SPECIAL ISSUE

Kenya Gazette Supplement No. 72 (National Assembly Bills No. 20)

REPUBLIC OF KENYA

KENYA GAZETTE SUPPLEMENT

NATIONAL ASSEMBLY BILLS, 2025

NAIROBI, 29th May, 2025

CONTENT

Bill for Introduction into the National Assembly—

PRINTED AND PUBLISHED BY THE GOVERNMENT PRINTER, NAIROBI

THE KENYA MEDICAL RESEARCH INSTITUTE BILL, 2025

ARRANGEMENT OF CLAUSES

Clause

THE KENYA MEDICAL RESEARCH INSTITUTE BILL, 2025

A Bill for

AN ACT of Parliament to make provision for the establishment, powers and functions of the Kenya Medical Research Institute; to provide for the effective conduct, co-ordination and promotion of research for human health in Kenya and for connected purposes

ENACTED by the Parliament of Kenya as follows—

PART I— PRELIMINARIES

Short title.

1. This Act may be cited as the Kenya Medical Research Institute Act, 2025.

Interpretation.

2. In this Act, unless the context otherwise requires—

"alternative medicine" means complementary medicine and includes a broad set of health care practices that are not part of Kenya's tradition and are not integrated into the dominant health care system;

"biobanks" means specialized institutions or repository that collect, store and manage biological materials;

"biological material" means living organisms or any substance derived from living organisms including human tissues, blood, genetic material, cells, microorganisms, toxins and other materials for use in scientific and medical research;

"biospecimens" means any material derived from a human or animal body for research, diagnostic or therapeutic purposes including blood, tissue, urine, saliva and genetic material;

"Board" means the Board of Directors of the Institute established under section 9;

"Cabinet Secretary" means the Cabinet Secretary responsible for matters relating to health;

"clinical trial" means a research study in which one or more human subjects are prospectively assigned to one or

more interventions to evaluate the effects of those interventions on health-related biomedical or behavioural outcomes;

"Commission" means the commission for University Education Established under section 4 of Universities Act; Cap. 210.

"Director-General" means the person appointed under section 16;

"human health" means a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity;

"incubation centres" means a transitory and facilitative platform that gives innovators technical assistance, infrastructure, access to inventors and investors and networking that may encourage and scale-up inventions;

"informed consent" means a process of obtaining permission before conducting a health care prevention on a person;

"Institute" means the Kenya Medical Research Institute established under section 5;

"intellectual property" mean any new or useful process, machine, composition of matter, life form, article of manufacture, software, copyrighted work and know-how and information associated with the above. It includes but is not restricted to such things as new or improved devices, circuit layouts, chemical compounds, drugs, genetically engineered biological organisms, data sets, databases, software or unique and innovative uses of existing inventions; and

"public health emergency" means the occurrence or imminent threat of an illness or health condition caused by bioterrorism, epidemic or pandemic disease or an infectious agent or toxin that causes substantial risks to humans by causing a significant number of human fatalities or permanent or long-term disability;

"research for human health" includes systematic investigation, experimentation, exploration, examination and evaluation for purposes of decision-policy-development, policy-development and practice in human health and includes clinical trials; and

"traditional medicine" includes the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health and in the prevention, diagnosis, improvement or treatment of physical and mental illness.

Objects of the Act.

3. The objects of this Act shall be to—

(a) establish the Kenya Medical Research Institute;

(b) establish mechanisms for the conduct, co-ordination, promotion and regulation of research for human health in Kenya; and

(c) provide for the protection and improvement of human health and quality of life through research and development, capacity building, innovation and service delivery.

Guiding Principles.

4. (1) The Institute shall, in the performance of its functions, be guided by—

(a) values and principles enshrined in Articles 6(3), 10, 27(4), 28 and 43(1)(a) of the Constitution;

(b) the values and principles of public service set out in Article 232(1) of the Constitution; and

(c) the principles of leadership and integrity set out under Chapter Six of the Constitution.

(2) Without prejudice to the generality of subsection (1), a person involved in the implementation of this Act shall have regard to —

(a) research excellence and integrity;

(b) respect, ethics and professional standards;

(c) honesty and transparency;

(d) openness and accountability; and

(e) commitment in service to the people.

PART II—THE KENYA MEDICAL RESEARCH INSTITUTE

Establishment of the Institute.

5. (1) There is established the Kenya Medical Research Institute.

(2) The Institute shall be a body corporate with perpetual succession and a common seal and shall, in its corporate name, be capable of—

(a) suing and being sued;

(b) taking, purchasing or otherwise acquiring, holding, charging and disposing of movable and immovable property;

(c) borrowing and lending money;

(d) entering into contracts; and

(e) doing or performing all other things or acts necessary for the proper performance of its functions under this Act, which may lawfully be done or performed by a body corporate.

Headquarters of the Institute.

6. (1) The headquarters of the Institute shall be in Nairobi.

(2) Notwithstanding subsection (1), the Institute shall ensure reasonable access of its services in all parts of the Republic in accordance with Article 6(3) of the Constitution and may establish such centres as it considers necessary for the proper discharge of its functions.

Functions of the Institute.

7. (1) The functions of the Institute shall be to—

(a) conduct research for human health;

(b) identify and make recommendations to the Cabinet Secretary on priorities for research for human health;

(c) establish and maintain infrastructure and systems for research for human health;

(d) build capacity for research for human health;

(e) undertake scientific and technological invention and innovation for human health and service delivery;

(f) establish incubation centres for invention, innovation and product development for health;

(g) provide specialized clinical, laboratory and diagnostic services for human health;

(h) provide technical and advisory support to government and other relevant agencies on matters

related to research for human health including the collection, storage, use, transfer or sharing of biological materials, disease surveillance, pandemic preparedness, outbreaks and emergency response;

(i) collect, store, use, transfer or share biological materials for research for human health;

(j) provide a scientific and ethics review mechanism on research for human health to ensure integrity and compliance with statutory requirements and regulations; and

(k) perform such other functions as may be prescribed by any other law or as necessary for the promotion of the objects of this Act.

Powers of the Institute.

8. (1) The Institute shall have all the powers necessary for the proper performance of its functions under this Act and any other written law.

(2) Without prejudice to the generality of subsection (1), the Institute shall have the power to—

(a) manage, control and administer the assets of the Institute in such manner and for such purpose as best promotes the objects for which the Institute is established in accordance with the Public Procurement and Assets Disposal Act; Cap. 412C.

(b) open such bank accounts for the funds of the Institute as may be necessary;

(c) determine the provisions to be made for capital and recurrent expenditure and for the reserves of the Institute;

(d) subject to approval of the Cabinet Secretary for National Treasury, invest any surplus funds of the Institute not immediately required for the purposes of this Act, as it may determine;

(e) receive gifts, grants, donations or endowments made to the Institute or any other monies in respect of the Institute and make legitimate disbursements therefrom in accordance with the provisions of this Act;

(f) levy fees for the services rendered by the Institute as may be determined from time to time by the Board;

(g) enter into association, collaboration or partnerships with such other bodies or organizations, within or outside Kenya, as it may consider desirable or appropriate and in furtherance of the purposes for which the Institute is established;

(h) create, develop, apply for and hold rights in intellectual property, and enter into agreements or arrangements for the commercial exploitation of such rights or otherwise as may be appropriate;

(i) obtain and maintain experimental laboratory plants and animals including organisms for research purposes;

(j) establish research centres and departments as may be considered necessary for the performance of its functions under this Act;

(k) obtain and maintain research biological and data repositories and the attendant infrastructure; and

(l) undertake any activity necessary for the performance of any of its functions.

The Board of Directors of the Institute.

9. (1) The Institute shall be managed by a Board of Directors which shall consist of—

(a) a non-executive chairperson appointed by the President;

(b) the Principal Secretary in the Ministry responsible for matters relating to health or a representative designated in writing;

(c) the Principal Secretary in the Ministry responsible for matters relating finance or a representative designated in writing;

(d) the Attorney-General or a representative designated in writing;

(e) the Principal Secretary in the Ministry responsible for matters relating to higher learning or a representative designated in writing;

(f) four members, not being public officers, two of whom shall be scientists with knowledge and expertise in research for human health, appointed by the Cabinet Secretary; and

(g) the Director-General who shall be an *ex officio* member of the Board.

(2) The Cabinet Secretary shall, in appointing persons as members of the Board under subsection 1(f), ensure that the appointments afford equal opportunity to men and women, the youth, persons with disabilities, minorities and marginalized groups and ensure regional balance.

(3) The appointment of the chairperson and members under subsection 1(f) shall be by notice in the *Gazette*.

Qualification for appointment as Chairperson or Member of the Board.

10. (1) A person shall qualify for appointment as the chairperson of the Board, where the person—

(a) holds a postgraduate degree in biomedical sciences or other health-related field from a university recognized in Kenya;

(b) has professional knowledge and experience of at least fifteen years in biomedical science or other health-related field;

(c) has served in a senior management level for a period of at least ten years; and

(d) meets the requirements of Chapter Six of the Constitution.

(2) A person shall qualify for appointment as a member of the Board under section 9(1) (f), where the person—

(a) holds a degree in biomedical sciences or medicine from a university recognized in Kenya;

(b) has professional knowledge and experience of at least ten years; and

(c) meets the requirements of Chapter Six of the Constitution.

(3) A person shall not qualify for appointment as a chairperson or a member of the Board, where the person—

(a) is an undischarged bankrupt;

(b) is declared to be of unsound mind;

(c) has been convicted of a criminal offence and sentenced to a term of imprisonment exceeding six months; or

(d) has been removed from office for contravening the provisions of the Constitution or any other written law.

Term of office.

11. (1) The chairperson and members appointed under section 9(1)(f) shall hold office for a term of three years and shall be eligible for re-appointment for one further term of three years.

(2) The members appointed under section 9(1)(b), (c), (d) and (e) shall hold office during their tenure of office unless removed from office by the appointing authority.

Vacation of office.

12. A person shall cease to be a chairperson or member of the Board, where that person —

(a) is unable to perform the functions of the office by reason of prolonged physical or mental illness;

(b) is otherwise unable or unfit to discharge his or her duties;

(c) is adjudged bankrupt;

(d) is convicted of a criminal offence and sentenced to imprisonment for a term exceeding six months;

(e) is absent from three consecutive meetings of the Board without lawful cause;

(f) resigns by notice in writing to the appointing authority;

(g) dies; or

(h) is removed from office in accordance with the provisions of the Constitution.

Committees of the Board.

13. (1) The Board may establish Committees for the effective performance of its functions under this Act.

(2) The Board may co-opt into the membership of a committee established under subsection (1), any person whose knowledge and expertise may be necessary for the

effective performance of the functions of the Institute in accordance with the Government directives issued from time to time.

(3) A person co-opted into a Committee under subsection (2), may attend the meetings of the Committee and participate in its deliberations, but shall not vote at such meetings.

Conduct of business and affairs of the Board.

14. (1) The Board shall conduct its business and affairs in accordance with the provisions of the First Schedule.

(2) Without prejudice to the provisions of subsection (1), the Board may regulate its own procedure.

Delegation by the Board.

15. The Board may, by resolution either generally or in any particular case, delegate to any committee of the Board or to any member, officer, employee or agent of the Board the exercise of any of the powers or the performance of any of the functions or duties of the Board under this Act.

Director-General of the Institute.

16. (1) The Board shall, through an open, transparent and competitive recruitment process, appoint a suitably qualified person to be the Director-General of the Institute.

(2) A person shall qualify for appointment as the Director-General of the Institute, where the person—

(a) holds a Doctor of Philosophy degree (PhD) in biomedical sciences or its equivalent, from a university recognized in Kenya;

(b) has had at least ten years post-qualification professional experience, five of which shall be in matters of—

(i) policy formulation;

(ii) policy-oriented research and analysis;

(iii) leadership; and

(iv) management of human resource or finance; and

(c) has served in a senior management level for a period of at least ten years; and

(d) meets the requirements of Chapter Six of the Constitution.

(3) A person shall not qualify for appointment as the Director-General of the Institute, where the person—

(a) is an undischarged bankrupt;

(b) is declared to be of unsound mind;

(c) has been convicted of a criminal offence and sentenced to a term of imprisonment exceeding six months; or

(d) has been removed from office for contravening the provisions of the Constitution or any other written law.

(4) The Director-General shall serve on such terms and conditions as the Board may determine.

(5) The Director-General shall hold office for a period of three years and shall be eligible for re-appointment for one further term of three years.

(6) The Director-General shall, in the performance of the functions and duties of the office, be responsible to the Board.

(7) The Director-General shall—

(a) be the Chief Executive Officer of the Institute;

(b) be the accounting officer of the Institute;

(c) be responsible for—

(i) implementing the decisions of the Board;

(ii) the day-to-day administration and management of the affairs of the Institute; and

(iii) co-ordination and supervision of the staff of the Institute; and

(d) perform any other lawful duties as may be assigned by the Board and the law.

Removal from office of the Director-General.

17. (1) The Director-General may be removed from office by the Board in accordance with the terms and condition of service, for—

(a) inability to perform the functions of the office arising out of physical or mental infirmity;

(b) gross misconduct or misbehaviour;

(c) incompetence or neglect of duty;

(d) conviction for a criminal offence with a sentence to imprisonment for a term exceeding six months;

(e) violation of the Constitution or any other written law; or

(f) any other grounds specified in the terms and conditions of service of the Director-General.

(2) Where the question of the removal of the Director-General under subsection (1) arises, the Board shall act in accordance with the principles of fair administrative action prescribed under Article 47 of the Constitution and the Fair Administrative Action Act. Cap. 7L.

Corporation Secretary.

18. (1) The Board shall, through an open, transparent and competitive recruitment process, appoint a suitably qualified person to be the Corporation Secretary of the Institute on such terms as the Board may, upon the advice of the Salaries and Remuneration Commission, determine.

(2) A person shall qualify for appointment as the Corporation Secretary if that person—

(a) holds a bachelor's degree in law from a university recognized in Kenya;

(b) is an Advocate of the High Court of Kenya;

(c) is a Certified Public Secretary;

(d) is a member in good standing of the Institute of Certified Public Secretaries of Kenya;

(e) has at least five years' experience as a corporation secretary or a similar governance role; and

(f) meets the requirements of Chapter Six of the Constitution.

(3) The Corporation Secretary shall be the Secretary to the Board and shall—

(a) in consultation with the Chairperson of the Board, issue notices for meetings of the Board;

(b) keep, in custody, the records of the deliberations, decisions and resolutions of the Board;

(c) transmit decisions and resolutions of the Board to the Director-General for execution, implementation and other relevant action;

(d) provide guidance to the Board on their duties and responsibilities on matters relating to governance; and

(e) perform such other duties as the Board may direct.

Staff of the Institute.

19. (1) The Board shall, through a competitive and transparent process, employ such officers, agents and other staff as may be necessary for the proper discharge of its functions under this Act, upon such terms and conditions of service as the Board may determine upon the advice of the Salaries and Remuneration Commission.

(2) The Board shall, in the appointment of staff, ensure—

(a) equalization of opportunities for the youth and persons with disability;

(b) that not more than two thirds of its staff are of the same gender; and

(c) that the appointment of staff reflects the ethnic and regional diversity of the people of Kenya.

Remuneration.

20. The chairperson, members of the Board and staff of the Institute shall be paid such remuneration, fees, allowances and such other reimbursements as may be approved by the Cabinet Secretary upon the advice of the Salaries and Remuneration Commission.

Protection from personal liability.

21. (1) No matter or thing done by a member of the Board or an officer, employee or agent of the Institute shall, where the matter or thing was done in good faith in the execution of the functions or powers of the Institute, render the member, officer, employee or agent personally liable for any action, claim or demand whatsoever.

(2) Notwithstanding subsection (1), nothing in this section shall exempt a member of the Board, officer, employee or agent of the Institute from individual responsibility for unlawful or criminal act committed by the member of the Board, officer, employee or agent of the Institute.

Common seal.

22. (1) There shall be a common seal of the Institute which shall be kept in the custody of the Corporation Secretary and shall not be used except on the direction of the Board.

(2) The affixing of the common seal of the Institute shall be authenticated by the signatures of the Chairperson and the Director-General and any document required by law to be made under seal and all decisions of the Board may be authenticated by the signatures of the Chairperson and the Director-General.

(3) The Board shall, in the absence of either the Chairperson or the Director-General, in any particular matter, nominate one member to authenticate the seal of the Institute on behalf of either the Chairperson or the Director-General.

(4) The common seal of the Institute when affixed to a document and duly authenticated, shall be judicially and officially noticed, and unless the contrary is proved, any necessary order by the Institute under this section shall be presumed to have been duly given.

PART III— CONDUCT OF RESEARCH FOR HUMAN HEALTH AND INNOVATION

Research areas.

23. (1) The Institute shall conduct research related to human health including—

(a) public health research;

(b) biomedical research;

(c) traditional and alternative medicine research; and

(d) clinical, applied and social science research.

(2) The research specified under subsection (1) may be—

(a) program based;

(b) investigator initiated;

(c) collaborative or team based; or

(d) in any other manner as may be deemed necessary to address national priorities.

Research priorities and agenda.

24. (1) The Institute shall formulate a national human health research priority for purposes of identifying health

research programmes and priorities in accordance with the national and international health research priorities.

(2) The Institute shall, through a consultative process with the relevant stakeholders including the Ministry, regional and international health research organizations, other research partners and collaborators, formulate a research agenda.

Initiation of research.

25. (1) The Institute may initiate research through—

(a) an investigator initiated initiative;

(b) a program based initiative;

(c) collaboration with local and international partners;

(d) a contract with various legal entities governed by the relevant regulatory frameworks;

(e) secondary research in accordance with the relevant policies, guidelines and laws; or

(f) any other initiative as the Board may from time to time determine.

(2) The modalities of initiating and conducting the research shall be prescribed by Regulations.

Scientific Steering Committee.

26. (1) There shall be established a Scientific Steering Committee which shall be responsible for—

(a) providing strategic scientific leadership; and

(b) the overall management of research in the Institute.

(2) The Scientific Steering Committee shall comprise of heads of directorates, programmes, research centres and scientific units at the Institute.

(3) The Scientific Steering Committee, for purposes of discharging its mandate, shall —

(a) develop a comprehensive research agenda aligned with the national health priorities;

(b) foster a culture of innovation and inter-disciplinary collaboration to drive high-impact research;

(c) periodically review and update the research priorities to ensure relevance and responsiveness to emerging health challenges;

(d) develop and implement a strategic funding plan to diversify research funding sources;

(e) identify sources for external research grants and partnerships for the implementation of the areas identified as the Institute's research priorities;

(f) establish structures to facilitate engagement of the scientific community in budgeting and financial management practices for optimization of resource allocation and utilization for science;

(g) engage in oversight and monitoring of human resource to ensure a skilled and motivated scientific workforce; and

(h) mobilize financial resources with all relevant stakeholders.

Training and professional development of human health research scientists.

27. The Scientific Steering Committee shall, for purposes of training and professional development of scientists, —

(a) establish a comprehensive training and mentorship program to enhance the skills and knowledge of human health research scientists;

(b) encourage participation in the national and international scientific conferences, workshops and exchanges;

(c) foster collaboration with academic institutions, industry or other research organizations to provide opportunities for advanced training and specialization; and

(d) promote a culture of continuous learning, knowledge sharing and innovation within the Institute.

Communication and participation.

28. The Scientific Steering Committee shall, for the purposes of ensuring communication and participation in discharging its functions, —

(a) implement a structured communication system within the Institute that encourages feedback and collaboration amongst stakeholders; and

(b) foster a culture of inclusivity to ensure that diverse perspectives and expertise contribute to the decision-making processes.

Inter-disciplinary collaboration.

29. The Scientific Steering Committee shall, for the purposes of inter-disciplinary collaboration—

(a) facilitate cross-disciplinary collaboration within the Institute and with external partners to encourage knowledge sharing, innovation and the integration of different scientific perspectives; and

(b) foster an environment that values teamwork and promotes interdisciplinary research approaches to address complex health challenges effectively.

Ethical considerations.

30. (1) The Institute shall uphold ethical standards and shall conduct research that is—

(a) scientifically valid;

(b) socially valuable; and

(c) protects the rights and welfare of research participants.

(2) The Institute shall, in conducting research, be guided by principles including—

(a) respect for research participants including upholding data privacy principles in accordance with the Data Protection Act; Cap. 411C.

(b) maximization of benefits and minimization of potential harms or risks to research participants and communities;

(c) fairness and equitability to research participants;

(d) scientific validity in conducting research;

(e) independent review to ensure the research meets ethical standards;

(f) respect for vulnerable research participants and communities;

(g) community engagement; and

(h) transparency and accountability in the research processes, methods, findings and dissemination.

(3) Without prejudice to the generality of subsection (2), the Institute shall in the case of—

(a) human participants ensure —

(i) respect of persons and communities through provision for the making of informed consent whether voluntary or informed participation;

(ii) minimize research risks by ensuring that research procedures do no harm;

(iii) maximize the benefit of research to research participants or the community; and

(b) animal subjects ensure—

(i) methods to minimize pain and distress are specified;

(ii) where applicable, a strong justification is made for not using proper drugs to alleviate pain and distress; and

(iii) where applicable, the method of euthanasia is specified.

(4) A research scientist shall, in conducting research, comply with the institutional, national and international regulations and treaties.

Establishment of the Scientific and Ethics Review Unit.
Cap. 511.

31. (1) There is established the Scientific and Ethics Review Unit within the Institute in accordance with the Science, Technology and Innovation Act.

(2) The Scientific and Ethics Review Unit shall comprise of multidisciplinary committees whose membership shall be drawn from within the Institute and other stakeholders as provided for under the Science, Technology and Innovation Act.

(3) The Institute shall, in consultation with the Scientific and Ethical Review Unit — Cap. 511.

(a) develop, review and implement policies, regulations, standards and procedures for scientific conduct and research ethics;

(b) ensure adherence to and compliance with set international and local standards for scientific conduct and research ethics;

(c) ensure that all research proposals adhere to scientific and ethical principles that are fundamental to the conduct of research involving human participants;

(d) review and approve research proposals submitted to the Scientific and Ethics Review Unit;

(e) monitor approved on-going research protocols to ensure adherence to scientific and ethical principles;

(f) provide and facilitate training in research methodology and ethics towards building capacity for researchers and committee members;

(g) review and approve material transfer agreements for use and transfer of biological material; and

(h) ensure adherence to animal use policies, ethics and regulations in the use of animals for research.

Membership to the Scientific and Ethics Review Unit committees.

32. (1) The members of the Scientific and Ethics Review Unit Committees shall be appointed by the Director-General.

(2) Each Committee of the Unit shall comprise at least eight members and a maximum of twenty members with varying expertise and possessing the professional competence necessary to promote comprehensive scientific and ethical review of research initiatives at the Institute.

(3) The core membership of each Committee of the Unit shall include at a minimum—

(a) at least two clinicians;

(b) at least two non-clinician scientists;

(c) at least one legal expert;

(d) at least one theologian, sociologist or ethicist;

(e) at least one biostatistician or epidemiologist;

(f) at least one community representative; and

(g) a representative of a national referral and teaching hospital or a public university ethics review committee.

(4) The appointment of additional members to the Scientific and Ethics Review Unit Committees —

(a) shall reflect the other specialties required; and

(b) may give consideration to community representation.

Code of conduct for members.

33. The Institute shall formulate a Code of Conduct for research for human health.

Community engagement in research.

34. The Institute shall, where the conduct of research involves the community, engage the community.

Data collection.

35. (1) A researcher shall collect data for purposes of obtaining knowledge or information required to answer an identified research issue.

(2) Data shall be collected from —

(a) literature;

(b) humans;

(c) animals;

(d) organisms;

(e) plants; or

(f) any other human health research-related materials.

(3) The sources of data collected under subsection (2) shall include—

(a) primary data categories collected through experiment, questionnaire, observation or interview; or

(b) secondary data categories collected through literature survey, official and unofficial reports or library resources.

(4) The researcher shall, in processing data collected, adhere to the relevant laws and guidelines.

Quality assurance in research.

36. (1) The Institute shall formulate comprehensive quality assurance plans specific to research studies, where applicable, for ensuring the integrity, reliability and validity of research outcomes.

(2) The internal quality assurance shall include regular monitoring, review and audit of research activities.

(3) The external quality assurance shall be conducted periodically by independent entities including regulatory agencies or accreditation bodies.

(4) The Institute shall from time to time engage peer review expert panels to provide guidance on best practice on matters of research for human health.

Management of research data.

37. The Institute shall, in managing research data,—

(a) collect and store human health research digital and non-digital data in accordance with the relevant laws;

(b) organize and document data to ensure traceability and facilitate subsequent analysis and interpretation;

(c) ensure data validation and quality assurance to mitigate errors for accuracy and completeness; and

(d) restrict access to authorized persons with strict protocols in place to safeguard against unauthorized access or disclosure.

Data management, analysis and dissemination.

38. (1) The Institute shall ensure suitable management and analysis of data and interpretation of research findings for reporting and dissemination.

(2) The Institute shall disseminate research findings through—

(a) knowledge management strategy implementation;

(b) stakeholder engagement and feedback;

(c) open access initiatives;

(d) publication in peer-reviewed journals; and

(e) stakeholder feedback and engagement.

(3) The relevant government agencies shall apply research findings in developing their policies where applicable.

Monitoring and evaluation.

39. The Institute shall ensure that research development and implementation processes make provision for monitoring and evaluation mechanisms.

PART IV— CLINICAL TRIALS

Conduct of clinical trials.

40. The Institute shall—

(a) facilitate research and continuous discovery of medicines and products, including alternative medicines and herbal products;

(b) offer technical expertise in the conduct of clinical trials;

(c) ensure the safety and well-being of research participants involved in clinical trials;

(d) uphold the integrity of data generated during clinical research;

(e) enhance the capabilities and competencies of healthcare professionals and research scientists in clinical trials and clinical trial management; and

(f) provide technical advice on the regulation of the conduct of clinical trials in Kenya.

Clinical trial research in public health emergencies.

41. (1) The Institute shall, in case of a public health emergency undertake such research or innovation or drug re-purposing that is necessary to address the public health emergency and prepare for future crisis.

(2) The Institute shall, in undertaking the research, innovation or drug re-purposing under subsection (1), ensure that—

(a) the research does not hinder the response to an emergency or the provision of proper healthcare;

(b) research participants are fairly selected and informed consent obtained;

(c) studies are designed to produce reliable results despite challenging conditions;

(d) the health needs of affected communities are prioritized; and

(e) the affected communities are prioritized in dissemination of research findings.

PART V—TRADITIONAL AND ALTERNATIVE MEDICINE

Responsibility of government in traditional and alternative medicine.

42. The Government of Kenya shall—

(a) recognize and integrate traditional and alternative medicine in a manner that complements the conventional healthcare system;

(b) safeguard public health by ensuring that traditional and alternative medicinal products and practices meet stringent quality, safety, and efficacy standards;

(c) promote the conservation of medicinal plant biodiversity and the sustainable use of resources, acknowledging the intrinsic value of traditional knowledge in health preservation; and

(d) foster biodiversity conservation as a critical component of sustainable healthcare.

Assessment of quality, efficacy, and safety.

43. (1) The Institute shall, upon reference, in collaboration with relevant agencies conduct comprehensive assessments of traditional and alternative medicinal products to determine their quality, efficacy and safety for purposes of safeguarding public health.

(2) The Institute, in conducting the assessments in subsection (1)—

(a) shall focus on utilizing Kenya's biodiversity and in particular, indigenous flora for the discovery of novel medicinal properties;

(b) shall employ a variety of scientific methodologies including biochemical, pharmacological and toxicological evaluations;

(c) may conduct preclinical and clinical trials to assess the safety and efficacy of traditional and alternative medicinal products; and

(d) shall oversight the standardization and validation of traditional and alternative medicinal products.

(3) The Institute shall support the relevant regulatory bodies to establish and enforce quality assurance standards and conduct market surveillance to ensure—

(a) that traditional and alternative medicinal products safe, efficacious and of high quality; and

(b) the proper labeling, advertising and marketing of traditional and alternative medicinal products to prevent misleading representation.

Support for development.

44. (1) The Institute shall—

(a) identify high-potential healthcare products derived from traditional and natural sources and support their development into scalable prototypes;

(b) authenticate natural medicinal products and promote sustainable conservation of their sources; and

(c) provide traditional medicine practitioners and herbal product developers with the necessary support and guidance.

(2) The Institute may, in the discharge of the duties in subsection (1), establish a framework for the identification and support of healthcare products derived from traditional and natural sources with significant potential for contribution to the health sector.

(3) The framework in subsection (2) shall—

(a) make provision for the criteria for the evaluation of healthcare products based on their safety, efficacy, sustainability and capacity to address unmet healthcare needs;

(b) require the Institute to lead research initiatives for the investigation of extracts, fractions and compounds derived from natural products for their potential therapeutic applications in disease management; and

(c) facilitate the development of healthcare products into scalable prototypes through providing the necessary technical, scientific and regulatory assistance.

Capacity building for practitioners.

45. (1) The Institute shall develop programs aimed at building the capacity of traditional and alternative medicine practitioners, herbal product developers and healthcare professionals to —

(a) ensure the safe and effective use of traditional and alternative medicines;

(b) recommend the integration of validated traditional and alternative medicine practices into the national healthcare system; and

(c) promote preservation and transmission of traditional medical knowledge.

Offences related to traditional medicinal products.

46. (1) A person commits an offence in relation to traditional medicinal products if that person engages in—

(a) knowingly adding conventional medicines or other unauthorized substances;

(b) making false, misleading or deceptive claims about ingredients, benefits or risks in print, electronic media or on billboards;

(c) selling or promoting products lacking demonstrable therapeutic benefit;

(d) making claims about curative, preventive or diagnostic properties without credible scientific evidence or established traditional knowledge;

(e) selling or distributing products with an unknown or inadequate toxicological assessment; or

(f) manufacturing, preparing or selling products under unsanitary or poor-quality conditions

and shall on conviction, be liable to a fine not exceeding three million shillings, or to imprisonment for a term not exceeding three years or to both.

Management of traditional and alternative medicine knowledge.

47. (1) The Institute shall establish and maintain a comprehensive national database for the codification and preservation of traditional and alternative medical knowledge.

(2) The database shall be a repository of scientifically validated knowledge, practices and formulations of traditional and alternative medicine.

PART VI—TRAINING AND CAPACITY BUILDING

Capacity building in matters of human health.

48. The Institute shall build capacity in matters of human health through—

(a) research; and

(b) training in research for human health and health sciences.

Training by the Institute.

49. (1) The Institute shall provide—

(a) post-graduate training in specialized human health research including the conduct of clinical trials, health sciences, pharmaceutical sciences,

biomedical sciences, public health and nutritional sciences, social and behavioural sciences, traditional and alternative sciences; and

(b) specialized short course training programmes in health sciences and research methods in accordance with the functions of the Institute and the training or capacity needs for the country or the region.

(2) The training programmes in subsection (1) may be provided in collaboration with other accredited institutions of higher learning or research. Cap. 210.

(3) The training programmes shall be aligned to the standard frame provided by the Commission.

(4) A new or revised training programme shall be submitted to the Commission for evaluation and approval in accordance with the Universities Act.

(5) The Institute shall determine the—

(a) curriculum of the training programmes;

(b) training manuals;

(c) training programmes and course units for each training programme; and

(d) academic calendar including the duration of each course of study and the conduct of examinations.

Specialized post-graduate degrees, diplomas and certificates Cap. 210.

50. (1) The Institute may, subject to accreditation by the Commission and the award of a Charter under the Universities Act, award—

(a) specialized postgraduate degrees, diplomas, certificates or other awards as may be provided for in the statutes developed pursuant to section 23(1) of the Universities Act; and Cap. 210.

(b) honorary postgraduate degrees or any other academic recognition upon a person who has rendered distinguished service to the advancement of any branch of learning or who has otherwise rendered service in any field of human health endeavour worthy of such a degree or academic recognition as provided for in the statutes developed pursuant to section 23(1) of the Universities Act. Cap. 210. Cap. 210.

(2) A specialized degree including an honorary degree or any other award conferred under subsection (1) may be cancelled or withdrawn by the Institute in the manner set out in the statutes developed pursuant to section 23(1) of the Universities Act.

Scholarships. Cap. 210.

51. The Institute may, subject to accreditation by the Commission and the award of a Charter under the Universities Act, award scholarships, fellowships, bursaries, prizes and such other awards as may be provided for in the statutes developed pursuant to section 23(1) of the Universities Act. Cap. 210.

Admission for training by the Institute.

52. (1) The Institute shall establish a criteria for the admission of qualified persons to the training programmes offered by the Institute.

(2)A person shall not qualify for admission to the training programme offered by the Institute, unless that person has met the admission requirements set by the Institute for that training programme.

(3) A person who wishes to be admitted to a training programme offered by the Institute shall apply in the prescribed form and pay the prescribed application fees.

(4) The Institute shall consider an application submitted under subsection (3) and if it is satisfied that the applicant meets the admission criteria, admit the applicant to the training programme.

PART VII—RESEARCH INFRASTRUCTURE

Establishment of research centres.

53. (1) The Board may establish such research centres and infrastructure as it may consider necessary for the effective discharge of the mandate of the Institute.

(2) The research centres shall be hubs of research, invention, innovation, collaboration and knowledge management.

Biobanks.

54. (1) The Institute shall establish biobanks for the collection, storage and management of biological materials.

(2) Despite subsection (1), the Institute may, by notice in the *Gazette,* designate any research institution, site or health establishment as a biobank.

(3) A biobank may —

(a) receive biological materials for storage purposes;

(b) store aliquots of biological materials for such period as may be prescribed; and

(c) dispose of biological materials in accordance with the prescribed Regulations.

(4) The Institute shall, in establishing the biobanks, —

(a) put in place processes and procedures for the operation of biobanks;

(b) ensure adherence to ethical, regulatory and quality standards for responsible management and use of biological materials and associated data for research, healthcare and public health;

(c) develop and implement guidelines or procedures for all aspects of biological materials management including —

(i) collection procedures including informed consent processes and documentation;

(ii) processing techniques to ensure sample integrity and quality control;

(iii) storage conditions including temperature monitoring and security measures; and

(iv) distribution protocols for access to biological materials and associated data by authorized users;

(d) restrict access to biological materials to authorized users; and

(e) implement data management systems to ensure secure storage, retrieval and sharing of clinical and metadata.

Exportation and importation of biological materials.

55. (1) A person shall not export or import biological materials without the prior written approval of the Institute as provided under subsection (2).

(2) The Institute may, on the recommendation of the Board, permit the export or import of biological materials where the applicant satisfies the requirements set out by the Institute in the export or import agreement or in the relevant laws and regulations.

(3) A person who contravenes this section commits an offence and is liable, on conviction, to a fine not exceeding two million shillings or to imprisonment for a period not exceeding five years, or to both.

(4) The Cabinet Secretary may prescribe Regulations to give effect to this section.

Designation of biobanks.

56. (1) Where the Institute designates a research institution, site or health establishment as a biobank in accordance with section 54, the Institute shall issue a permit in the prescribed manner.

(2) Every biobank shall comply with the requirements of the relevant laws.

(3) A person who keeps biological materials without a permit issued under this Act, commits an offence and is liable, on conviction, to a fine not exceeding two million shillings or to imprisonment for a term not exceeding five years, or to both.

Research data banks.

57. (1) The Institute shall—

(a) establish research data banks;

(b) store human research data in the research data bank for availability and accessibility; and

(c) store human research data in a secure form with restricted access in accordance with the relevant laws.

(2) An authorized person shall —

(a) take reasonable measures to ensure that no person collects, uses, discloses, retains or disposes of research data unless it is in accordance with the law; and

(b) be responsible for any sensitive data that is collected, used, disclosed, retained or disposed of by the authorized person's agents.

(3) For purposes of this section—

"authorized person" means the research scientist responsible for the ethical design and conduct of a research study.

Access to health research data banks.

58. (1) The Institute may access research data banks or any information collected by research scientist for human health.

(2) The Cabinet Secretary may, in consultation with the Board, make Regulations for ensuring that data banks for internally and externally funded health research are kept in a central research repository.

Establishment of botanical gardens.

59. (1) The Institute may establish botanical gardens for purposes of human health research and capacity building.

(2) The Cabinet Secretary, in consultation with the Board, may prescribe Regulations to give effect to this section.

Establishment of animal houses and insectaries.

60. (1) The Institute may establish animal houses or insectaries for the purposes of conducting research for human health and capacity building.

(2) An animal house established under this Act shall comply with the applicable laws.

(3) The Cabinet Secretary may prescribe Regulations to give effect to this section.

Establishment of research clinics.

61. (1) The Institute may establish research clinics for the conduct of research for human health.

(2) Despite subsection (1), the Institute may designate any research institution, site or health establishment as a research clinic.

PART VIII—INTELLECTUAL PROPERTY

Rights to vest in the Institute.

62. (1) The rights to an invention or innovation made by the Institute shall vest in the Institute unless there is an agreement to the contrary.

(2) The Institute may apply for a patent in respect of any invention or innovation contemplated in subsection (1) and shall, for the purposes of the Copyright Act and the Industrial Property Act, be regarded as the assignee of the inventor or innovator of the invention or innovation where an inventor or innovator contributed to that invention or innovation.

Withholding intellectual

63. Any information on intellectual property that may not be required to be included in any statement of corporate

intent, annual report or financial statements by the Institute may be properly withheld and may be released upon request in accordance with the provisions of the Access to Information Act.

property information.

Cap. 7M.

64. (1) The Institute shall establish a mechanism for the notification of inventions, discoveries or technical developments.

Registration of intellectual property.

(2) The mechanism in subsection (1) shall, in collaboration with the relevant government agencies, provide for the protection of intellectual property rights of an invention, discovery or technical development.

(3) Despite the provisions of subsection (2), the Institute shall at all times reserve the right not to protect or commercialize intellectual property where—

(a) the intellectual property is not in the best interests of the Institute, inventor, innovator or the public; or

(b) there are no reasonable prospects of commercial success.

(4) The Institute shall, in collaboration with the relevant institutions, establish and maintain a database on innovations.

65. (1) All rights and obligations relating to an invention shall belong exclusively to the Institute or the sponsoring entity as the case maybe, subject to the Institute or sponsoring entity being fully responsible for any and all expenses in the generation of the innovation or invention, fees, and any other charges resulting from the application for, granting or maintenance of intellectual property rights.

Ownership of intellectual property.

(2) Where an intellectual property right held by the Institute or sponsoring entity is not being worked or has not been licensed within two years from the date of the notification of the invention, the inventor may apply to succeed the intellectual property right or for a licence to work that intellectual property right on terms to be mutually agreed by the inventor and the Institute or sponsoring entity as the case may be.

(3) All rights and obligations relating to any invention produced by an employee or associate of the Institute or

sponsoring entity without making significant use of the time and resources of the Institute or sponsoring entity, and not subject to any agreement expressly stating otherwise, shall belong exclusively to the inventor or innovator.

(4) Despite the provisions of this section, ownership of a patent shall be forfeited to the relevant national body where the—

(a) forfeiture is necessary in the interests of the security of the country; or

(b) scientific innovation, invention, or patent is of strategic importance to the country in accordance with the relevant laws.

Commercialization of intellectual property.

66. (1) The Institute or sponsoring entity as the case may be, shall have the sole discretion regarding the commercialization of intellectual property owned by it and shall ensure that reasonable efforts are made to keep the inventors or innovators informed, and where appropriate involved in the commercialization of the intellectual property to which they contributed.

(2) The decision on the mode of commercialization of intellectual property under subsection (1) shall rest with the owner of the intellectual property.

(3) The mode of commercialization of intellectual property may include—

(a) licensing;

(b) assignment or sale;

(c) formation of a commercialization entity or joint venture; or

(d) donation or royalty free access on humanitarian or other grounds.

Benefits.

67. (1) Where an intellectual property right reaches the stage of commercialization, a share of royalties accruing to the inventor or innovator shall be forwarded to the inventor or innovator in accordance with minimum requirements set out in the relevant laws.

(2) Where financial benefits are derived from the transfer or licensing of intellectual property rights, any direct costs incurred including expenses relating to the

generation of the invention, fees, and any other charges resulting from the application for, granting or maintenance of the intellectual property rights and in marketing the invention or innovation shall first be recovered by the owner of the intellectual property.

(3) Awards for intellectual property beneficiaries shall continue to be paid to—

(a) an innovator or inventor where the inventor has left the employment of the Institute or sponsoring entity as the case may be; and

(b) the estate of the innovator or inventor where the inventor is dead.

(4) An innovator or inventor or estate of the innovator or inventor shall, for purposes of subsection (3), notify the Institute or sponsoring entity of any changes in contact details.

(5) Where an invention makes significant use of knowledge or resources that may be related directly to a particular community or area, the Institute or the sponsoring entity shall take the necessary action to ensure that any transfer or licensing of intellectual property rights to a person or entity is in the best interests of that community or area.

PART IX—FINANCIAL PROVISIONS

Funds of the Institute.

68. (1) The funds of the Institute shall comprise of —

(a) monies allocated by Parliament for the purposes of the Institute;

(b) monies as may accrue to or vest in the Institute in the course of the exercise of its powers or the performance of its functions under this Act;

(c) monies from fees paid to the Institute in respect of the services offered by it;

(d) monies as may be payable to the Institute pursuant to this Act or any other written law;

(e) gifts, grants, donations or endowments as may be given to the Institute; and

(f) monies from any other lawful source provided for the Institute.

(2) All the funds donated, lent or issued to the Institute under this Act shall be accounted for and appropriated in accordance with the Public Finance Management Act. Cap. 412A.

69. (1) All monies in the Institute which are not immediately required to be applied for the purposes of this Act shall be invested— Investment of funds.

(a) in such investment in a reputable bank on the advice of the Central Bank of Kenya, being an investment in which trust funds, or part thereof, are authorized by law to be invested; and

(b) in government securities as may be approved by the National Treasury.

(2) All investments made under this section shall be held in the name of the Institute.

70. The financial year of the Institute shall be the period of twelve months ending on the thirtieth day of June in each year. Financial year.

71. (1) The Institute shall, within three months after the end of the financial year, cause to be prepared estimates of its revenue and expenditure for that financial year. Annual estimates.

(2) The annual estimates shall make provision for all estimated expenditure of the Institute for the financial year concerned, and in particular shall provide for the—

(a) payment of salaries, allowances and other charges in respect of the staff of the Institute;

(b) payment of allowances and any other emoluments to the members of the Board;

(c) payment of pensions, gratuities and other charges in respect of retirement benefits which are payable out of the funds of the Institute;

(d) proper maintenance of buildings and grounds of the Institute;

(e) acquisition, maintenance, repair and replacement of the equipment and other movable property of the Institute; or

(f) creation of such reserve funds to meet future or contingent liabilities in respect of retirement

benefits, insurance or replacement of buildings or equipment, or in respect of such other matters as the Institute may consider appropriate.

(3) The annual estimates shall be approved by the Institute before the commencement of the financial year to which they relate and after the approval, the annual estimates shall not be increased without prior consent of the Board.

(4) No expenditure shall be incurred for the purposes of the Institute except in accordance with the annual estimates approved under subsection (3).

Accounts and audit.

72. (1) The Board shall cause to be kept all proper books and records of accounts of the income, expenditure, assets and liabilities of the Institute.

(2) Within three months at the end of each financial year, the Board shall submit to the Auditor-General, the accounts of the Institute together with—

(a) a statement of income and expenditure of the Institute during the year; and

(b) a statement of the assets and liabilities of the Institute on the last day of that year.

Cap.412A. Cap. 412B.

(3) The accounts of the Institute shall be audited and reported upon in accordance with the provisions of the Public Finance Management Act and the Public Audit Act.

Annual report.

73. (1) The Board shall, within three months after the end of each financial year, prepare and submit to the Cabinet Secretary a report on the operations of the Institute for the immediately preceding year.

(2) The Cabinet Secretary shall, within three months of submission of the report under subsection (1), transmit the report to Parliament.

PART X—DELEGATED LEGISLATION

Regulations.

74. (1) The Cabinet Secretary shall, in consultation with the Board of Directors, make regulations for the better carrying into effect the functions of the Act.

(2) Without prejudice to the generality of subsection (1), the regulations made under this section may provide for —

(a) the fees to be charged under this Act;

(b) the forms to be used in connection with this Act;

(c) the establishment and management of biobanks;

(d) the establishment and management of incubation centres;

(e) the scientific and ethics review mechanism;

(f) the collection, storage, use and transfer of biological materials;

(g) maintenance of repositories of research for human health data;

(h) the criteria for the admission of qualified persons to the training programmes offered by the Institute;

(i) the categories of examinations and the manner in which such examinations shall be administered;

(j) any other matter that may be related to the conduct of research for human health.

(3) For the purpose of Article 94(6) of the Constitution—

(a) the purpose and objective of the delegation under this section is to enable the Cabinet Secretary to make regulations for better carrying into effect the provisions of this Act; and

(b) the authority of the Cabinet Secretary to make regulations under this Act is limited to bringing into effect the provisions of this Act and fulfilment of the objectives specified under this section.

(4) The principles and standards applicable to the delegated power referred to under this Act are those set out in—

(a) the Statutory Instruments Act; Cap. 2A.

(b) the Interpretation and General Provisions Act; Cap. 2.

(c) the general rules of international law as specified under Article 2(5) of the Constitution; and

(d) any treaty and convention ratified by Kenya under Article 2(6) of the Constitution.

PART XI—GENERAL PROVISIONS

Risk management.

75. The Institute shall undertake risk management through identification and documentation of risks their impact occurrence and specify measures for mitigation and monitor outcomes.

Integration of legal frameworks.
Cap. 411C.
No. 15 of 2023.
Cap. 79C.

76. The Institute shall in executing its mandate be guided by policies and legislation including—

(a) the Data Protection Act and policy;

(b) the Digital Health Act and policy;

(c) the ICT policy; and

(d) the Computer Misuse and Cybercrime Act;

Experts.

77. The Board may engage on behalf of the Institute, the service of such experts in respect of any of the functions of the Institute in connection with which they are considered to have special competence.

Duty to protect personal data held by the Institute.
Cap. 411C.

78. The members of the Board, officers, staff or agents of the Institute have a duty to safeguard the personal data of a person held by the Institute in accordance with the provisions of Article 31 (c) and (d) of the Constitution, the Data Protection Act and any other relevant law.

Disclosure of information held by the Institute.

79. (1) The Institute shall ensure that the right of access to information guaranteed under Article 35 of the Constitution is guaranteed subject to the limitations provided under Article 24 of the Constitution and to the nature and extent specified under subsections (2) and (3).

(2) An officer, member of staff, or agent of the Institute shall not disclose information acquired in the course of his or her duties under the Act except, with the written consent of the Director-General.

(3) The Institute shall not disclose any information that would in the opinion of the Institute compromise the integrity of research for human health, patent and other related rights.

Confidentiality.

80. The Institute shall keep information acquired for purposes of the performance of the functions of Institute confidential and shall disclose such information only to the extent that it considers necessary for the proper performance of the functions of the Institute.

Exemptions. Cap. 412A.

81. The Institute may, subject to the Public Finance Management Act and any other relevant law, be exempted from such taxes, duties, fees, levy, cess or other charges pertaining to laboratory and clinical equipment and supplies, specialized research software, research vehicles, educational materials, technical assistance grants and renewable energy technologies as the Cabinet Secretary responsible for matters relating to the National Treasury may, by notice in the *Gazette*.

Offences.

82. (1) A person who—

(a) refuses or fails, without reasonable cause to comply with a request to furnish the Institute with any information or to produce any documents or records; or

(b) in furnishing such information under paragraph (a), makes a statement which he knows to be false, commits an offence and shall be liable, on conviction, to a fine not exceeding five hundred thousand shillings or to imprisonment for a term not exceeding three years, or to both.

(2) A person who receives information in contravention of the provisions of this Act shall not disclose or publish the information so received.

(3) A person who contravenes subsection (2) commits an offence and shall be liable, on conviction, to a fine not exceeding five hundred thousand shillings or to imprisonment for a term not exceeding three years, or to both such fine and imprisonment.

General penalty.

83. A person who contravenes the provisions of this Act, commits an offence and shall be liable, on conviction, to a fine not exceeding five million shillings or to imprisonment for a term not exceeding three years, or to both.

Relationship with the National Commission for Science Technology and Innovation.

84. The Institute shall, in performing its functions, cooperate with the National Commission for Science Technology and Innovation and shall, in relation to the National Commission for Science Technology and Innovation—

(a) be responsible for research for human health;

(b) review and approve research proposals in human health in accordance with this Act.

PART XII- REPEAL AND TRANSITIONAL PROVISIONS

Interpretation of part. L.N. 35/2021.

85. In this Part, "former institute" means the Kenya Medical Research Institute established under the Kenya Medical Research Institute Order, 2021.

Reference to the former Institute.

86. Any reference in any written law or in any document or instrument to the former Institute shall, on and after the commencement of this Act, be construed to be a reference to the Institute.

Agreements, contracts and other binding instruments.

87. (1) Every agreement, deed, bond or other instrument to which the former Institute was a party or which concerned the former Institute and whether or not of such a nature that the rights, liabilities and obligations thereunder could be assigned, shall have effect as if the Institute were a party thereto or affected thereby instead of the former Institute and as if for every reference, whether express or implied, therein to the former Institute were substituted in respect of anything to be done on or after the commencement of this Act.

(2) Any agreement, contract, project, memorandum of understanding or any other binding instrument entered into under or in respect of the former Institute before the commencement of this Act shall continue to hold and be implemented by the Institute.

Assets and liabilities.

88. (1) All funds, assets and other property, both movable and immovable, which immediately before the commencement of this Act were vested in, acquired under, held for and on behalf of the former Institute shall, by virtue of this section and without further assurance, vest in the Institute.

(2) All rights, obligations, powers and liabilities which immediately before the commencement of this Act were vested in, imposed on or enforceable against the former Institute shall be vested in, imposed on or enforceable against the Institute.

(3) Every officer having the power or duty to effect or amend any entry in a register relating to property, or to

issue or to amend any certificate or other document effecting or evidencing title to property, shall, without payment of a fee or other charge and upon request made by or on behalf of the Institute, do all such things as are by law necessary to give final effect to the transfer of property referred to under subsection (1).

Directions, orders, etc. of the former Institute.

89. A direction, notice, order, permit, authorization, licence or any other document that was granted, issued or made under the repealed Order, and that was valid immediately before the coming into force of this Act, shall be given effect as if granted, issued or made under this Act.

Annual estimates of the former Institute.

90. The annual estimates of the former Institute for the financial year in which this Act comes into operation shall be deemed to be the annual estimates of the Institute for the remainder of that financial year:

Provided that such estimates may be varied by the Institute in such manner as the Cabinet Secretary may approve.

Legal proceedings.

91. All actions, suits or legal proceedings by or against the former Institute subsisting immediately before the commencement of this Act shall be carried out on, prosecuted by, or against the Institute, and no such suits, actions or legal proceedings shall abate or be affected by the coming into operation of this Act.

Board of the former Institute.

92. A person who immediately before the commencement of this Act was a chairperson or a member of the Board of the former Institute shall, upon commencement of this Act, remain in office for the remainder of the term of that person.

Staff of the former Institute.

93. (1) A person who, immediately before the commencement of this Act was an officer, employee or member of staff of the former Institute, not being then under notice of dismissal or resignation shall, on the commencement of this Act, be deemed to be an employee of the Institute on the same terms and conditions.

Disciplinary proceedings.

94. (1) Where on the commencement of this Act any disciplinary proceedings against any officer or member of staff of the former Institute are in the course of being heard, or have been heard or investigated by the former Institute but no order or decision has been made thereon,

the Institute shall carry on and complete the hearing or investigation and make an order or render a decision, as the case may be.

(2) Where on the commencement of this Act, any such officer or member of staff of the former Institute is interdicted or suspended, the Institute shall deal with such officer or member of staff in such manner as it deems appropriate having regard to the offence committed by that officer or member of staff, including the completion of disciplinary proceedings that have been commenced against that officer or member of staff.

(3) Where on the commencement of this Act, any penalty, other than dismissal, has been imposed on any officer or member of staff of the former Institute pursuant to disciplinary proceedings and the penalty has not been, or remains to be, served by such officer or member of staff, that officer or member of staff shall upon transfer to the Institute, serve or continue to serve such penalty to its full as if it had been imposed by the Institute, where applicable.

(4) Despite the generality of subsection (1) and (2), the provisions on discipline in the human resource instruments of the former Institute shall apply until the conclusion of the disciplinary process.

Pension.

95. (1) A member of staff of the former Institute who becomes a member of staff of the Institute shall continue to be governed by the existing Government pension arrangements or any other statutory voluntary pension scheme.

(2) Any person whose services are transferred to the Institute, on the commencement of this Act, and who being a member of any statutory voluntary pension scheme or provident fund, shall for the purposes of this Act, continue to be governed by the same regulations under those schemes or funds, as if the person had not been so transferred, and for the purposes of the regulations governing those schemes or funds, service with the Institute shall be deemed to be service in the former Institute.

(3) The Board may, by order, make provisions with respect to pension or provident fund benefits of the

members of staff of the Institute and with respect to the pension scheme and provident fund of the former Institute.

(4) This section shall apply to the staff of the former Institute with necessary modifications.

Repeal of L.N. 35/2021.

96. Subject to the provisions of this Part, the Kenya Medical Research Institute Order, 2021 is repealed.

Amendment of Cap. 511.

97. The Fourth Schedule to the Science, Technology and Innovation Act is amended by deleting paragraph 5.

SCHEDULE *(s. 14(1))*

CONDUCT OF BUSINESS AND AFFAIRS OF THE BOARD

Meetings.

1. (1) The Board shall meet not less than four times in every financial year and not more than four months shall elapse between the date of one meeting and the date of the next meeting.

(2) The chairperson may call a special meeting of the Board at any time the chairperson deems fit for expedient transaction of the business of the Board.

(3) The notice for a meeting of the Board shall be given in writing to each member of the Board at least fourteen days before the day of the meeting.

(4) In the case of a special, or extra-ordinary meeting, a notice of less than fourteen days' notice shall be considered sufficient.

(5) Notwithstanding the provisions of subparagraph (2), the chairperson may, upon requisition in writing by at least two thirds of the members, convene a special meeting of the Board at any time for the transaction of the business of the Board.

(6) The notice to be given under subparagraph (2) and (3) shall state—

(a) the venue and time of the meeting; and

(b) the agenda with sufficient details of business to be discussed at the meeting.

(7) The chairperson shall preside at every meeting of the Board at which the chairperson is present but in the chairperson's absence, the members present shall elect from among themselves a chairperson who shall, with respect to that meeting and the business transacted thereat, have all the powers of the chairperson.

(8) Unless a unanimous decision is reached, a decision on any matter before the Board shall be by the concurrence of a majority of all the members present and voting at the meeting.

(9) The Board may, with approval of the Cabinet Secretary, co-opt or invite any number of persons to act as

MEMORANDUM OF OBJECTS AND REASONS

The principal object of this Bill is to make provision for the establishment, powers and functions of the Kenya Medical Research Institute. The Bill also makes provision for the effective conduct, co-ordination and promotion of research for human health in the country.

The Kenya Medical Research Institute as currently established vide a Legal Order has an inadequate legal framework. The Bill therefore redresses this by providing an elaborate legal framework for the regulation, conduct, promotion and co-ordination research for human health.

Part I (clause 1 to 4) provides for preliminary matters including the short title, the objects and guiding principles of the proposed Bill. It further provides various definitions such as research for human health, incubation centres and human health among others.

Part II (clause 5 to 22) provides for the establishment of the Kenyan Medical Research Institute, its functions, powers; the composition of the Board of Directors of the Institute, their term of office and qualifications for appointment. It further provides for the appointment of a Director-General who shall be the accounting officer and Chief Executive Officer of the Institute and the functions of the Director-General. It also provides for the manner of appointment of staff of the Institute.

Part III (clause 23-39) provides for the conduct of research for human health. It sets out the scope, methodology and ethical considerations in the conduct of research that involves humans, animals and communities among other things.

Part IV (clause 40-41) provides for the conduct of clinical trials by the Institute within the scope of research for human health particularly during public health emergencies.

Part V (clause 42-47) provides for the conduct of research in traditional and alternative medicine as a way of encourage the use and integration of traditional and alternative medicinal products in the healthcare system in the country.

Part VI (clause 48-52) provides gives the Institute the responsibility of building capacity in matters of human health through research and training in research for human health and health sciences. The Institute, subject to subject to accreditation by the Commission for University Education and the award of a Charter under the Universities Act, Cap. 210 will be able to offer specialized post-graduate degrees, diplomas and certificates and short courses on matters related to health sciences.

Part VII (clause 53-61) provides for research infrastructure including biobanks, botanical gardens and research centres among others which shall be used as hubs of research, invention, innovation, collaboration and knowledge management in matters of human health.

Part VIII (clause 62-67) provides for the management of intellectual property arising out of inventions or innovations made by the Institute or arising out of the performance of the functions of the Institute.

Part IX (clause 68-73) provides the sources of funds of the Institute, the audit of these funds as well as the annual report by the Board on the utilization of its funds and the activities undertaken in a given financial year.

Part X (clause 74) provides for the delegation of power to the Cabinet Secretary in the Ministry responsible for health to make regulations for the better carrying into effect of the functions of the Act in consultation with the Board of Directors of the Institute.

Part XI (clause 75-84) provides for the general provisions such as offences and matters of risk management and confidentiality in the conduct of research, disclosure of information, protection of personal data [redacted] relationship between the Institute and National Commission for [redacted] Technology and Innovation.

Part X (clause 85-97) provides for the repeal and transitional provisions as the Kenya Medical Research Institute Order, 2021 is being repealed.

The **Schedule of the Bill** provides for the conduct of the business and affairs of the Board.

Statement on the delegation of legislative powers and limitation of fundamental rights and freedoms

The Bill delegates legislative powers to the Cabinet Secretary but it does not limit fundamental rights and freedoms.

Statement on whether the Bill concerns County Governments

The Bill does not concern county governments in terms of Article 110(1)(a) of the Constitution.

Statement that the Bill is not a money Bill within the meaning of Article 114 of the Constitution

This Bill is a money Bill within the meaning of Article 114 of the Constitution.

Dated the 20th May, 2025.

JAMES NYIKAL,
Member of Parliament.