-8.
5. Biobank and Population Cohort Network. International Agency for Research on Cancer. World Health Organization. Available at: https://bcnet.iarc.fr/ Last accessed May 10, 2024.
6. Cheong IH, Kozlakidis Z. The Importance of Cancer Biobanks in Low-and Middle-Income Countries. InBiobanks in Low-and Middle-Income Countries: Relevance, Setup and Management 2022 Mar 16 (pp. 147-154). Cham: Springer International Publishing.
7. Gramatiuk S, Alekseenko M, Sarkisian T, Muradyan A, Sargsyan K. Biobanking Concepts Specific for Developing Countries. InBiobanks in Low-and Middle-Income Countries: Relevance, Setup and Management 2022 Mar 16 (pp. 33-37). Cham: Springer International Publishing.
8. Henderson MK, Kozlakidis Z, Fachiroh J, Wiafe Addai B, Xu X, Ezzat S, Wagner H, Marques MM, Yadav BK. The responses of biobanks to COVID-19. Biopreservation and Biobanking. 2020 Dec 1;18(6):483-91.
9. Medina PB, Garcia DL, Cheong IH, Lin RT, Kozlakidis Z. Construction and application of biobanks for infectious diseases: focus on SARS-CoV-2. Innovations in Digital Health, Diagnostics, and Biomarkers. 2022 Jan 1;2(2022):40-7.
10. Allocca CM, Bledsoe MJ, Albert M, Anisimov SV, Bravo E, Castelhano MG, Cohen Y, De Wilde M, Furuta K, Kozlakidis Z, Martin D. Biobanking in the COVID-19 era and beyond: Part 1. How early experiences can translate into actionable wisdom. Biopreservation and biobanking. 2020 Dec 1;18(6):533-46.
11. Amu H, Dowou RK, Saah FI, Efunwole JA, Bain LE, Tarkang EE. COVID-19 and health systems functioning in sub-Saharan Africa using the “WHO Building Blocks”: the challenges and responses. Frontiers in Public Health. 2022 Apr 4;10:856397.
12. Ngwa W, Addai BW, Adewole I, Ainsworth V, Alaro J, Alatise OI, Ali Z, Anderson BO, Anorlu R, Avery S, Barango P. Cancer in sub-Saharan Africa: a lancet oncology commission. The Lancet Oncology. 2022 Jun 1;23(6):e251-312.
13. Mendy M, Caboux E, Sylla BS, Dillner J, Chinquee J, Wild C, BCNet Survey Participants. Infrastructure and facilities for human biobanking in low-and middle-income countries: a situation analysis. Pathobiology. 2015 Mar 16;81(5-6):252-60.
14. Medina PB, Kealy J, Kozlakidis Z. Integrating research infrastructures into infectious diseases surveillance operations: Focus on biobanks. Biosafety and Health. 2022 Dec 1;4(6):410-3.

15. Ezzat S, Biga R, Kozlakidis Z. Biobanking in LMIC settings for infectious diseases: Challenges and enablers. Biosafety and health. 2022 Oct 25;4(05):290-2.
16. Conradie EH, Malherbe H, Hendriksz CJ, Dercksen M, Vorster BC. An overview of benefits and challenges of rare disease biobanking in Africa, Focusing on South Africa. Biopreservation and Biobanking. 2021 Apr 1;19(2):143-50.
17. Abdelhafiz AS, Ahram M, Ibrahim ME, Elgamri A, Gamel E, Labib R, Silverman H. Biobanks in the low-and middle-income countries of the Arab Middle East region: challenges, ethical issues, and governance arrangements—a qualitative study involving biobank managers. BMC Medical Ethics. 2022 Aug 14;23(1):83.
18. Bull S, Bhagwandin N. The ethics of data sharing and biobanking in health research. Wellcome Open Research. 2020;5.
19. Kozlakidis, Z. (2016). Biobanking with Big Data: A Need for Developing 'Big Data Metrics'. Biopreservation and Biobanking, 14(5), pp.450–451. doi: https://doi.org/10.1089/bio.2015.0106.
20. Nansumba H, Ssewanyana I, Tai M, Wassenaar D. Role of a regulatory and governance framework in human biological materials and data sharing in National Biobanks: Case studies from Biobank Integrating Platform, Taiwan and the National Biorepository, Uganda. Wellcome Open Research. 2019;4.
21. Fernando B, King M and Sumathipala A. Advancing good governance in data sharing and biobanking -international aspects [version 1; peer review: 1 approved] Wellcome Open Research 2019, 4:184. https://doi.org/10.12688/wellcomeopenres.15540.1
22. Akintola SO. Legal implications of data sharing in biobanking research in low-income settings: The Nigerian experience. South African Journal of Bioethics and Law. 2018 Aug 3;11(1):15-9.
23. Vodosin, P., Jorgensen, A.K., Mendy, M., Kozlakidis, Z., Caboux, E. and Zawati, M.H. (2021). A Review of Regulatory Frameworks Governing Biobanking in the Low and Middle Income Member Countries of BCNet. Biopreservation and Biobanking, 19(5), pp.444–452. doi: https://doi.org/10.1089/bio.2020.0101.
24. Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. Bmj. 2021;372:n71.
25. Kelly D, Chen Y, Cornwell SE, Delellis NS, Mayhew A, Onaolapo S, Rubin VL. Bing Chat: The Future of Search Engines?. Proceedings of the Association for Information Science and Technology. 2023 Oct;60(1):1007-9.
26. The Human Heredity and Health in Africa (H3Africa) initiative. Available at: https://h3africa.org/ Accessed on May 10, 2024.
27. O'Doherty KC, Shabani M, Dove ES, Bentzen HB, Borry P, Burgess MM, Chalmers D, De Vries J, Eckstein L, Fullerton SM, Juengst E. Toward better governance of human genomic data. Nature genetics. 2021 Jan;53(1):2-8.
28. Mulder N, Abimiku AL, Adebamowo SN, de Vries J, Matimba A, Olowoyo P, Ramsay M, Skelton M, Stein DJ. H3Africa: current perspectives. Pharmacogenomics and personalized medicine. 2018 Apr 10:59-66.
29. Nnamuchi O. H3Africa: An Africa exemplar? Exploring its framework on protecting human research participants. Developing World Bioethics. 2018 Jun;18(2):156-64.

30. Mahomed S. Human biobanking in developed and developing countries: An ethico-legal comparative analysis of the frameworks in the United Kingdom, Australia, Uganda, and South Africa. Cambridge Quarterly of Healthcare Ethics. 2021 Jan;30(1):146-60.
31. Nnamuchi O. Biobank and genomic research in Uganda: Are extant privacy and confidentiality regimes adequate?. The Journal of Law, Medicine & Ethics. 2016 Mar;44(1):85-95.
32. Orji UJ. Regionalizing data protection law: a discourse on the status and implementation of the ECOWAS Data Protection Act. International Data Privacy Law. 2017 Aug 1;7(3):179-89.
33. Goddard M. The EU General Data Protection Regulation (GDPR): European regulation that has a global impact. International Journal of Market Research. 2017 Nov;59(6):703-5.
34. Shabani M, Chassang G, Marelli L. The Impact of the GDPR on the Governance of Biobank Research. GDPR and biobanking: Individual rights, public interest and research regulation across Europe. 2021:45-60.
35. Slokenberga S, Tzortzatou O, Reichel J. GDPR and biobanking: Individual rights, public interest and research regulation across Europe. Springer Nature; 2021.
36. Staunton C, Slokenberga S, Mascalzoni D. The GDPR and the research exemption: considerations on the necessary safeguards for research biobanks. European Journal of Human Genetics. 2019 Aug;27(8):1159-67.
37. World Health Organization. Global Digital Health Index. Available at: www.digitalhealthindex.org/. Accessed on May 10, 2024.
38. DLA Piper. Data Protection Laws of the World. Available at: www.dlapiperdataprotection.com/index.html. Accessed on May 10, 2024.
39. Lokossou VK, Atama NC, Nzietchueng S, Koffi BY, Iwar V, Oussayef N, Umeokonkwo CD, Behravesh CB, Sombie I, Okolo S, Ouendo EM. Operationalizing the ECOWAS regional one health coordination mechanism (2016–2019): Scoping review on progress, challenges and way forward. One Health. 2021 Dec 1;13:100291.
40. Kintossou AK, N'dri MK, Money M, Cissé S, Doumbia S, Soumahoro MK, Coulibaly AF, Djaman JA, Dosso M. Study of laboratory staff knowledge of biobanking in Côte d'Ivoire. BMC Medical Ethics. 2020 Dec;21:1-6.
41. Umozurike UO. The African Charter on human and peoples' rights. American Journal of International Law. 1983 Oct;77(4):902-12.
42. Babalola O. Transborder flow of personal data (TDF) in Africa: Stocktaking the ills and gains of a divergently regulated business mechanism. Computer Law & Security Review. 2024 Apr 1;52:105940.
43. Ball KM. African union convention on cyber security and personal data protection. International Legal Materials. 2017 Feb;56(1):164-92.
44. Moodley K, Singh S. "It's all about trust": reflections of researchers on the complexity and controversy surrounding biobanking in South Africa. BMC medical ethics. 2016 Dec;17:1-9.
45. Tindana P, Molyneux S, Bull S, Parker M. 'It is an entrustment': Broad consent for genomic research and biobanks in sub-Saharan Africa. Developing world bioethics. 2019 Mar;19(1):9-17.
46. Olinger HN, Britz JJ, Olivier MS. Western privacy and/or Ubuntu? Some critical comments on the influences in the forthcoming data privacy bill in South Africa. The International Information & Library Review. 2007 Mar 1;39(1):31-43.

47. Reviglio U, Alunge R. “I am datafied because we are datafied”: An Ubuntu perspective on (relational) privacy. Philosophy & Technology. 2020 Dec;33(4):595-612.

The health-related acts are listed in Table 1.

Country	Title	Implemented	Relevant section
Angola	Law 8/04 on HIV and AIDS (2004)		
Africa	Ethics and Governance Framework for Best Practice in Genomic Research and Biobanking in Africa-2017		
Africa	H3Africa Guideline for Informed Consent-2017		
Africa	H3Africa Consortium Data Sharing, Access and Release Policy-2020		
Benin	Portant Code D'éthique Et De Déontologie Pour La Recherche En Santé En République Du Bénin.		
Botswana	Public Health Act 2007		
Ethiopia	National Health Research Ethics Review Guidelines	2014	Chapter 9
Gambia	Guidelines of the National DNA bank, 2001		Section 7
Global	UNAIDS - Considerations and Guidance for Countries Adopting National Health Identifiers	2014	
Kenya	The Health Act No. 21 of 2017	Yes	
Kenya	National Guidelines for Ethical Conduct of Research Involving Human Participants	2020	
Malawi	Policy Requirements, Procedure and Guidelines for the Conduct and Review of Human Genetic Research in Malawi-2012		
Mauritius	Ethical Guidelines for Biomedical Research Involving Human Subjects-2003		
Nigeria	Policy Statement on Storage of Human Samples in Biobanks and Biorepositories in Nigeria (PS1.02013)-2013		
Nigeria	National Code of Health Research Ethics-2007		
Nigeria	Keeping Personal Health Information Safe and Secure: A Guide to Privacy and Data Security Laws in Nigeria	Oct-15	
Nigeria	HIV and AIDS (Anti-Discrimination) Act 2014		Section 13
Nigeria	National Health Act 2014	Oct-14	
Sierra Leone	GUIDELINES FOR CONDUCTING CLINICAL TRIALS OF MEDICINES, FOOD SUPPLEMENTS, VACCINES AND MEDICAL DEVICES IN SIERRA LEONE	2014	
South Africa	No. 61 of 2003: National Health Act	2004	Chapter 9
South Africa	Guidelines on Ethics for medical research, reproductive biology and genetic research		
South Africa	Human Genetics and Genomics in South Africa: Ethical, Legal and Social Implications - 2018		
South Africa	Ethics in Health Research - 2015		
Sudan	National Guidelines for Ethical Conduct of Research Involving Human Subjects (2008)		
Tanzania	Human DNA Regulation Act, 2009 (Act No. 8 of 2009)		
Tanzania	THE HIV AND AIDS (PREVENTION AND CONTROL) ACT, 2008		Part 5
Tanzania	Guidelines Of Ethics For Health Research In Tanzania - 2009		
Uganda	HIV and AIDS Prevention and Control Act, 2014	Yes	Section 29-31
Uganda	National Guidelines for Research involving Humans as Research Participants-2014		
Zambia	The National Health Research Act, 2013	Yes	Section 26, 32, 47-53
Zimbabwe	HEALTH PROFESSIONS ACT Acts 6/2000, 22/2001,14/2002, 28/2004	2001	

Table 1: Health-Related Acts Regarding Data Protection in Sub-Saharan African Countries

The general data protection acts which have covered some health-related aspects are presented in Table 2.

Country	Title	Implemented	Relevant section
Botswana	The eHealth Strategy of Botswana (2020-2024) - 2020		
Botswana	Data protection act 2018		Section 23
Botswana	Data Protection Act 2021	15,Oct,2021	
Côte d'Ivoire	LAW No. 2013-450 dated June 19, 2013 on the protection of personal data	19-Jun-13	Chapter4-art 21
Eswatini	The Data Protection Act - Act No.5 of 2022		
Gabon	Law No. 001/2011 on the Protection of Personal Data “the Law” - 2011		
Ghana	Data protection act, 2012	10, May, 2012	Section 62
Kenya	The Data Protection Act No. 24 of 2019	Yes	
Kenya	The Data Protection General Regulations 2021	Yes	Section 57
Malawi	The Data Protection Bill 2021		
Nigeria	NIGERIA DATA PROTECTION REGULATION 2019: IMPLEMENTATION FRAMEWORK	2020	
Nigeria	Nigeria Data Protection Bill, 2022	2023	Section 6-8
Rwanda	Law No. 058/2021 of 13 October 2021	2021	
Rwanda	STANDARD OPERATING PROCEDURES (SOPs)		Section 10,31,35
Senegal	Act No 2008-12 of 25 Jan 2008		
South Africa	The Protection of Personal Information Act (POPIA) Act no 4 of 2013	Nov.2013	Section 32
Tanzania	THE PERSONAL DATA PROTECTION ACT-13/6/2023		
Togo	Charte du Comité de Bioéthique pour la Recherche en Santé-2009		
Togo	Law No. 2019-014 (DPA Law)		Chapter 1
Uganda	Data Protection and Privacy Act of 2019	Yes	
Uganda	Data Protection and Privacy Regulations, 2021	May 2021	
Uganda	Personal Data Protection Office Website		Page 10
Zambia	Data Protection Act, No.3 of 2021 (Data Act)	Apr-21	
Zimbabwe	Data Protection Act 2021 (Act 5 of 2021)	NO	Part 5, Section 12

Table 2: General Data Protection Acts in Sub-Saharan African Countries

These acts are also presented in the map in Figure 1.

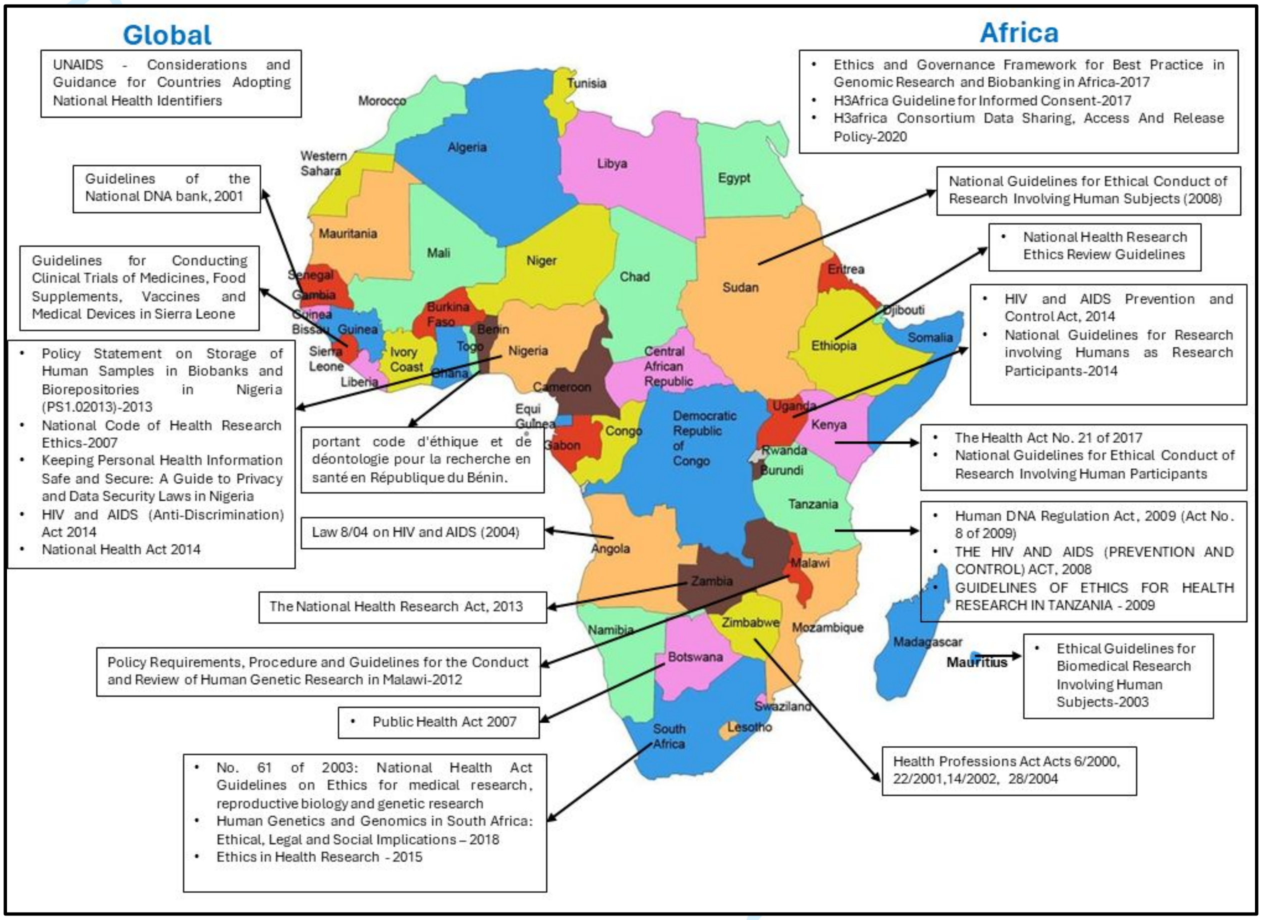

Figure 1: Health-Related Acts Regarding Data Protection in Sub-Saharan African Countries

Supplementary information

List of articles identified through the literature search.

1. Nordling L. A new law was supposed to protect South Africans' privacy. It may block important research instead. Science. 2019 Feb 20. Available at https://www.sciencemag.org/news/2019/02/new-law-was-supposed-protect-south-africans-privacy-it-may-block-important-research. Last visited May 10, 2024.
2. Matandika L, Ngóngóla RT, Mita K, Manda-Taylor L, Gooding K, Mwale D, Masiye F, Mfutso-Bengo J. A qualitative study exploring stakeholder perspectives on the use of biological samples for future unspecified research in Malawi. BMC medical ethics. 2020 Dec;21:1-0.
3. Adeyoju, A. A Quick Guide on the Data Protection Regime in Nigeria. 2020 Jan 4. Available at: http://dx.doi.org/10.2139/ssrn.3522188. Last visited May 10, 2024.
4. Vodosin P, Jorgensen AK, Mendy M, Kozlakidis Z, Caboux E, Zawati MN, BCNet members. A review of regulatory frameworks governing biobanking in the low and middle income member countries of BCNet. Biopreservation and Biobanking. 2021 Oct 1;19(5):444-52.
5. Jinabhai CC, Onwubu SC, Sibiya MN, Thakur S. Accelerating implementation of district health information systems: perspectives from healthcare workers from kwazulu-natal, South Africa. South African Journal of Information Management. 2021;23(1):1-8.
6. Bowmans. Africa guide to data protection. 2022 March. Available at: https://bowmanslaw.com/wp-content/uploads/2022/06/Data-Protection_01.06.2022.pdf. Last visited May 10, 2024.
7. Privacy International. Analysis of Kenya’s Data Protection Act, 2019. 2020 Jan. Available at: https://privacyinternational.org/sites/default/files/2020-02/Analysis%20of%20Kenya%20Data%20Protection%20Act%2C%202019_Jan2020.pdf. Last visited May 10, 2024.
8. Slokenberga S. Biobanking and data transfer between the EU and Cape Verde, Mauritius, Morocco, Senegal, and Tunisia: adequacy considerations and Convention 108. International Data Privacy Law. 2020 May 1;10(2):132-45.
9. Adebamowo CA, Callier S, Akintola S, Maduka O, Jegede A, Arima C, Ogundiran T, Adebamowo SN, BridgELSI Project as part of the DS-I Africa Consortium. The promise of data science for health research in Africa. Nature Communications. 2023 Sep 29;14(1):6084.
10. And linked presentation online: ‘Biobanks and Genomics Perspectives from Africa’, (2017) Available at: https://www.wma.net/wp-content/uploads/2017/01/Adebamowo-Perspectives-on-Biobanking.pdf. Last visited May 10, 2024.
11. Adigun M, Ojebuyi BR, Akinyemi J, Wahab K, Akpalu A, Sarfo FS, Owolabi LF, Musbahu R, Bello A, Obiako R, Ogunronbi M. Legal Implications of Stroke Biobanking and Genomics Research in Sub-Saharan Africa. Journal of Law & Medicine. 2022 Jun 1;29(2).
12. Staunton C, Moodley K. Challenges in biobank governance in Sub-Saharan Africa. BMC medical Ethics. 2013 Dec;14:1-8.

13. Sippel D, Marckmann G, Ndzie Atangana E, Strech D. Clinical ethics in Gabon: the spectrum of clinical ethical issues based on findings from in-depth interviews at three public hospitals. PLoS One. 2015 Jul 10;10(7):e0132374.
14. Manda DL. Confidentiality in African Healthcare Ethics: A Problematic Concept?. Journal of Gleanings from Academic Outliers. 2012 Jun 1;1(1).
15. Nienaber A. Consent to and authorisation of the export and use of human biological specimens for future research-perspectives from three African countries. Comparative and International Law Journal of Southern Africa. 2011 Jul 1;44(2):225-54.
16. Igumbor JO, Bosire EN, Vicente-Crespo M, Igumbor EU, Olalekan UA, Chirwa TF, Kinyanjui SM, Kyobutungi C, Fonn S. Considerations for an integrated population health databank in Africa: lessons from global best practices. Wellcome Open Research. 2021;6.
17. Collaboration on International ICT Policy for East and Southern Africa (CIPESA). Covid-19 and data rights in Uganda. 2022 Apr. Available at: https://cipesa.org/wp-content/files/documents/COVID-19-and-Data-Rights-in-Uganda-Report-.pdf. Last accessed May 10, 2024.
18. Oluwadamilare Olaniyi, A. Data protection in the Nigerian health sector. 2023, July 24. Available at: https://www.linkedin.com/pulse/data-protection-nigerian-health-sector-adetunji-oluwadamilare-olaniyi/. Last accessed May 10, 2024.
19. DLA Piper. Data Protection Laws of the world- Nigeria. 2024, Jan 18. Available at: https://www.dlapiperdataprotection.com/system/modules/za.co.heliosdesign.dla.lotw.data_protection/functions/handbook.pdf?country-1=NG#:~:text=Nigeria%20Data%20Protection%20Regulation&text=The%20NDPR%20provides%20legal%20safeguards,to%20by%20the%20Data%20Subject. Last accessed May 10, 2024.
20. Staunton C, Tschigg K, Sherman G. Data protection, data management, and data sharing: Stakeholder perspectives on the protection of personal health information in South Africa. PLoS One. 2021 Dec 20;16(12):e0260341.
21. Network PE. Electronic health privacy and security in developing countries and humanitarian operations. Protecting medical information in eHealth projects. London: London School of Economics and Political Science. 2010:1-28.
22. Sathar MA. Ethical issues associated with using human biological material in collaborative research with developed countries: a case study (Doctoral dissertation, University of the Witwatersrand). 2011. Available at: https://www.semanticscholar.org/paper/Ethical-issues-associated-with-using-human-material-Sathar/4dc0d2ad992e3bcf3c5e8d06022c44509c8d1012. Last accessed May 10, 2024.
23. Slokenberga S, Reichel J, Niringiye R, Croxton T, Swanepoel C, Okal J. EU data transfer rules and African legal realities: is data exchange for biobank research realistic?. International Data Privacy Law. 2019 Feb 1;9(1):30-48.
24. Inau ET, Nalugala R, Nandwa WM, Obwanda F, Wachira A, Cartaxo A. FAIR Equivalency, regulatory framework and adoption potential of FAIR Guidelines in health in Kenya. Data Intelligence. 2022 Oct 1;4(4):852-66.
25. Diwani S, Sam A. Framework for Data Mining In Healthcare Information System in Developing Countries: A Case of Tanzania. IJCER. 2013 Oct:3(10):1-7.

26. Kaawa-Mafigiri D, Ekusai Sebatta D, Munabi I, Mwaka ES. Genetic and genomic researchers' perspectives on biological sample sharing in collaborative research in Uganda: a qualitative study. Journal of Empirical Research on Human Research Ethics. 2023 Jul;18(3):134-46.
27. Chanda-Kapata P, Kapata N, Moraes AN, Chongwe G, Munthali J. Genomic research in Zambia: confronting the ethics, policy and regulatory frontiers in the 21st Century. Health research policy and systems. 2015 Dec;13:1-7.
28. AIDS Law Brief Background Paper. University of Washnigton/Makerere University. Health Information Privacy & HIV/AIDS in Uganda. 2015 Sept. Available at: https://globalhealth.washington.edu/sites/default/files/ALB_Background_Paper-Health_Information_Confidentiality_in_Uganda.pdf. Last accessed May 10, 2024.
29. Tegegne MD, Melaku MS, Shimie AW, Hunegnaw DD, Legese MG, Ejigu TA, Mengestie ND, Zemene W, Zeleke T, Chanie AF. Health professionals' knowledge and attitude towards patient confidentiality and associated factors in a resource-limited setting: a cross-sectional study. BMC medical ethics. 2022 Mar 14;23(1):26.
30. Ledikwe JH, Grignon J, Lebelonyane R, Ludick S, Matshediso E, Sento BW, Sharma A, Semo BW. Improving the quality of health information: a qualitative assessment of data management and reporting systems in Botswana. Health research policy and systems. 2014 Dec;12:1-0.
31. AIDS Law Brief Background Paper. University of Washnigton/Makerere University. Health Information Privacy & HIV/AIDS in Tanzania. 2015 Sept. Available at: https://globalhealth.washington.edu/sites/default/files/ALB_Background_Paper-Health_Information_Confidentiality_in_Tanzania.pdf. Last accessed May 10, 2024.
32. Basajja M, Nambobi M. Information streams in health facilities: The case of Uganda. Data Intelligence. 2022 Oct 1;4(4):882-98.
33. Ndlovu K, Mars M, Scott RE. Interoperability frameworks linking mHealth applications to electronic record systems. BMC health services research. 2021 May 13;21(1):459.
34. Kenya Legal and Ethical Network on HIV & AIDS (KELIN) and 3 others v Cabinet Secretary Ministry of Health and 4 others. eKLR HC Petition No 250 of 2015 Judgement. (2016). Available at: https://kenyalaw.org/caselaw/cases/view/132167/. Last accessed May 10, 2024.
35. And further related information and documents available at Kenya Legal and Ethical Issues Network on HIV and AIDS (KELIN), https://www.kelinkenya.org/. Last accessed May 10, 2024.
36. Ministry of Health, Ghana. Legal and policy framework for health information and health data reporting (2008). Available at: https://www.moh.gov.gh/wp-content/uploads/2016/02/Policy-and-Legal-Framework-for-HMIS.pdf. Last accessed May 10, 2024.
37. Townsend BA, Sihlahla I, Naidoo M, Naidoo S, Donnelly DL, Thaldar DW. Mapping the regulatory landscape of AI in healthcare in Africa. Frontiers in Pharmacology. 2023 Aug 24;14:1214422.
38. Nyaga BM, Ondego JC, Joel M. Mediation and Data Protection Law in Kenya: Appraising ADR for Optimal Access to Justice under the DPA 2019. Kenya School of Law, Forthcoming. 2023 Apr 20.
39. Barchi F, Little MT. National ethics guidance in Sub-Saharan Africa on the collection and use of human biological specimens: a systematic review. BMC medical ethics. 2016 Dec;17:1-25.
40. Kirigia JM, Kathyola DD, Muula AS, Ota MM. National health research system in Malawi: dead, moribund, tepid or flourishing?. BMC health services research. 2015 Dec;15:1-4.

41. Mackworth-Young CR, Schneiders ML, Wringe A, Simwinga M, Bond V. Navigating 'ethics in practice': An ethnographic case study with young women living with HIV in Zambia. Global public health. 2019 Dec 2;14(12):1689-702.
42. Enabulele O, Enabulele JE. Nigeria's National Health Act: An assessment of health professionals' knowledge and perception. Nigerian Medical Journal. 2016 Sep 1;57(5):260-5.
43. Greenleaf G. Now 157 countries: Twelve data privacy laws in 2021/22. 176 Privacy Laws & Business International Report. 2022 Jun 16;1:3-8.
44. Alderibigbe TO, Sodipo B. Patient's medical records, privacy and copyright in Nigeria: on-going research. University of Western Australia Law Review. 2017 Oct 1;42(2):88-109.
45. Roehrs S. Privacy, HIV/AIDS and public health interventions. South African Law Journal. 2009 Jan 1;126(2):360-97.
46. Staunton C, Adams R, Anderson D, Croxton T, Kamuya D, Munene M, Swanepoel C. Protection of Personal Information Act 2013 and data protection for health research in South Africa. International Data Privacy Law. 2020 May 1;10(2):160-79.
47. Hogan Lovells. Recent developments in African data protection laws - Outlook for 2023 [authored by Aissatou Sylla]. 2023 Feb 24. Available at: https://www.engage.hoganlovells.com/knowledgeservices/news/recent-developments-in-african-data-protection-laws-outlook-for-2023. Last accessed May 10, 2024.
48. de Vries J, Munung SN, Matimba A, McCurdy S, Ouwe Missi Oukem-Boyer O, Staunton C, Yakubu A, Tindana P, H3Africa Consortium. Regulation of genomic and biobanking research in Africa: a content analysis of ethics guidelines, policies and procedures from 22 African countries. BMC medical ethics. 2017 Dec;18:1-9.
49. Marutha N. The application of legislative frameworks for the management of medical records in Limpopo Province, South Africa. Information Development. 2019 Sep;35(4):551-63.
50. Townsend BA, Scott RE. The development of ethical guidelines for telemedicine in South Africa. South African Journal of Bioethics and Law. 2019 Jun 1;12(1):19-26.
51. McMillan JR, Conlon C. The ethics of research related to health care in developing countries. Journal of medical ethics. 2004 Apr 1;30(2):204-6.
52. Staunton C, De Vries J. The governance of genomic biobank research in Africa: reframing the regulatory tilt. Journal of Law and the Biosciences. 2020 Jan;7(1):lsz018.
53. Townsend B. The lawful sharing of health research data in South Africa and beyond. Information & Communications Technology Law. 2022 Jan 2;31(1):17-34.
54. Were V, Moturi C. Toward a data governance model for the Kenya health professional regulatory authorities. The TQM Journal. 2017 Jun 12;29(4):579-89.
55. Nicholas N, Nicholas S. Understanding confidentiality and the law on access to medical records. Obstetrics, Gynaecology & Reproductive Medicine. 2010 May 1;20(5):161-3.
56. Personal Data Protection Office, Uganda. What is Data and What Amounts to Personal Data? [authored by Rhona Adong Wacha]. Available at: https://www.pdpo.go.ug/updates/data-protection-and-privacy-in-ugandas-public-and-private-health-sector. Last accessed May 10, 2024.