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REPUBLIC OF KENYA
THE NATIONAL ASSEMBLY
THIRTEENTH PARLIAMENT – FIFTH SESSION – 2026

COMMITTEE ON DELEGATED LEGISLATION

REPORT
ON
THE CONSIDERATION OF THE DRAFT CHARTER FOR THE ESTABLISHMENT OF
THE KENYA MEDICAL RESEARCH INSTITUTE

APRIL 2026

The Directorate of Audit, Appropriations
& General-Purpose Committees
The National Assembly
Parliament Buildings


 THE NATIONAL ASSEMBLY PAPERS LAID	
DATE: 07 APR 2026	
DAY: <i>Monday</i>	
TABLED BY:	<i>Hon Samuel Chapkong'o</i>
CLERK-AT THE-TABLE:	<i>A. Shabaka</i>



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LIST OF ABBREVIATIONS AND ACRONYMS

AG	Attorney General
BETA	Bottom-Up Economic Transformation Agenda
CBS	Chief of the Order of the Burning Spear
CEO	Chief Executive Officer
CUE	Commission for University Education
DLS	Directorate of Legislative and Procedural Services
EGH	Elder of the Order of the Golden Heart
EBS	Elder of the Order of the Burning Spear
GoK	Government of Kenya
IDeAL	Initiative to Develop African Research Leaders
IHR	International Health Organization
JKUAT	Jomo Kenyatta University of Agriculture and Technology
KEMRI	Kenya Medical Research Institute
KENIA	Kenya National Innovation Agency
LN	Legal Notice
MDA	Ministry, Department and Agency
MP	Member of Parliament
NACOSTI	National Commission for Science, Technology and Innovation
NRF	National Research Fund
OAG	Office of the Auditor-General
ODM	Orange Democratic Movement
PhD	Doctor of Philosophy
RVF	Rift Valley Fever
UDM	United Democratic Movement
UDA	United Democratic Alliance
UHC	Universal Health Coverage
UPA	United Progressive Alliance
UPIA	United Party of Independent Alliance
WDM–Kenya	Wiper Democratic Movement–Kenya
WHO	World Health Organization



LIST OF ANNEXURES

- Annexure 1: Adoption Schedule
- Annexure 2: Minutes
- Annexure 3: Draft Charter
- Annexure 4: Cabinet Memorandum
- Annexure 5: Letter of Recommendation from the Commission of University Education

CHAIRPERSON'S FOREWORD

The Draft Charter for the Kenya Medical Research Institute (KEMRI) was tabled in the House on Wednesday, 1st April 2026 by the Leader of Majority, for parliamentary approval pursuant to section 24 (1)(a) of the Universities Act, 2012.

The Charter seeks to establish KEMRI as a specialized degree-awarding institution of strategic national importance, with a mandate to advance capacity building in highly specialized human health research and to strengthen the coordination, conduct, and promotion of health research in Kenya. This initiative is informed by national priorities, including lessons from the COVID-19 pandemic, which underscored the need for enhanced local capacity in the development and manufacture of vaccines, diagnostics, and biotherapeutics.

The Charter further aligns with the Kenya Kwanza Initiative on strengthening local research, development, manufacturing, and commercialization of health technologies, which necessitates a highly skilled biomedical workforce supported through specialized postgraduate training. KEMRI's existing capacity, including its internationally recognized clinical trials platform, has contributed to the development and licensing of key vaccines such as the malaria RTS vaccine, the cervical cancer Gardasil vaccine, and the pneumococcal conjugate vaccine. Additionally, the Institute has played a role in vaccine innovation, including work associated with the ChAdOx platform that informed global COVID-19 vaccine development.

On 24th June 2025, the Cabinet declared KEMRI as an Institution of Strategic National Importance, recognizing its critical role in biosecurity, biosurveillance, epidemic intelligence, and national health security. Subsequently, the Institute applied to the Commission for University Education (CUE) for conferment of a Charter as a specialized degree-awarding institution. The application process involved consultations with key stakeholders, including the Ministries of Health and Education, the Office of the Attorney General, professional regulatory bodies, and other sector actors. Following a comprehensive accreditation process and a needs assessment study, the CUE confirmed that KEMRI met all prescribed requirements and recommended the award of the Charter.

The Cabinet, at its 4th Cabinet Meeting – 2025 held on 24th June 2025, had earlier approved the establishment of KEMRI and authorized submission of the Charter to Parliament for approval. The Draft Charter was reviewed by the Office of the Attorney General and submitted to Parliament for approval in accordance with section 24(1) of the Universities Act, No. 42 of 2012.

In undertaking its scrutiny, the Committee on Delegated Legislation held a meeting on Thursday, 2nd April 2026 with the Principal Secretary, State Department for Higher Education and Research, the Chairperson of the KEMRI Board, and the Commission for University Education. The Committee reviewed the Draft Charter and satisfied itself that due process had been followed, including compliance with all statutory and accreditation requirements.

Having examined the Draft Charter for the establishment of the Kenya Medical Research Institute, the **Committee recommends that the House APPROVES the award of**

Charter for the Establishment of the Kenya Medical Research Institute pursuant to section 24(1)(a) of the Universities Act, No. 42 of 2012.

I sincerely thank the Speaker and the Office of the Clerk of the National Assembly for the invaluable support accorded to the Committee in the discharge of its mandate. I also wish to thank the Committee Membership and the Secretariat for their diligence in considering these Regulations. On behalf of the Members of the Committee on Delegated Legislation and pursuant to Standing Order 210, it is my pleasure and duty to present to the House the Committee's ***Report on the Consideration of the Draft Charter for the Establishment of the Kenya Medical Research Institute.***



HON. CHEPKONG'A KIPRONO SAMUEL, CBS, MP.

CHAIRPERSON, COMMITTEE ON DELEGATED LEGISLATION.

1.0 PREFACE

1.1 Establishment and Mandate of the Committee

1. The Select Committee on Delegated Legislation is established under **Standing Order No. 210** of the National Assembly Standing Orders and is mandated to consider statutory instruments submitted to Parliament for consideration. The Committee is expected to consider, in respect to any statutory instrument, whether it is in accordance with the provisions of the Constitution, the Act pursuant to which it is made or other relevant written laws.
2. The Committee is mandated to consider, in respect of any statutory instrument, whether it:
 - a) is in accordance with the provisions of the Constitution, the Act pursuant to which it is made or other relevant written laws;
 - b) infringes on fundamental rights and freedoms of the public;
 - c) contains a matter which, in the opinion of the Committee should more properly be dealt with in an Act of Parliament;
 - d) contains imposition of taxation;
 - e) directly or indirectly bars the jurisdiction of the Courts;
 - f) gives retrospective effect to any of the provisions in respect to which the Constitution or the Act does not expressly give any such power;
 - g) involves expenditure from the Consolidated Fund or other public revenues;
 - h) is defective in its drafting or for any reason the form or purport of the statutory instrument calls for any elucidation;
 - i) appears to make some unusual or unexpected use of the powers conferred by the Constitution or the Act pursuant to which it is made;
 - j) appears to have had an unjustifiable delay in its publication or laying before Parliament;
 - k) makes rights, liberties or obligations unduly dependent upon non-reviewable decisions;
 - l) makes rights, liberties or obligations unduly dependent on insufficiently defined administrative powers;
 - m) inappropriately delegates legislative powers;
 - n) imposes a fine, imprisonment or other penalty without express authority having been provided for in the enabling legislation;

- o) appears for any reason to infringe on the rule of law;
- p) inadequately subjects the exercise of legislative power to Parliamentary scrutiny; and
- q) accords to any other reason that the Committee considers fit to examine.

1.2 Committee Membership

3. The Committee membership comprises –

Chairperson

Hon. Chepkong'a Kiprono Samuel, CBS, M.P.

Ainabkoi Constituency

UDA

Vice-Chairperson

Hon. Githinji Robert Gichimu, M.P.

Gichugu Constituency

UDA

Committee Members

Hon. Mbui Robert, CBS, M.P.

Kathiani Constituency

WDM-Kenya

**Hon. (Maj) (Rtd) Dekow Barrow
Mohamed, M.P.**

Garrisa Township Constituency

UDA

**Hon. Julius Lekakeny Ole Sunkuli,
EGH, EBS, M.P.**

Kilgoris Constituency

KANU

Hon. Kamene Joyce, M.P

Machakos County

WDM-Kenya

**Hon. Dr. Onchoke, Mamwacha
Charles, M.P.**

Bonchari Constituency

UPA

Hon. Dr. Kimaiyo, Gideon Kipkoech, M.P.

Keiyo South Constituency

UDA

Hon. Waithaka, John Machua, M.P.

Kiambu Constituency

UDA

Hon. Chebor, Paul Kibet, M. P

Rongai Constituency

UDA

Hon. Yakub Adow Kuno, M. P

Bura Constituency

UPIA

**Hon. (Maj) (Rtd) Abdullahi, Bashir
Sheikh, M.P.**

Mandera North Constituency

UDM

Hon. Mwirigi John Paul, M.P.

Igembe South Constituency

Hon. Oduyo, Jared Okello, M.P.

Nyando Constituency

UDA

Hon. Chepkorir Linet, M.P.

Bomet County

UDA

Hon. Oluoch, Anthony Tom M.P.

Mathare Constituency

ODM

Hon. Moses Okoth Omondi M.P.

Ugunja Constituency

ODM

Hon. Mugabe Innocent Maino, M.P.

Likuyani Constituency

ODM

ODM

Hon. Munyoro Joseph Kamau, M.P

Kigumo Constituency

UDA

Hon. Lenguris Pauline, M.P.

Samburu County

UDA

Hon Mnyazi Amina Laura, MP.

Malindi Constituency

ODM

1.3 Committee Secretariat

4. The Secretariat facilitating the Committee comprises –

(1) Ms. Wanjiru Mwaura	Principal Clerk I (Team Leader)
(2) Mr. Dima Dima	Deputy Director-DLS
a. Mr. Brian Langwech	Clerk Assistant III
b. Mr. Grace Odedere	Clerk Assistant III
c. Ms. Peter Barasa	Legal Counsel II
d. Ms. Angela Musau	Legal Counsel II
e. Ms. Brenda Michira	Research Officer III
f. Mr. Noah Chemweno	Serjeant at Arms
g. Mr. Daniel Psirmoi	Media Relations Officer

2.0 CONSIDERATION OF THE DRAFT CHARTER FOR THE ESTABLISHMENT OF THE KENYA MEDICAL RESEARCH INSTITUTE

2.1 Purpose of the Statutory Instrument

5. Section 24(1)(a) of the Universities Act, No. 42 of 2012 provides that the President, on the recommendation of the Commission for University Education, through the relevant Cabinet Secretary, and with the approval of Parliament, by award of Charter, establish a specialized degree-awarding institution or institutions whose mandate shall be of strategic national importance.
6. The Charter establishes the Kenya Medical Research Institute (KEMRI) as a specialized degree-awarding research institute, which shall be a body corporate with perpetual succession and a common seal, and shall perform all those functions performed by a body corporate.
7. The Charter confers upon KEMRI the authority to award specialized postgraduate degrees and postdoctoral qualifications in the highly specialized strategic areas of research for human health, including Health Products and Technologies, Health Systems and Preventive Sciences, Molecular Biomedical Sciences, and Population Health and Biosurveillance.
8. The Draft Charter, a copy of the Cabinet Memorandum and a letter from the Commission of University Education, recommending the award of charter for the establishment of the Kenya Medical Research Institute were submitted to Parliament for parliamentary approval.

2.2 Legislative Context

9. Section 4 of the Universities Act establishes the Commission for University Education as the national regulator in charge of universities in Kenya. Additionally, Section 5 of the Act mandates the Commission to accredit universities and all academic programmes offered in these universities.
10. Additionally, sections 13(1), 14, 20(3) provide that every university in Kenya shall be established by a charter, by Letter of Interim Authority or by a legal order respectively.
11. Furthermore, section 24(1)(a) of the Universities Act, Cap 210 provides that the President, on the recommendation of the Commission through the Cabinet Secretary for Education, and with the approval of Parliament, may by award of Charter establish a specialized degree-awarding or research institution whose mandate shall be of strategic national importance.

2.3 Policy Background

2.3.1 Establishment and History

12. The KEMRI is a State Corporation established in 1979 under the Science and Technology Act, Cap 250, Laws of Kenya. KEMRI was created to fill the health research void left by the

dissolution of the East African Medical Research Council following the breakup of the East African Community.

13. It was constituted as the national body responsible for carrying out research in human health in Kenya and has since grown into one of Africa's foremost health research institutions. Any person who wishes to offer university education in Kenya is required to apply to the Commission for accreditation as a university in Kenya.

2.3.2 Policy Reforms Informing the Current Legal Framework

a) Science Technology and Innovation Act, No. 28 of 2013

14. Following the promulgation of the new Constitution, in 2010, the Science and Technology Act, Cap 250 of 1977 was repealed and replaced by the Science, Technology and Innovation Act, No. 28 of 2013, which came into effect in January 2013. The Act was developed subject to a national Science Technology Innovation Policy and Strategy aimed at aligning the existing legal framework to the new Constitution.
15. The Science Technology and Innovation Act established the National Commission for Science, Technology and Innovation (NACOSTI), as a successor to the National Council for Science and Technology, the Kenya National Innovation Agency (KENIA), and the National Research Fund (NRF).
16. The KEMRI is recognized as a Research Institute under the Fourth Schedule of the Act. The Act also introduced a strengthened framework for intellectual property rights in research, mandatory research licensing, and periodic external evaluation of research institutes.
17. Further, the Constitution of Kenya, 2010 introduced devolved governance under Chapter Eleven (11) and guaranteed the right to the highest attainable standard of health under Article 43. In response, KEMRI developed a framework for coordinating its research activities across all the forty-seven counties through regional offices and has signed Memoranda of Understanding with several county governments to establish research stations, biosurveillance nodes and community-based research platforms.

b) Universities Act, Cap 210

18. The Universities Act, Cap 210, was enacted in December 2012, with a view of aligning the legal framework regulating universities in Kenya with the new Constitution. The Act introduced section 24(1)(a), which empowers the President, on the recommendation of the Commission for University Education and with the approval of Parliament, to establish by Charter a specialized degree-awarding or research institution whose mandate is of strategic national importance. This provision opened the legal pathway for KEMRI to seek a Charter as a specialised degree-awarding research institution.

c) Kenya Medical Research Institute Order, Legal Notice No. 35 of 2021

19. The KEMRI was reconstituted as a legal entity through the Kenya Medical Research Institute Order published in the Kenya Gazette Vol. CXXIII – No. 69 on 9th April 2021 as Legal Notice No. 35 of 2021, made under the Science, Technology and Innovation Act, Cap 511.
20. The Order re-established KEMRI as a body corporate with perpetual succession. It provided the legal foundation upon which KEMRI's application for Charter was advanced by expanding its mandate to include—
 - a) conducting health, biomedical and public health research;
 - b) building research capacity: collaborating with local and international institutions;
 - c) advising the Government on health research policy;
 - d) undertaking scientific and technological innovation; and
 - e) establishing incubation centres linking research, academia, industry and policymakers in the health products value chain.

2.3.3 Policy Context Informing the Recommendation for Award of Charter to the KEMRI

21. The establishment of KEMRI as a chartered institution is driven by several intersecting national imperatives including the lessons from the COVID-19 pandemic which accelerated Kenya's drive to build the country's local capacity to manufacture health products and technologies including vaccines, diagnostics and biotherapeutics.
22. The Kenya Kwanza Government initiative for local research and development, manufacturing and commercialization of specialized health products demands a trained biomedical workforce that can only be sustainably produced through specialized postgraduate training.
23. On 18th February 2023 during the European Union Business Forum in Nairobi, the Government of Kenya affirmed its priority to develop a credible workforce in the biotechnology sector to enable a robust bio-manufacturing industry. Consequently, line ministries were directed to establish a bio-manufacturing training ecosystem in Kenya, with KEMRI being identified as the key institution to anchor this initiative.
24. In addition, the KEMRI has a globally recognized and accredited clinical trials platform, which has supported multinational pharmaceutical companies in developing and licensing new vaccines, including the malaria RTSs vaccine, the cervical cancer Gardasil vaccine, and the pneumococcal conjugate vaccine.
25. Furthermore, the first-ever licensed vaccine against Rift Valley Fever Virus (RVF), developed at KEMRI using the ChadOx platform, was subsequently used by Oxford University and AstraZeneca to develop the first global COVID-19 vaccine commonly referred to as the COVISHIELD.
26. On the other hand, KEMRI is the country's leading organization in combating bio-threat pathogens, with scientists conducting research to discover and develop new diagnostic tools,

drugs, vaccines and other biological devices for national pandemic preparedness and response.

27. On 24th June 2025, the Cabinet of the Republic of Kenya declared the Kenya Medical Research Institute as an Institution of Strategic National Importance, recognizing KEMRI's critical role in biosecurity, biodefense, biosurveillance, epidemic intelligence, and national health security.
28. This declaration fulfilled the mandatory prerequisite under section 24(1)(a) of the Universities Act, enabling the Commission for University Education to formally recommend KEMRI for the award of Charter.
29. In the foregoing, granting of this Charter directly supports Kenya's obligations under key national and international frameworks including Kenya Vision 2030, the Bottom-Up Economic Transformation Agenda (BETA), the Sustainable Development Goals, specifically SDG 3 on Good Health and Well-being, the Universal Health Coverage (UHC), and the International Health Regulations (IHR) 2005 of the World Health Organization (WHO).

2.4 Process Preceding the Recommendation for Award of Charter

30. The KEMRI applied to the Commission for University Education for establishment as a specialized degree-awarding institution. In processing this application, guidance was sought from multiple stakeholders including the Ministry of Health, the Ministry of Education, and the Office of the Attorney General.
31. The Institution was taken through the full accreditation process and met all minimum requirements prescribed by the Commission. The Commission confirmed KEMRI's readiness based on:
 - a) A highly trained corps of biomedical and clinical scientists with the qualifications and experience to supervise postgraduate and postdoctoral research;
 - b) State-of-the-art laboratory infrastructure, including BSL-2 and BSL-3 containment facilities, genomics and bioinformatics platforms, clinical trial units, and national reference laboratories;
 - c) Demonstrated track record in postgraduate training through a collaboration with the Institute of Tropical Medicine and Infectious Disease, of Jomo Kenyatta University of Agriculture and Technology (JKUAT), which has graduated 120 PhD candidates in health-related fields; and the Initiative to Develop African Research Leaders (IDeAL), based at KEMRI Kilifi in partnership with UK universities, has graduated more than 99 PhD candidates and postdoctoral fellows;
 - d) An extensive international network of partners, collaborators and funders, providing a sustainable ecosystem for research and scholarship funding; and
 - e) Demonstrated institutional capacity to initiate, manage and disseminate competitive research grants, generating approximately Kenya shillings seven billion (KShs 7 billion) equivalent to 70% of its annual budget, from research grants and income-generating activities.

32. The KEMRI was accordingly recommended by the Commission for University Education for the award of Charter as a specialized degree-awarding institution under section 24(1)(a) of the Universities Act, Cap 210.
33. The proposed Institute will conduct research related to human health including but not limited to—
 - a) Public health research;
 - b) Biomedical research;
 - c) Traditional and alternative medicine research;
 - d) Clinical, applied and social science research;
 - e) Biodefence research; and
 - f) other relevant fields related to the promotion, protection, and advancement of human health.
34. The institute will succeed the Kenya Medical Research Institute established under the Kenya Medical Research Institute Order, 2021 and shall have its headquarters in Nairobi.

2.5 Summary of the Draft Charter for the Establishment of the Kenya Medical Research Institute

35. **Part I** provides for preliminary provisions
36. **Part II** provides for the establishment and functions of the Institute.
37. **Part III** provides for Membership and Governance of the Institute which includes;
 - a) Membership of the Institute
 - b) The Chancellor
 - c) The Chairperson of the Board
 - d) The Board
 - e) The Vice-Chancellor
 - f) The Research and Academic Board
 - g) Students' Association
 - h) Alumni Association
38. **Part IV** provides for the Management of the Institute
39. **Part V** provides for the Conduct of Research for Human Health and Innovation
40. **Part VI** is on Medical Services and Clinical Trials
41. **Part VII** is on Traditional and Alternative Medicine
42. **Part VIII** provides for National Biosecurity and Biosurveillance
43. **Part IX** is on Intellectual Property
44. **Part X** is on Financial Provisions

45. **Part XI** is on miscellaneous provisions which include associations, collaborations or linkages, instruments of governance, statutes, instruments of authority, protection of name, performance of functions in the absence of office holder, convocation, transition, and variation and revocation of the Charter.

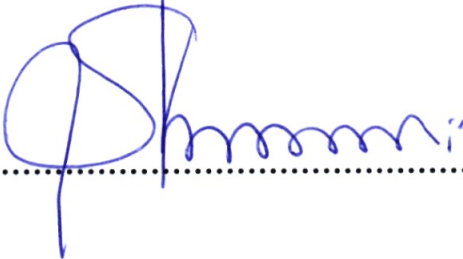

3.0 COMMITTEE OBSERVATIONS

46. The Committee having engaged the Principal Secretary of Higher Learning and Research, the Chairperson of the KEMRI Board and the Commission for University Education on Thursday, 2nd April 2026, in its consideration of the Draft Charter, observed the following—

- a) **THAT** the Cabinet at its 4th Cabinet Meeting – 2025 held on 24th June 2025 considered and approved the Establishment of the Kenya Medical Research Institute as a specialized degree-awarding institution of strategic national importance.
- b) **THAT** the Draft Charter was reviewed by the Office of the Attorney General and duly submitted to Parliament for approval in accordance with section 24(1) of the Universities Act, No.42 of 2012.
- c) **THAT** the Commission for University Education subjected the Ins to an accreditation process and confirmed that it had met all minimum requirements statutory and academic requirements prescribed by the Commission.
- d) **THAT** the application for award of Charter was informed by a comprehensive needs assessment study and broad stakeholder consultations, including line ministries, national and county government entities, professional regulatory bodies, academic institutions, collaborators, and sector partners.
- e) **THAT** the proposed Kenya Medical Research Institute will offer specialized capacity building in human health research and strengthen Kenya's position in biomedical innovation.
- f) **THAT** the Institute shall succeed the Kenya Medical Research Institute established under the Kenya Medical Research Institute Order, 2021 and shall have its headquarters in Nairobi.


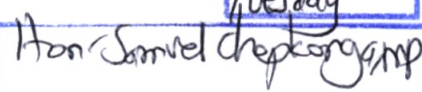
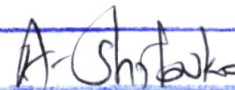
4.0 COMMITTEE RECOMMENDATION

47. Having examined the Draft Charter for the Establishment of the Kenya Medical Research Institute, the **Committee recommends that the House APPROVES the award of Charter for the Establishment of the Kenya Medical Research Institute in accordance with section 24(1) of the Universities Act, No. 42 of 2012.**

Signed  Date 

**THE HON. CHEPKONG'A SAMUEL KIPRONO, CBS, MP
(CHAIRPERSON)**

COMMITTEE ON DELEGATED LEGISLATION

 THE NATIONAL ASSEMBLY PAPERS LAID	
DATE: 07 APR 2026	
DAY: Tuesday	
TABLED BY:	
CLERK-AT THE-TABLE:	

SCHEDULE

THE UNIVERSITIES ACT
(*Cap. 210*)

THE KENYA MEDICAL RESEARCH INSTITUTE CHARTER

PREAMBLE

WHEREAS the Government of Kenya, realizing the need to build capacity in the highly specialized strategic area of research for human health, wishes to establish the Kenya Medical Research Institute situated in Nairobi City County in the Republic of Kenya as a specialized degree-awarding Research Institute;

AND WHEREAS the Kenya Medical Research Institute has applied to the Commission for University Education, for the grant of Charter and provide for the establishment, control, governance, and administration of the Kenya Medical Research Institute and for connected purposes, in the manner provided in the Universities Act;

AND WHEREAS the Government of Kenya declared the Kenya Medical Research Institute as an institution of strategic national importance, critical for biosecurity, biodefense, biosurveillance, epidemic intelligence, and national health security;

AND WHEREAS the Commission for University Education has visited and inspected the Kenya Medical Research Institute and is satisfied that the objects of the Institute are consistent with the provisions of section 24 of the Universities Act and the advancement of university education in Kenya;

AND WHEREAS the Commission for University Education is also satisfied that the Kenya Medical Research Institute has complied with the provisions of the Act;

AND WHEREAS the Commission for University Education has submitted a draft Charter, the text whereof is annexed hereto, to the Cabinet Secretary for Education on the said Institute, and the Cabinet Secretary for Education is satisfied that the Kenya Medical Research Institute be granted the Charter;



LEGAL NOTICE NO.....

THE UNIVERSITIES ACT
(Cap. 210)

**CHARTER FOR THE KENYA MEDICAL RESEARCH
INSTITUTE**

IN EXERCISE of the powers conferred by section 24 of the Universities Act, the Cabinet Secretary for Education certifies that the Charter set out in the Schedule hereto has been granted to the Kenya Medical Research Institute in accordance with the provisions of the Act.

Made on the..... day of2026.

JULIUS MIGOS OGAMBA,
Cabinet Secretary for Education.

AND WHEREAS the Cabinet Secretary for Education has submitted this Charter to me with recommendations thereon;

AND WHEREAS Parliament has approved the establishment of the said Kenya Medical Research Institute in accordance with the requirements of the Universities Act;

AND WHEREAS I am satisfied that granting the Kenya Medical Research Institute a Charter will be of strategic national importance in national health security, and in capacity building in the highly specialized area of research for human health and to provide for the effective conduct, co-ordination and promotion of research for human health in Kenya and for connected purposes;

NOW WHEREFORE, by these presents, be it known in exercise of the powers conferred upon me by section 24 of the Universities Act, I, William Samoei Ruto, President and Commander-in-Chief of the Defence Forces of the Republic of Kenya, grant this Charter annexed hereto to the Kenya Medical Research Institute.

THE KENYA MEDICAL RESEARCH INSTITUTE CHARTER
ARRANGEMENT OF PARAGRAPHS

PART I—PRELIMINARY

- 1—Citation.
- 2—Interpretation.

**PART II—ESTABLISHMENT AND FUNCTIONS OF THE
INSTITUTE**

- 3—Establishment of the Institute.
- 4—Vision.
- 5—Mission.
- 6—Philosophy.
- 7—Functions of the Institute.
- 8—Admission of students.
- 9—Establishment of campuses and regional offices.
- 10—Conferment, granting, cancellation and withdrawal of degrees and other awards.
- 11—Scholarships, fellowships and other awards.

**PART III—MEMBERSHIP AND GOVERNANCE OF THE
INSTITUTE**

- 12—Membership of the Institute.
- 13—The Chancellor.
- 14—Board of the Institute.
- 15—Chairperson of the Board.
- 16—Functions of the Board
- 17—Vice-Chancellor.
- 18—Research and Academic Board.
- 19—Student Association.
- 20—Alumni Association.

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- 21—Management Board.
- 22—Directorates.
- 23—Regional Offices.
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- 25—Research for human health.
- 26—Research priorities and agenda.
- 27—Initiation of research.
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- 29—Establishment of the Scientific and Ethics Review Unit.
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- 33—Research data.
- 34—Quality assurance in research.
- 35—Management of research data.
- 36—Data analysis and dissemination.
- 37—Monitoring and evaluation.

PART VI—MEDICAL SERVICES AND CLINICAL TRIALS

- 38—Medical services.
- 39—Conduct of clinical trials.
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PART VII—TRADITIONAL AND ALTERNATIVE MEDICINE

- 41—General mandate.
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PART IX—INTELLECTUAL PROPERTY

- 51—Rights to vest in the Institute.
- 52—Withholding of intellectual property information.
- 53—Registration of intellectual property.
- 54—Ownership of intellectual property.
- 55—Commercialization of intellectual property.
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PART X—FINANCIAL PROVISIONS

- 57—Financial year.
- 58—Funds of the Institute.
- 59—Investment of funds.
- 60—Annual estimates.
- 61—Accounts and audit.

PART XI—MISCELLANEOUS PROVISIONS

- 62—Associations, collaborations or linkages.
- 63—Instruments of governance.
- 64—Statutes.
- 65—Instruments of authority.
- 66—Protection of name.
- 67—Performance of functions in absence of office holder.
- 68—Convocation.
- 69—Transition.
- 70—Variation and revocation.

**THE KENYA MEDICAL RESEARCH
INSTITUTE CHARTER
PART I—PRELIMINARY**

Citation **1.** This Charter may be cited as the Kenya Medical Research Institute Charter.

Interpretation. **2.** In this Charter, unless the context otherwise requires—

“Academic year” means a continuous period of teaching, examination, and study organized in a full year mode, semester mode, trimester mode, and quarter mode and the period should not be less than thirty weeks in a calendar year;

Cap 210; “Act” means the Universities Act;

“Alumni” means persons who have completed a programme of study or training at the Institute and have been awarded a qualification.

“biobank” means a facility established by the Institute for the systematic collection, processing, storage, and controlled use of biological materials and associated data for research and related purposes.

“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;

“Board” means the Governing Board of the Institute established under paragraph 14;

“Cabinet Secretary” means the Cabinet Secretary for the time being responsible for university education;

“Chancellor” means the Chancellor of the Institute appointed under paragraph 13;

“Charter” means a Charter granted to the Kenya Medical Research Institute in accordance to section 24 (1) (a) of the Act;

“Commission” means the Commission for University Education established by section 4 of the Act;

“Convocation” means the assembly of the Institute convened for the conferment of degrees and other academic awards established under paragraph 68;

“Critical Infrastructure for National Health Security” means essential facilities, systems, technologies, and specialized workforce that the country must maintain to safely and effectively conduct research that improves public health and protects the public from health threats;

“Research Data Platforms” means specialized facilities that are either physical, digital, or hybrid, that collect, store, manage, analyze, and safeguard data used in health and biomedical research;

“Research Databank” means a structured repository established by the Institute for the secure collection, storage, management, and controlled access of research data and associated information for scientific and related purposes.

“Health Security” means the systems, policies, capacities, actions, and arrangements required to prevent, detect, respond to, and recover from biological threats, public health emergencies, epidemics, pandemics, bioterrorism events and other

hazards that pose risks to human health, national stability, and the security of the Country;

“High Containment Facilities” means specialized laboratories, including Biosafety Level 3 (BSL-3), Biosafety Level 4 (BSL-4), and any other controlled research environments, designed and operated to handle high-risk pathogens safely in accordance with national and international biosafety and biosecurity standards;

“Human health” means a state of complete physical, mental, and social well-being of a person 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;

“Intellectual property” means any new or useful process, machine, composition of matter, life form, article of manufacture, software, copyrighted work and know-how and associated information;

“Institute” means the Kenya Medical Research Institute established under Paragraph 3;

“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 and Academic Board” means the Research and Academic Board established under paragraph 18;

“Research for human health” means systematic investigation, experimentation, exploration, examination and evaluation for purposes of decision-policy-development, policy-development and practice in human health and clinical trials;

“Regulatory sandbox” means a framework managed by regulators that encourages innovation by allowing researchers and companies to test new products, services, and business models within a monitored “safe space” where regulatory requirements may be relaxed or modified;

“Schools” means schools of the Institute established by the Statutes;

“Specialized Laboratories” means purpose-built facilities that support advanced scientific investigations, requiring specialized equipment, technical expertise, and regulatory oversight beyond routine laboratory functions aimed at understanding diseases, developing diagnostics, producing vaccines, strengthening surveillance, and improving overall public health;

“Statutes” means the statutes of the Institute made under paragraph 64;

“Student association” means an association of students recognized by the Board as being an organization representative of the students of the Institute and as provided by paragraph 19;

“Student” means a person duly admitted and registered to pursue a programme of study, training, or research at the Institute.

“Vice-Chancellor” means the Chief Executive Officer of the Institute appointed under paragraph 17.

PART II —ESTABLISHMENT AND FUNCTIONS OF THE INSTITUTE

Establishment of the Institute.

3. (1) There is established an Institute to be known as Kenya Medical Research Institute, which shall be a health research institution with specialized degree awarding status in accordance with section 24(1)(a) of the Act.
- (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) purchasing or otherwise acquiring, holding, charging and disposing of movable and immovable property;
 - (c) receiving investing, borrowing and lending money;
 - (d) entering contracts; and
 - (e) doing or performing any such other things or acts, including entering into such contracts as may be necessary or expedient, for the furtherance of the provision of this Charter which may be done by a corporate body
- (3) Notwithstanding the provisions of paragraph 7, the Institute established under graph (1) shall focus on national health security and biosecurity, health research and innovation, specialized postgraduate training and degree award, and the translation of science into policy, products, and services for improved public health.
- (4) The seat of the Institute shall be situated in Nairobi City County in the Republic of Kenya.
- (5) Notwithstanding the provisions of subparagraph (4), the Institute may establish such Faculties, Departments, Regional Offices, for Research and Academia, and Specialized Centers of Excellence within the country.
- (6) The Institute shall be the successor to the Kenya Medical Research Institute established under the Kenya Medical Research Institute Order, 2021, and all assets, liabilities, rights and obligations of that Institute shall vest in the Institute.
- (7) The overall management of the Institute in regard to this Charter shall be vested in the Ministry for time being responsible for

matters related to health in collaboration with the Ministry responsible for matters related to University Education.

- (8) The Institute shall, in the performance of its health research mandate, be subject to the policy direction of the Ministry for the time being responsible for matters relating to health.

Vision.

4. To be a global leader in research for human health.

Mission.

5. To advance and improve human health through research, innovation, capacity development and service delivery.

Philosophy.

6. The Institute shall be guided by the following philosophy—
- (a) dedication to the advancement of human health through excellence in research, teaching and innovation, and through collaboration and partnerships;
 - (b) promotion of innovation, research and academic leadership, upholding integrity, generation of intellectual property, and translation of research into solutions that improve human health; and
 - (c) generation and dissemination of knowledge that contributes to the advancement of human health and society, through collaboration with local and international partners and the development of transformational leaders.

Functions of the Institute.

7. The Institute shall—
- (a) conduct research on human health;

- (b) provide specialized postgraduate education, research and training in health sciences and related disciplines;
- (c) conduct examinations and confer postgraduate degrees in health sciences, and related disciplines;
- (d) collaborate with other institutions, entities and bodies in research, training, innovation for health, health security and health service provision, and related matters;
- (e) undertake scientific and technological invention, innovation, and product development for human health and service delivery;
- (f) establish and operationalize incubation and innovation centres to translate research outcomes into health products, technologies, and solutions;
- (g) establish and maintain institutional infrastructure, systems, and platforms to support research, innovation, postgraduate training and medical services;
- (h) establish and maintain Critical Infrastructure for National Health Security to enhance resilience for health security;
- (i) establish Biosecurity Structures, for the prevention, detection, and response to biological threats and public health risks;
- (j) establish such mechanisms for providing independent expert guidance on the Institute's scientific and academic work and related matters;
- (k) support continuous national surveillance, preparedness, and response to public health emergencies including research, innovation and drug repurposing;
- (l) establish and maintain biosafety and biosecurity systems to prevent misuse of biological research, ensure responsible

science, and protect public health and national security;

- (m) formulate national human health research agenda for purposes of identifying health research programmes and priorities;
- (n) provide specialized laboratory, diagnostic, and clinical services in support of research, training, surveillance, outbreak response and healthcare delivery;
- (o) provide scientific, technical and security support services to the Government on matters relating to health security, biosecurity and bioterrorism;
- (p) manage biological materials and data in accordance with ethical, scientific, and regulatory requirements;
- (q) establish and oversee an integrated scientific, ethical, and regulatory review mechanisms to ensure integrity, compliance, and quality in research;
- (r) establish and coordinate a regulatory sandbox for research for human health to support emerging science and technology and inform the regulatory frameworks of the resulting innovations.
- (s) develop, apply for, and hold rights in intellectual property, and enter into agreements or arrangements for their protection and commercial exploitation;
- (t) mobilize resources and establish endowment, investment, and enterprise funds, including public-private partnerships and commercialization of intellectual property and innovative products;
- (u) offer specialized medical, clinical, and diagnostic services through facilities such as a Research and Teaching Hospital for translational research and advanced healthcare;

- (v) establish and maintain National Health Research Data Centres to support data access, security knowledge management, and evidence-based policy application;
- (w) advise the National Government and County Governments on matters relating to research for human health, biosecurity, biodefence bioterrorism, emergency preparedness and capacity building for human health; and
- (x) perform any other functions as may be prescribed by law or necessary for the promotion of the objectives of this Charter.

Admission of students.

8. (1) Admission of students to the Institute for specialised training, including postgraduate degrees and other awards, shall be open to persons who satisfy the prescribed entry requirements set out in the Statutes and any applicable national admission criteria.

(2) The Institute shall charge such fees as may be approved by the Board from time to time.

Establishment of campuses and regional offices.

9. (1) The Board may, on the recommendation of the Research and Academic Board on the advise of the Commission, establish such campuses, regional offices and other centres within Kenya as it may consider necessary for the effective discharge of the functions of the Institute.

(2) A campus, regional office or centre established under sub-paragraph (1) may comprise such faculties, schools, departments, units or stations as may be provided for in the Statutes.

(3) The organisation and administration of campuses, regional offices and centres established under this paragraph shall be as prescribed in the Statutes.

Conferment, granting, cancellation and withdrawal of degrees and other awards.

10. (1) Subject to this Charter and the Statutes, the Institute may—

- (a) award postgraduate degrees and such other academic qualifications as may be provided for in the Statutes; and
- (b) award honorary degrees or other academic distinctions to any person who has rendered distinguished service to the advancement of knowledge, or in any field of human health, in accordance with the Statutes.

(2) The Board may, on the recommendation of the Research and Academic Board and in accordance with the Statutes, revoke or withdraw any degree, honorary degree or other academic award conferred by the Institute.

Scholarships, fellowships and other awards.

11. The Institute may, in accordance with this Charter and the Statutes, award scholarships, fellowships, bursaries, prizes and other awards as may be approved by the Board.

PART III—MEMBERSHIP AND GOVERNANCE OF THE INSTITUTE

Membership of the Institute.

12. The members of the Institute shall be—

- (a) the Chancellor;
- (b) the members of the Board;
- (c) the Vice Chancellor;
- (d) the Heads of Directorates or equivalent;
- (e) the Head of Programmes;
- (f) the Heads of Administrative Departments;
- (g) the Deans of Schools;
- (h) the Head of Legal Services/Corporation Secretary;
- (i) the Head of Finance;
- (j) the Staff of the Institute;
- (k) the Research and Academic Staff of the Institute;
- (l) the Head of Library;
- (m) the Registrars;
- (n) the Alumni;
- (o) the students; and

- (p) such other persons or bodies as may be admitted into association with the Institute in accordance with the Statutes.

(2) Members of the Institute shall have such rights and privileges as may be prescribed in the Statutes.

The Chancellor.

13.(1) The President of the Republic of Kenya and Commander in Chief of the Defence Forces shall be the Chancellor of the Institute.

(2) The Chancellor shall—

- (a) be the titular head of the Institute;
- (b) confer degrees and other academic awards in the name of the Institute;
- (c) cause a visitation of the Institute to be conducted in accordance with the Act and the Statutes;
- (d) give such directions of a general nature as may promote the betterment of the Institute; and
- (e) perform such other functions as may be provided in this Charter or the Statutes.

Board of the Institute.

14.(1) There shall be a Board of the Institute which shall be the governing body of the Institute.

(2) The Board shall consist of—

- (a) the Chairperson appointed under paragraph 15;
- (b) the Principal Secretary responsible for university education or a representative;
- (c) the Principal Secretary responsible for health or a representative;
- (d) the Principal Secretary responsible for finance or a representative;
- (e) the Chief Executive Officer of the Council of Governors or a representative;
- (f) three members, not being public officers, appointed by the Cabinet Secretary for

the time being responsible for matters related to Health, of whom:

- (i) two shall be research scientists at level of Professors with knowledge and experience in specialized fields essential to the Institute's National Security mandate, including, genomics, bio-surveillance, vaccine science, biodefense, emerging infectious diseases or health security and related disciplines; and
 - (ii) one person from the public or the private sector with proven entrepreneurial or resource mobilization skills.
- (g) two members, not being public officers, appointed by the Cabinet Secretary for the time being responsible for matters related to Education, of whom:
- (i) one shall have experience in finance management;
 - (ii) one shall be a distinguished professional with experience in university management;
- (h) the Vice-Chancellor, who shall be an *ex officio* member; and the Corporation Secretary, who shall be the secretary to the Board.
- (3) A person appointed under sub-paragraph (2)(f) or (g) shall—
- (a) possess relevant academic or professional qualifications;
 - (b) have at least ten years' experience in the relevant field; and
 - (c) meet the requirements of Chapter Six of the Constitution.
- (4) The Corporation Secretary shall be appointed through a competitive process and shall—

- (a) be an advocate of the High Court of Kenya with at least ten years' experience;
 - (b) be a certified public secretary in good standing; and
 - (c) meet the requirements of Chapter Six of the Constitution.
- (5) The Chairperson and members of the Board, other than ex officio members, shall hold office for a term of three years and shall be eligible for re-appointment for one further term.
- (6) The office of a member shall become vacant if the member—
- (a) resigns in writing to the appointing authority;
 - (b) is unable to perform the functions of office;
 - (c) is adjudged bankrupt;
 - (d) is convicted of an offence and sentenced to imprisonment for a term exceeding six months;
 - (e) is found guilty of gross misconduct; or
 - (f) dies.

Chairperson of the Board.

15.(1) There shall be a Chairperson of the Board who shall be appointed by the President.

- (2) A person qualifies for appointment as Chairperson if that person—
- (a) holds an earned doctorate degree from a university recognised in Kenya;
 - (b) has at least fifteen years' experience in a relevant field, ten of which shall be at senior management level; and
 - (c) meets the requirements of Chapter Six of the Constitution.

Functions of the Board.

16.(1) The Board shall—

- (a) provide strategic direction of the Institute;
- (b) approve Statutes and policies of the Institute;
- (c) appoint staff and determine terms and conditions of service;

- (d) approve budgets, expenditure and investment of funds;
 - (e) administer assets of the Institute;
 - (f) approve fees and charges;
 - (g) approve the establishment of academic and research units;
 - (h) approve scholarships, fellowships and other awards on the recommendation of the Research and Academic Board;
 - (i) ensure compliance with the Constitution and applicable laws; and
 - (j) perform such other functions as may be necessary for the attainment of the objects of the Institute.
- (2) The Board may—
- (a) establish committees; and
 - (b) delegate its functions, except its core functions, in accordance with the Statutes.

Vice-Chancellor.

17.(1) There shall be a Vice-Chancellor of the Institute who shall be the Chief Executive Officer of the Institute.

(2) The Vice-Chancellor shall be appointed by the Chancellor on the advice of the Board, upon such terms and conditions of service as the Board may determine.

(3) The Vice-Chancellor shall be the accounting officer of the Institute and shall be responsible to the Board for the overall research, academic and administrative management of the Institute.

(4) A person qualifies for appointment as the Vice-Chancellor of the Institute if that person—

- (a) holds an earned doctorate degree in health, biomedical sciences or related disciplines from a university recognised in Kenya;
- (b) is a professor;

- (c) has ten years' relevant post-doctoral work experience, five of which shall be at senior management level; and
 - (d) meets the requirements of Chapter Six of the Constitution.
- (5) The Vice-Chancellor shall—
- (a) be the research, academic and administrative head of the Institute;
 - (b) have overall responsibility for the direction, organisation, development, administration and programmes of the Institute;
 - (c) be the Chairperson of the Management Board and the Research and Academic Board;
 - (d) be responsible to the Board for the general conduct, discipline and welfare of the students and staff of the Institute; and
 - (e) be responsible to the Board for academic, research, health security and other programmes of the Institute
- (6) The Vice-Chancellor shall be appointed upon such terms and conditions of service as may be specified in the instrument of appointment, the Regulations or the Statutes.
- (7) The Vice-Chancellor shall hold office for a term of five years and shall be eligible for re-appointment for one further term.
- (8) The process of filling a vacancy in the office of the Vice-Chancellor shall be provided for in the Statutes.

Research and Academic Board.

18.(1) There shall be a Research and Academic Board of the Institute which shall be responsible for all research and academic matters of the Institute.

(2) The Research and Academic Board shall consist of—

- (a) the Vice-Chancellor, who shall be the Chairperson;
 - (b) the Heads of Directorates or equivalent;
 - (c) the Heads of Programmes, Research and Academic Departments;
 - (d) the Registrars;
 - (e) the Principal Librarian;
 - (f) the Deans of Schools;
 - (g) the Professors of the Institute;
 - (h) the Head of Quality Assurance;
 - (i) the Head of the Scientific and Ethics Review Unit;
 - (j) the Head of Security;
 - (k) chief medical officer or equivalent;
 - (l) head of examination
 - (m) two student representatives elected by the student organisation’;
 - (n) two academic and research staff representatives; and
 - (o) such other members as the Board may determine from time to time.
- (3) The Director responsible for Academic and Student Affairs or equivalent shall be the Secretary to the Research and Academic Board.
- (4) The Research and Academic Board shall—
- (a) ensure the maintenance of research and academic standards;
 - (b) develop and review the research and training agenda in line with national and global priorities;
 - (c) approve curricula, syllabi and delivery modes;

- (d) regulate all matters relating to admission of students, conduct of examinations and academic awards;
- (e) determine persons who have attained the prescribed standard of proficiency for the award of degrees or other qualifications;
- (f) recommend to the Board the conferment of honorary degrees and distinctions;
- (g) recommend to the Board the establishment or abolition of academic and research units;
- (h) promote interdisciplinary research, innovation and the translation of research output into policy;
- (i) develop systems for research ethics, quality assurance and integrity;
- (j) promote mobilisation of resources with stakeholders;
- (k) develop policies for the appointment and promotion of research and academic staff;
- (l) promote collaboration with universities, research institutions and industry;
- (m) establish mechanisms for the welfare of research and academic staff and students;
- (n) recommend to the Board the approval of fellowships, scholarships and research grants;
- (o) monitor and evaluate the performance of research and academic programmes;
- (p) recommend policies on intellectual property, publication and technology transfer;
- (q) recommend the establishment or harmonisation of colleges, faculties, schools and departments;
- (r) determine the dates of the academic year;
- (s) develop quality assurance systems;

- (t) recommend criteria for the appointment and promotion of research and academic staff;
 - (u) review the Statutes from time to time and present recommendations to the Board, provided that the Statutes shall be reviewed at least once every five years;
 - (v) propose regulations and procedures for the discipline of students and make recommendations to the Board;
 - (w) propose Statutes for approval by the Board;
 - (x) discontinue a student from a programme of study on academic grounds; and
 - (y) perform any other function necessary to advance the academic and research mandate of the Institute.
- (5) The Research and Academic Board shall exercise such other powers as may be conferred by the Act, the Statutes or the Regulations, and may perform such other acts as the Board may authorise.
- (6) Notwithstanding any provision of this Charter, the Board shall not initiate any action in respect of academic matters except upon receipt of a report or proposal from the Research and Academic Board, and shall not reject or amend any such report or proposal without further reference to the Research and Academic Board.
- (7) The Research and Academic Board may establish such committees as it may consider necessary.

Students Association.

19. There shall be a students' association which shall be established in accordance with the Act, this Charter and the Statutes.

Alumni Association.

20. (1) There shall be an Alumni Association which shall consist of all persons whose

names appear on the Alumni Association membership register, to be compiled and kept by the Secretary of the Association, and such members as may be prescribed in the Statutes.

- (2) The functions and powers of the Alumni Association shall be as prescribed in the Statutes.

PART IV—MANAGEMENT OF THE INSTITUTE

Management Board.

21. (1) There shall be an Institute Management Board whose membership shall consist of—

- (a) the Vice Chancellor, who shall be the Chairperson;
- (b) the Heads of Directorates
- (c) the Head of Procurement;
- (d) the Head of Human Resource Management;
- (e) the Head of Quality Assurance;
- (f) the Registrars;
- (g) the Head of Library; and
- (h) Any other officer as may be determined by the Board from time to time.

(2) The Management Board shall—

- (a) implement decisions and policies approved by the Board;
- (b) assist the Vice Chancellor in the day-to-day management and administration of operations, finances, and human resources of the Institute;
- (c) prepare annual budgets, work plans, and performance reports for submission to the Board;
- (d) develop and monitor implementation of strategic, master, and operational plans;

- (e) ensure efficient utilization of resources and adherence to procurement and financial regulations;
 - (f) coordinate activities across directorates, research centres, departments and schools;
 - (g) recommend policies, procedures, and internal regulations to the Board;
 - (h) oversee performance management, monitoring, and evaluation;
 - (i) promote staff development, mentorship, and institutional culture;
 - (j) manage risk, safety, and compliance systems;
 - (k) facilitate communication and stakeholder engagement; and
 - (l) perform any other functions assigned by the Board.
- (3) The Institute Management Board shall develop its own procedures of conduct of its meetings.

Directorates.

- 22.** (1) There shall be such Directorates of the Institute as the Board may determine.
- (2) The heads of Directorates shall be appointed by the Board and shall exercise such powers and perform such duties as may be provided in the Statutes.

Regional Offices.

- 23.** (1) The Institute may establish such Regional Offices as the board may determine.
- (2) Each Regional Office shall have a head appointed by the Board who shall be the research, academic and administrative head of their respective regions.

Staff of the Institute.

- 24.** (1) The Board shall appoint such staff as may be necessary for the discharge of the functions of the Institute.
- (2) The staff of the Institute shall consist of_
- (a) academic and research staff
 - (b) technical staff
 - (c) administrative staff; and
 - (d) support staff.
- (3) The staff specified under sub-paragraph 2 shall be as may be specified in the Statutes.
- (4) All members of staff of the Institute shall, subject to this Charter, be appointed in the manner and upon such terms and conditions of the service prescribed in their instrument of engagement.
- (5) (i) The Board may request for the secondment of an officer where a requisite skill may be required.
- (ii) Where a person is seconded to the Institute from another institution, the Government, or any other public service, such person shall be engaged on terms and conditions agreed upon with the Board.
- (6) All members of staff of the Institute shall—
- (a) be subject to the general authority of the Vice Chancellor; and
 - (b) be deemed to be employed in accordance with the Statutes or otherwise specifically provided by the Statutes or by the terms of a particular appointment.

PART V— CONDUCT OF RESEARCH FOR HUMAN HEALTH AND INNOVATION

Research for human health.

- 25.** (1) The Institute shall conduct research related to human health, including but not limited to—

- (a) public health research;
 - (b) biomedical research;
 - (c) traditional and alternative medicine research;
 - (d) clinical, applied and social science research;
 - (e) biodefence research; and
 - (f) other relevant fields related to the promotion, protection and advancement of human health.
- (2) The research specified under sub-paragraph (1) may be—
- (a) programme-based;
 - (b) investigator-initiated;
 - (c) collaborative or team-based; or
 - (d) As may be determined by the board to address national priorities.
- (3) The research shall be conducted in such manner as may be provided for in the Statutes and policies of the Institute, and with due regard to global best practices.

Research priorities and agenda.

- 26.** The Institute shall formulate national human health research priorities for the purpose of identifying health research programmes and priorities in accordance with national and international health research priorities.
- (2) The research priorities and agenda shall be formulated in such manner as may be provided for in the Statutes.

Initiation of research.

- 27.** (1) The Institute may initiate research through—
- (a) investigator-initiated initiatives;
 - (b) programme-based initiatives;
 - (c) collaboration with local and international partners;

- (d) contracts with legal entities in accordance with applicable regulatory frameworks;
 - (e) secondary research in accordance with relevant policies, guidelines and laws; or
 - (f) any other initiative as the Board may, from time to time, determine.
- (2) The modalities for initiating and conducting research shall be as may be prescribed in the Statutes.

Ethical considerations.

- 28.** (1) The Institute shall uphold ethical standards and shall conduct research that is—
- (a) scientifically valid;
 - (b) socially valuable; and
 - (c) protective of the rights and welfare of research participants.
- (2) In conducting research, the Institute shall be guided by the following principles—
- (a) respect for research participants, including data privacy in accordance with the Data Protection Act;
 - (b) maximisation of benefits and minimisation of risks to research participants and communities;
 - (c) fairness and equity to research participants;
 - (d) scientific validity;
 - (e) independent ethical review;
 - (f) respect for vulnerable research participants and communities;
 - (g) community engagement; and
 - (h) transparency and accountability in research processes, methods, findings and dissemination.

- (3) Without prejudice to the generality of subparagraph (2), the Institute shall—
 - (a) in relation to human participants, ensure—
 - (i) respect for persons and communities, including informed consent;
 - (ii) minimisation of research risks; and
 - (iii) maximisation of benefits to participants or the community;
 - (b) in relation to animal subjects, ensure—
 - (i) methods to minimise pain and distress are specified;
 - (ii) justification is provided where pain relief is not used; and
 - (iii) where applicable, the method of euthanasia is specified.
- (4) A research scientist shall comply with institutional, national and international laws, regulations and treaties, and as may be provided for in the Statutes.

Establishment of the
Scientific and Ethics
Review Unit.

- 29.** (1) There is established within the Institute a Scientific and Ethics Review Unit.
- (2) The Unit shall comprise multidisciplinary committees whose membership shall be drawn from within the Institute and other stakeholders.
- (3) The Unit shall—
 - (a) develop, review and implement policies, regulations, standards and procedures for scientific conduct and research ethics;
 - (b) ensure compliance with international and national standards for scientific conduct and research ethics;
 - (c) ensure that research proposals adhere to scientific and ethical principles;
 - (d) review and approve research proposals;

- (e) monitor ongoing research to ensure compliance;
- (f) facilitate training in research methodology and ethics;
- (g) review and approve the import and export of biological materials and related agreements in accordance with applicable laws; and
- (h) ensure compliance with animal use policies and regulations.

Membership of Scientific and Ethics Review Unit Committees.

- 30.** (1) Members of the Committees shall be appointed by the Vice-Chancellor.
- (2) Each Committee shall consist of not fewer than eight and not more than twenty members with relevant expertise.
- (3) The membership shall include—
- (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 university ethics review committee.
- (4) Additional members—
- (a) shall reflect relevant expertise; and
 - (b) may include community representation.
- (5) The Committees shall regulate their own procedure in accordance with the Statutes and shall operate independently.

Code of conduct for research.

- 31.** The Institute shall formulate a code of conduct for research for human health.

Community engagement in research.

32. The Institute shall, where research involves the community, ensure community engagement.

Research data.

- 33.** (1) A researcher shall collect data for purposes of obtaining knowledge required to address a research issue.
- (2) Data collected shall constitute strategic research data and shall be classified as sovereign national data safeguarded under the law to support—
- (a) health research;
 - (b) public health monitoring;
 - (c) innovation and biotechnology;
 - (d) emergency response; and
 - (e) national security.
- (3) The use, storage, transfer and management of such data shall comply with national cyber-security standards and applicable laws.
- (4) Data may be collected from—
- (a) literature;
 - (b) humans;
 - (c) animals;
 - (d) organisms;
 - (e) plants; or
 - (f) any other relevant source.
- (5) Data sources shall include—
- (a) primary data collected through experiments, questionnaires, observation or interviews; or
 - (b) secondary data obtained through literature, reports or other sources.
- (6) A researcher shall comply with applicable laws and guidelines in processing data.

Quality assurance in research.

- 34.** (1) The Institute shall establish quality assurance plans to ensure integrity, reliability and validity of research outcomes.
- (2) Internal quality assurance shall include monitoring, review and audit of research activities.
- (3) External quality assurance shall be conducted by independent entities.
- (4) The Institute may engage peer review panels to provide guidance on best practices.

Management of research data.

- 35.** The Institute shall—
- (a) collect and store data in accordance with applicable laws;
- (b) organise and document data for traceability;
- (c) ensure data validation and quality assurance; and
- (d) restrict access to authorised persons.

Data analysis and dissemination.

- 36.** (1) The Institute shall ensure proper management, analysis and interpretation of data.
- (2) Research findings shall be disseminated through—
- (a) knowledge management strategies;
- (b) stakeholder engagement;
- (c) open access initiatives;
- (d) publication in peer-reviewed journals; and
- (e) other appropriate mechanisms.
- (3) Relevant government agencies may apply research findings in policy development.
- (4) Data management, analysis and dissemination shall be conducted as provided in the Statutes.

Monitoring and evaluation.

37. The Institute shall provide for monitoring and evaluation mechanisms in research development and implementation processes.

PART VI-MEDICAL SERVICES AND CLINICAL TRIALS

Medical services.

38. (1) The Institute may provide clinical or health-related services.

(2) The services to be provided will consider the health needs of the public and as may be provided for in the Statutes.

Conduct of clinical trials.

39. 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.

Clinical trial research in public health emergencies.

40. (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 sub-paragraph (1), ensure that—

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

- (b) research participants are 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 VII-TRADITIONAL AND ALTERNATIVE MEDICINE

General mandate.

41. In the exercise of its functions under this Charter, the Institute shall promote the development, validation and integration of traditional and alternative medicine through research, collaboration and technical support.

Research, validation and standards.

- 42.** (1) The Institute may, on its own initiative or upon request, undertake or support the scientific assessment of traditional and alternative medicinal products and practices for purposes of determining their quality, safety and efficacy.
- (2) In carrying out activities under sub-paragraph (1), the Institute may—
- (a) apply appropriate scientific methodologies, including biochemical, pharmacological and toxicological evaluation;
 - (b) undertake or facilitate pre-clinical and clinical studies;
 - (c) prioritise research on indigenous flora and biodiversity with potential therapeutic value; and

- (d) develop and promote approaches for the standardisation and validation of medicinal products and practices.
- (3) The Institute may develop, publish and disseminate guidelines, standards and technical recommendations relating to traditional and alternative medicine.
- (4) The Institute may provide technical and advisory support to relevant authorities and stakeholders in matters relating to quality assurance, product standards and public health safeguards.

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 sub-paragraph (1)—
 - (a) shall focus on utilizing Kenya's biodiversity and in particular, indigenous flora and fauna 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 oversee 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.
- (4) 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.
- (5) The Institute may, in the discharge of the duties in sub-paragraph (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.
- (6) The framework in sub-paragraph (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;
 - (c) facilitate the development of healthcare products into scalable prototypes through

- providing the necessary technical, scientific and regulatory assistance; and
- (d) support for development.

Capacity building for practitioners.

44. 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.

Management of traditional and alternative medicine knowledge.

45. (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 VIII—NATIONAL BIOSECURITY AND BIOSURVEILLANCE

National Biosecurity and biosurveillance platform.

46. (1) The Institute shall develop, operate, and maintain a National Biosecurity and Biosurveillance platform for preventing, detecting, research and responding to biological threats and public health emergencies of national concern;

- (2) The platform shall have the following functions—

- (a) surveillance, monitoring and early detection of diseases, outbreaks and public health risks, including emerging and re-emerging infections;
 - (b) biosurveillance, epidemiological intelligence and real-time threat assessment;
 - (c) coordinating national or institutional responses during outbreaks;
 - (d) developing preparedness plans and standard operating procedures;
 - (e) ensuring biosafety and laboratory biosecurity, including secure handling, storage, transport and disposal of pathogens and biological materials;
 - (f) preventing accidental or deliberate release of harmful biological agents, including mitigation of insider threats;
 - (g) evaluating and modelling biological threats, including pandemics, antimicrobial resistance, zoonotic spill-overs and bioterrorism risks;
 - (h) providing scientific, technical and policy advisory services to Government on matters relating to biosecurity, biodefense and bioterrorism;
 - (i) coordinating with national security agencies, regulators and global bodies on matters related to bio surveillance and health security;
 - (j) training health workers, responders, researchers and relevant personnel in disease outbreak management, biosafety, biosecurity, surveillance and emergency response;
 - (k) maintaining systems for cyber-biosecurity to safeguard sensitive biological data, digital research platforms and Critical Infrastructure for National Health Security;
 - (l) perform any other functions as may be prescribed for in the Statutes.
- (3) The Vice Chancellor shall have authority to issue, suspend or revoke security clearance

for any person accessing sensitive areas, based on national security risk assessment.

Biobanks.

47. (1) The Institute shall establish biobanks for the collection, storage and management of biological materials.
- (2) Despite sub-paragraph (1), the Institute may collaborate with other institutions, sites or health establishments in management of biobanks;
- (3) 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 administrative 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;
 - (v) restrict access to biological materials to authorized users; and
 - (vi) implement data management systems to ensure secure storage, retrieval and sharing of clinical and metadata.

Research data banks.

48. (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 paragraph, “authorized person” means the research scientist responsible for the ethical design and conduct of a research study.

Regulatory Sandbox.

- 49.** (1) The Institute may establish a Regulatory framework to allow scientists and companies to test new products, services, and business models in a monitored safe space with adapted regulatory requirements.
- (2) The Regulatory Sandbox framework may be established by the Board, on the recommendation of the Research and Academic Board as may be provided by the Statutes.

Research hospitals and clinics.

- 50.** (1) The Institute may establish research hospitals and clinics for the conduct of research for human health.
- (2) The research hospitals and clinics may be established by the Board, on the

recommendation of the Research and Academic Board and in consultation with the Commission and any other relevant agency as may be provided by the Statutes.

PART IX—INTELLECTUAL PROPERTY

Rights to vest in the Institute.

51. (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.

Cap. 130.
Cap. 509.

(2) The Institute may apply for a patent in respect of any invention or innovation contemplated in sub-paragraph (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 property information.

52. 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.

Registration of intellectual property.

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

(2) The mechanism in sub-paragraph (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 sub-paragraph (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.

Ownership of intellectual property.

- 54.** (1) All rights and obligations relating to an invention shall belong 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.
- (2) Where an intellectual property right held by the Institute or sponsoring entity is not being worked on the inventor may apply to succeed the intellectual property right or for a licence to work that intellectual property through start-up company on terms to be mutually agreed by the inventor and the Institute or sponsoring entity as the case may be.
- (3) The Institute will support inventors to grow start-up companies through incubators, accelerators or other means mutually agreed by the Institute and the inventor.
- (4) 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.

- (5) Despite the provisions of this paragraph, 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.

55. (1) The Institute or sponsoring entity, 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 sub-paragraph (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 of intellectual
property.

56. (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 sub-paragraph (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 X—FINANCIAL PROVISIONS

Financial year.

- 57.** The financial year of the Institute shall be the period of twelve months commencing on the 1st of July and ending on the 30th of June in the following year.

Funds of the Institute.

- 58.** The funds of the Institute shall comprise of—

Cap. 241.

- (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 Charter;
- (c) tuition fees;
- (d) fees from services rendered;
- (e) thirty percent of the National Research Fund allocated for health research under the Health Act;
- (f) monies as may be payable to the Institute pursuant to this Charter or any other written law;
- (g) donations;
- (h) research and training grants;
- (i) endowment;
- (j) gifts and trusts;
- (k) monetization of intellectual property;
- (l) revenue from sale of innovative products;
- (m) income from auxiliary activities; and
- (n) other sources that the Board may identify from time to time.

Investments of funds.

- 59.** (1) All monies in the Institute which are not immediately required to be applied for the purposes of this Charter shall be invested—
- (a) in such investment in a reputable bank, 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 paragraph shall be held in the name of the Institute.

Annual estimates.

60. (1) Before the commencement of a financial year, the Board shall cause to be prepared estimates of the revenue and expenditure of the Institute for that year.

(2) The annual estimates shall make provisions for all the estimated expenditure of the institute for the financial year concerned, and shall provide for—

- (a) the payment of the salaries, allowances and other charges in respect of the staff of the Institute;
- (b) the payment of the pensions, gratuities and other charges in respect of retirement benefits which are payable out of the funds of the Institute;
- (c) the proper maintenance of the buildings and grounds of the Institute;
- (d) the acquisition, maintenance, repair and replacement of equipment and other movable assets of the Institute;
- (e) the funding of the cost of teaching, research and outreach activities of the Institute;
- (f) development purposes; and
- (g) the creation of such funds to meet future or contingent liabilities of such other matters as the Board may deem fit.

(3) The Vice Chancellor may incur expenditure for purposes of the Institute in accordance with estimates approved by the Board, and any approved expenditure under any vote head of the estimates may not be exceeded without the prior approval of the Board.

Accounts and audit.

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

- (2) Within a period of three months from the end of each financial year, the Board shall submit to the Auditor General the accounts of the
- (3) The accounts of the Institute shall be audited by the Auditor-General in accordance with the provisions of the Public Audit Act (Cap. 412B).
- (4) Subject to the Public Finance Management Act, the Institute shall maintain financial autonomy with full authority to solicit, manage, and utilize tuition fees, grants, donations, endowments, and other financial resources specifically in support of its academic, research, and institutional development mandates.

PART XI- MISCELLANEOUS PROVISIONS

Associations,
collaborations or linkages.

- 62.** The Board may enter into association, collaboration, or linkages with other bodies or organizations within or outside Kenya for purposes of –
- (a) training and exchange programs;
 - (b) research and development;
 - (c) running specialized programs in support of government institutions; and
 - (d) any other areas as the Institute may consider desirable or appropriate and in furtherance of the purpose for which the Institute is established.

Instruments of governance.

- 63.** (1) The Institute shall conspicuously display all its instruments of governance.
- (2) Where any instrument under this Charter is revoked, the Institute shall, within fourteen days of such revocation, return the original instrument of governance to the Commission subject to the provisions of the Act.

Statutes.

- 64.** (1) In the performance of its functions under this Charter, the Board shall, subject to this Charter, make Statutes generally for the governance, control, and administration of the Institute.
- (2) Notwithstanding the provisions of subparagraph (1), the Board shall make statutes for the better carrying into effect of the purposes of this Charter, and in particular for —
- (a) establishment of Campuses, Regional Offices, Centres, Colleges, Schools, Faculties, and Departments;
 - (b) description of specialized postgraduate degrees, honorary degrees, and other qualifications;
 - (c) requirements for conferment of specialized postgraduate degrees, honorary degrees, and other qualifications;
 - (d) conduct of examinations and assessments;
 - (e) prescribing fees and other charges;
 - (f) prescribing the rules and regulations for the conduct and organization of student affairs;
 - (g) conduct of research for human health and innovation
 - (h) the establishment of medical services and clinical trials;
 - (i) the conduct of traditional and alternative medicine;
 - (j) the implementation of national biosecurity and biosurveillance;
 - (k) management of intellectual property;
 - (l) setting the terms and conditions of service, including the appointment, dismissal, and recommendation of retirement benefits of the members of the staff of the Institute;
 - (m) constitution and procedure of meetings of the Board, and the establishment, composition, and terms of reference of committees of the Board; the fees to be charged under this Charter;
 - (n) the establishment and management of biobanks;

- (o) the establishment and management of Animal houses and insectaries ;
- (p) the establishment and management of Botanical gardens;
- (q) the establishment and management of Research hospitals and clinics;
- (r) the establishment and management of Sandboxes ;
- (s) the establishment and management of incubation centres;
- (t) the scientific and ethics review mechanism;
- (u) the establishment of Critical Infrastructure for National Health Security;
- (v) the collection, storage, use and transfer of biological materials;
- (w) maintenance of repositories of research for human health data;
- (x) the criteria for the admission of qualified persons to the training programmes offered by the Institute;
- (y) the categories of examinations and the manner in which such examinations shall be administered;
- (z) any other matter that may be related to the implementation of this charter.

Instruments of authority.

- 65.** (1) The Institute shall possess the mace, the common seal and the logo as instruments of authority.
- (2) The Mace shall be kept in such custody as the Board may direct and used as specified in the Statutes.
- (3) The Common Seal of the Institute shall be kept in such custody and used only as the Board shall direct and may be affixed, as and when required under the applicable law to legal documents and instruments or as determined by the Board.
- (4) The Common Seal of the Institute shall be authenticated by the signatures of the Vice

Chancellor, together with any other person duly authorized by the Board.

- (5) The Common Seal of the Institute, when affixed on any document and duly authenticated, shall be judicially and officially noticed, and, unless and until the contrary is proved, any order or authorization of the Board under this paragraph shall be presumed to have been duly given.
- (6) All documents other than those required by law to be under Seal, made on behalf of the Board, and all decisions of the Board shall be under the hand of the Chairperson, the Vice Chancellor, or the respective Heads of Directorates or any other member of the Board duly authorized by the Board on its behalf.
- (7) No person, body, authority, and/or organization performing any function related to administration, registration of companies, business, trade, advertisement, calling, profession, shall use the Common Seal and Logo of the Institute except with the consent of the Board and/or authorized representative of the Board.

Protection of name.

- 66.** (1) Notwithstanding the provisions of any other written law, no public officer performing functions relating to the registration of companies, business or societies shall accept for such registration any name which includes the words "Kenya Medical Research" together with the word "Institute", in whatever order, or "KEMRI", unless the application for the registration is accompanied by the written consent of the Board.
- (2) Any person who except with the written consent of the Board, uses the word "Kenya Medical Research", together with the word

“Institute”, in whatever order, or “KEMRI”, in furtherance of, or in connection with, any advertisement for any trade, business, calling, or profession, commits an offence and shall, on conviction, be liable to the penalties specified under the Act.

- (3) Notwithstanding the foregoing, nothing in this paragraph shall be construed as preventing the bona-fide use by staff, students and alumni in pursuance of the functions of the Institute.

Performance of functions
in the absence of office
holder.

67. (1) In the event of incapacity of the Vice Chancellor, the Board shall appoint one of the head of directorates to carry out the functions of the Vice Chancellor during the period of incapacity for a maximum period of one hundred and eighty calendar days.
- (2) In the event of simultaneous incapacity of the Vice Chancellor and the heads of directorates, the Board shall appoint one of the heads of departments, heads of centres or heads of regional offices, to perform the functions of the Vice Chancellor during the incapacity for a maximum period of one hundred and eighty calendar days.
- (3) In the event of simultaneous incapacity of the Vice Chancellor and the heads of directorates, and the heads of departments, heads of centres or heads of regional offices of the Institute, the Board shall appoint a Senior Research Scientist at the level equivalent to a head of directorates to perform the functions of the Vice Chancellor during the incapacity for a maximum period of one hundred and eighty calendar days.
- (4) In the event of incapacity of any member of staff of the Institute, the Vice Chancellor may appoint a suitable person to perform the functions of the said member of staff during

the period of absence for a maximum period of one hundred and eighty calendar days.

- (5) Subject to the discretion of the Board upon the expiry of the above prescribed period, the position shall fall vacant and the process of filling the position as provided for in the Institute's Human Resource Instruments, the Charter, Statutes, or applicable laws may commence.
- (6) For the purposes of this paragraph, "incapacity" means absence from Kenya or the inability for any reason to perform the functions of the office held.

Convocation.

- 68.** (1) There shall be convocation of the Institute which shall consist of such members as may be specified in the Statutes.
- (2) The convocation shall be convened for purposes of conferment of awards and for such other functions as the Statutes may specify.

Transition.

- 69.** (1) In this paragraph, "Former Institute" means the Kenya Medical Research Institute established under the Kenya Medical Research Institute Order, 2021.
- (2) Any assets and liabilities of the Former Institute existing immediately before the grant of this charter shall be deemed to be the assets and liabilities of the Institute under this Charter without conveyance.
- (3) Any member of staff of the Former Institute existing immediately before the grant of this Charter shall be deemed to be a member of staff of the Institute under this Charter on the terms and conditions of service applicable to them immediately before the commencement of this Charter.

- (4) Any persons or students pursuing studies or undertaking research in the Former Institute under collaborative arrangements shall continue to pursue studies or undertake research on the terms on conditions applicable immediately before the commencement of this Charter.
- (5) Any legal proceedings in which the Former Institute is a party and are pending determination shall at the grant of this Charter be deemed legal proceedings under this Charter.
- (6) All rights, duties and obligations held by the Kenya Medical Research Institute constituted under the Kenya Medical Research Institute Order, 2021, by anybody on behalf of the Institute, existing at the commencement of this Charter, shall be automatically and fully transferred to the Kenya Medical Research Institute under this Charter.
- (7) Any reference to the Kenya Medical Research Institute or "KEMRI" in any contract or document shall, for all purposes, be deemed to be a reference to the Kenya Medical Research Institute established under paragraph 3 of this Charter.
- (8) The implementation of this Charter shall be effected over a transition period of five years from the date of commencement, during which the Board shall ensure continuity of operations and phased adoption of all provisions of this Charter.

Variation and revocation.

70. This Charter may be varied, amended or revoked in accordance with sections 22 and 22A of the Act.

Given under my hand and the public seal of the Republic of Kenya:

On the.....day of 2026

WILLIAM SAMOEI RUTO
President

Dated this.....day of2026.

JULIUS MIGOS OGAMBA,
Cabinet Secretary for Education.



REPUBLIC OF KENYA

EXECUTIVE OFFICE OF THE PRESIDENT

THE CABINET OFFICE

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When replying please quote

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SECRET

CAB/GEN.3/1/1 VOL. XXIV/(42)

24th June, 2025

Dr. Oluga Fredrick Ouma, OGW
Principal Secretary
State Department for Medical Services
Ministry of Health
NAIROBI

Ms. Mary Muthoni Muriuki, CBS
Principal Secretary
State Department for Public Health and
Professional Standards
Ministry of Health
NAIROBI

Dr. Beatrice M. Inyangala, PhD., CBS
Principal Secretary
State Department for Higher Education and Research
Ministry of Education
NAIROBI

Dr. Chris K. Kiptoo, PhD., CBS
Principal Secretary
The National Treasury
NAIROBI

Hon. Shadrack J. Mose, CBS
Solicitor- General
State Law Office
NAIROBI

DECLARATION OF KENYA MEDICAL RESEARCH INSTITUTE (KEMRI) AS AN INSTITUTION OF NATIONAL STRATEGIC IMPORTANCE

I refer to the 4th Cabinet Meeting - 2025 held on 24th June, 2025 during which the Cabinet Secretary for Health jointly with the Cabinet Secretary for Education; the

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Cabinet Secretary for the National Treasury; and the Attorney-General presented Cabinet Memorandum **CAB(25)95**.

The Memorandum apprised Cabinet on the proposed declaration of KEMRI as an institute of national strategic importance; and sought Cabinet approval for KEMRI to be conferred as charter as a specialized degree awarding institution for biotechnology research and development.

I wish to inform you that Cabinet **considered** the Memorandum and:

- I. **Noted** the contents of the Memorandum;
- II. **Approved** the declaration of KEMRI as an institute of national strategic importance; and
- III. **Directed** the Cabinet Secretary for Health; the Cabinet Secretary for Education; the Cabinet Secretary for the National Treasury; and the Attorney-General to take necessary action.

Please proceed and take action as directed by **Cabinet**.



Mercy Wanjau, (Mrs.), EGH
SECRETARY TO THE CABINET

Copy to: Hon. Aden Bare Duale, EGH
Cabinet Secretary
Ministry of Health
NAIROBI

Mr. Julius Migos Ogamba, EBS
Cabinet Secretary
Ministry of Education
NAIROBI

Hon. FCPA John Mbadl Ng'ongo, EGH
Cabinet Secretary
The National Treasury
NAIROBI

Hon. Dorcas Oduor, SC, EBS
Hon. Attorney-General
The State Law Office
NAIROBI

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Mr. Felix K. Koskei, EGH
Chief of Staff & Head of the Public Service
Executive Office of the President
NAIROBI

Ms. Wanjiku Wakogi, CBS
Chief of Staff
Office of the Deputy President
Executive Office of the President
NAIROBI

Dr. Idris Salim Dokota, PhD., CBS
Principal Secretary
State Department for Cabinet Affairs
Office of the Deputy President
NAIROBI

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EXPLANATORY MEMORANDUM

EXPLANATORY MEMORANDUM TO THE KEMRI CHARTER

PART I

NAME OF THE STATUTORY INSTRUMENT: KEMRI CHARTER

NAME OF THE PARENT ACT: UNIVERSITIES ACT, CAP 210

ENACTED PURSUANT TO: SECTION 24(1)(a)

NAME OF THE MINISTRY OR AGENCY: COMMISSION FOR UNIVERSITY EDUCATION

1. Purpose of the Statutory Instrument

Pursuant to section 24(1)(a) of the Universities Act, Cap 210, the President, on the recommendation of the Commission for University Education, through the Cabinet Secretary for Education, and with the approval of Parliament, may by award of Charter establish a specialized degree-awarding or research institution whose mandate shall be of strategic national importance. The Charter annexed herein establishes the Kenya Medical Research Institute (KEMRI) as a specialized degree-awarding research institute, which shall be a body corporate with perpetual succession and a common seal, and shall perform all those functions performed by a body corporate.

The Charter confers upon KEMRI the authority to award specialized postgraduate degrees and postdoctoral qualifications in the highly specialized strategic areas of research for human health, including Health Products and Technologies, Health Systems and Preventive Sciences, Molecular Biomedical Sciences, and Population Health and Biosurveillance.

2. Legislative Context

Section 4 of the Universities Act establishes the Commission for University Education as the national regulator in charge of universities in Kenya. Section 5 of the Act mandates the Commission to accredit universities and all academic programmes offered in these universities. Under section 13(1), every university in Kenya shall be established by a charter (under sections 19, 24 and 25 of the Act) or by a legal order under section 20(3) for Constituent Colleges, or by Letter of Interim Authority (under section 14 of the Act). Any person who wishes to offer university education in Kenya is required to apply to the Commission for accreditation as a university in Kenya.

Under section 24(1)(a) of the Universities Act, Cap 210, the President, on the recommendation of the Commission through the Cabinet Secretary for Education, and with the approval of Parliament, may by award of Charter establish a specialized degree-awarding or research institution whose mandate shall be of strategic national importance.

It is under this specific provision that the KEMRI Charter is being granted, recognizing KEMRI as an institution of strategic national importance critical for biosecurity, biodefense, biosurveillance, epidemic intelligence, and national health security.

3. Policy Background

3.1 Establishment and Legislative History

The Kenya Medical Research Institute (KEMRI) is a State Corporation established in 1979 under the Science and Technology Act, Cap 250, Laws of Kenya. KEMRI was created to fill the health research void left by the dissolution of the East African Medical Research Council following the breakup of the East African Community. It was constituted as the national body responsible for carrying out research in human health in Kenya and has since grown into one of Africa's foremost health research institutions.

3.2 Policy Reforms Informing the Current Framework

(a) Science, Technology and Innovation Act, No. 28 of 2013

Following the promulgation of the new Constitution, in 2010, The Science and Technology Act, Cap 250 of 1977 was repealed and replaced by the Science, Technology and Innovation Act, No. 28 of 2013, which came into effect in January 2013. The Act was developed on the basis of a national Science Technology Innovation Policy and Strategy aimed at aligning the existing legal framework to the new Constitution. The STI Act, established the National Commission for Science, Technology and Innovation (NACOSTI) as successor to the National Council for Science and Technology, the Kenya National Innovation Agency (KENIA), and the National Research Fund (NRF). KEMRI is recognized as a research institute under the Fourth Schedule of the Act. The Act also introduced a strengthened framework for intellectual property rights in research, mandatory research licensing, and periodic external evaluation of research institutes.

Further, the Constitution of Kenya, 2010 introduced devolved governance under Chapter Eleven and guaranteed the right to the highest attainable standard of health under Article 43. In response, KEMRI developed a framework for coordinating its research activities across all forty-seven counties through regional offices and has signed Memoranda of Understanding with several county governments to establish research stations, biosurveillance nodes and community-based research platforms.

(b) Universities Act, Cap 210

The Universities Act, Cap 210, enacted in December 2012, with a view of aligning the legal framework regulating universities in Kenya with the new Constitution, introduced Section 24(1)(a), which empowers the President, on the recommendation of the Commission for University Education and with the approval of Parliament, to establish by Charter a specialized degree-awarding or research institution whose mandate is of strategic national importance. This provision opened the legal pathway for KEMRI to seek a Charter as a specialised degree-awarding research institution.

(c) Kenya Medical Research Institute Order, Legal Notice No. 35 of 2021

KEMRI was reconstituted as a legal entity through the Kenya Medical Research Institute Order published in the Kenya Gazette Vol. CXXIII — No. 69 on 9th April 2021 as Legal Notice No. 35 of 2021, made under the Science, Technology and Innovation Act, Cap 511. The Order re-established KEMRI as a body corporate with perpetual succession and

expanded its mandate to include: conducting health, biomedical and public health research; building research capacity; collaborating with local and international institutions; advising the Government on health research policy; undertaking scientific and technological innovation; and establishing incubation centres linking research, academia, industry and policymakers in the health products value chain. This Order provided the immediate legal foundation upon which KEMRI's application for Charter was advanced.

3.3 Policy Context Informing the Charter

The establishment of KEMRI as a chartered institution is driven by several intersecting national imperatives:

- i. The lessons of the COVID-19 pandemic accelerated Kenya's drive to build local capacity to manufacture health products and technologies including vaccines, diagnostics and biotherapeutics. The Kenya Kwanza Government initiative for local research and development, manufacturing and commercialization of specialized health products demands a trained biomedical workforce that can only be sustainably produced through specialized postgraduate training.
- ii. On 18th February 2023 during the EU Business Forum in Nairobi, the Government of Kenya affirmed its priority to develop a credible workforce in the biotechnology sector to enable a robust bio-manufacturing industry. Line ministries were directed to establish a bio-manufacturing training ecosystem in Kenya, with KEMRI identified as the key institution to anchor this initiative.
- iii. KEMRI has a globally recognized and accredited clinical trials platform, which has supported multinational pharmaceutical companies in developing and licensing new vaccines, including the malaria RTSs vaccine, the cervical cancer Gardasil vaccine, and the pneumococcal conjugate vaccine. The first-ever licensed vaccine against Rift Valley Fever virus (RVF), developed at KEMRI using the ChadOx platform, was subsequently used by Oxford University and AstraZeneca to develop the first global COVID-19 vaccine, COVISHIELD.
- iv. KEMRI is the country's leading organization in combating bio-threat pathogens, with scientists conducting research to discover and develop new diagnostic tools, drugs, vaccines and other biological devices for national pandemic preparedness and response.

On 24th June 2025, the Cabinet of the Republic of Kenya declared the Kenya Medical Research Institute as an Institution of Strategic National Importance, recognizing KEMRI's critical role in biosecurity, biodefense, biosurveillance, epidemic intelligence, and national health security. This declaration fulfilled the mandatory prerequisite under section 24(1)(a) of the Universities Act, enabling the Commission for University Education to formally recommend KEMRI for the award of Charter.

The granting of this Charter directly supports Kenya's obligations under key national and international frameworks including Kenya Vision 2030, the Bottom-Up Economic Transformation Agenda (BETA), the Sustainable Development Goals (SDG 3 - Good Health and Well-being), Universal Health Coverage, and the International Health Regulations (IHR) 2005 of the World Health Organization.

4. Consultation Outcome

In 2021, KEMRI commissioned a comprehensive Needs Assessment Study to inform the application for specialized degree-awarding status. The study adopted a cross-sectional mixed methods design, collecting both qualitative and quantitative data through Key Informant Interviews and surveys administered to stakeholders across Kenya.

Stakeholders consulted included professional regulatory bodies, peer institutions, line national and county ministries, county health directors, funders, collaborators, students and alumni. The scope of the assessment covered KEMRI's presence across the 47 counties, with targeted representation from Nairobi, Kisumu, Kericho, Busia, Bungoma, Kiambu, Kirinyaga, Embu, Mombasa, Kilifi and Uasin Gishu counties.

The needs assessment findings confirmed the following:

1. There is a high level of demand and interest in KEMRI's proposed Doctoral (PhD) programmes in Medical Product Development and Evaluation, Health Systems and Preventive Sciences, Molecular Biological Sciences (including Genome Science), Population Health, Biosurveillance and Epidemiology, and Data Science and Artificial Intelligence;
2. Significant skills gaps exist in all the proposed disciplines. Stakeholders rated the skills gap in Medical Product Development and Evaluation at 81.3% and in Molecular Biological Sciences at 75%, signaling a critical national deficit in these areas;
3. KEMRI has the facilities, resources and expertise to implement the curriculum requirements for the proposed doctoral programmes, including state-of-the-art laboratory infrastructure, BSL-3 containment facilities, a globally accredited clinical trials platform, and a critical mass of highly skilled scientists and academic supervisors;
4. Employment opportunities for graduates trained in the proposed disciplines exist both within Kenya and internationally, confirming the economic and national security value of the programmes;
5. Over 70% of current KEMRI postgraduate students expressed a desire to advance their studies within KEMRI, demonstrating strong internal demand and continuity of the research pipeline.

Thus, significant skills gaps exist in all the proposed disciplines, signaling a critical national deficit in these areas.

Emanating from the above findings, it is clear that there is a need to establish KEMRI as a degree awarding institution to close this gap, which is caused by the nature of training required in biosecurity, biodefense, biosurveillance, epidemic intelligence, and national health security training.

On 24th June 2025, the Cabinet declared KEMRI as an Institution of National Strategic Importance, critical for biosecurity, biodefense, biosurveillance, epidemic intelligence, and national health security. The Commission for University Education, having conducted inspections and audits of KEMRI's facilities in December 2022 and in 2025, confirmed that KEMRI meets the minimum standards and requirements for the award of a Charter.

Following this decision, the Commission recommended to the Cabinet Secretary the award of Charter to KEMRI by the President, upon approval of Parliament.

5. Guidance

KEMRI applied to the Commission for University Education for establishment as a specialized degree-awarding institution. In processing this application, guidance was sought from multiple stakeholders including the Ministry of Health, the Ministry of Education, and the Office of the Attorney General.

The Institution was taken through the full accreditation process and met all minimum requirements prescribed by the Commission. The Commission confirmed KEMRI's readiness based on:

- i. A highly trained corps of biomedical and clinical scientists with the qualifications and experience to supervise postgraduate and postdoctoral research;
- ii. State-of-the-art laboratory infrastructure, including BSL-2 and BSL-3 containment facilities, genomics and bioinformatics platforms, clinical trial units, and national reference laboratories;
- iii. Demonstrated track record in postgraduate training through a collaboration with the Institute of Tropical Medicine and Infectious Disease, of Jomo Kenyatta University of Agriculture and Technology (JKUAT), which has graduated 120 PhD candidates in health-related fields; and the Initiative to Develop African Research Leaders (IDeAL), based at KEMRI Kilifi in partnership with UK universities, has graduated more than 99 PhD candidates and postdoctoral fellows;
- iv. An extensive international network of partners, collaborators and funders, providing a sustainable ecosystem for research and scholarship funding;
- v. Demonstrated institutional capacity to initiate, manage and disseminate competitive research grants, generating approximately Kenya shillings seven billion (KShs 7 billion) equivalent to 70% of its annual budget, from research grants and income-generating activities.

KEMRI was accordingly recommended by the Commission for University Education for the award of Charter as a specialized degree-awarding institution under section 24(1)(a) of the Universities Act, Cap 210.

6. Impact

The Charter is not likely to impose significant costs on the public or infringe on fundamental rights and freedoms. In the circumstances, a full regulatory impact assessment is not deemed applicable for this instrument.

7. Monitoring and Review

The Commission for University Education will monitor the implementation of the Charter and, where there is need to review, the same will be done through amendments from time to time in accordance with the Universities Act.

The Ministry of Health, as the sector ministry, will also exercise oversight over KEMRI's research mandate and national health security functions in accordance with the KEMRI Act and applicable laws.

8. Contact

For further information regarding this Explanatory Memorandum, please contact:

Dr. Beatrice Muganda Inyangala, CBS

Principal Secretary

Ministry of Higher Education

Jogoo House "B", Harambee Avenue

P.O. Box 30040 – 00100

Nairobi, Kenya

The Principal Secretary

State Department for Medical Services

Ministry of Health

Afya House, Cathedral Road

P.O. Box 30016 – 00100

Nairobi, Kenya

The Director General

Kenya Medical Research Institute (KEMRI)

Mbagathi Road, off Mbagathi Way

P.O. Box 54840 – 00200

Nairobi, Kenya

The Commission Secretary/Chief Executive Officer

Commission for University Education

Upper Hill, Red Hill Road

P.O. Box 54999 – 00200

Nairobi, Kenya

MINUTES OF THE 13TH SITTING OF THE COMMITTEE ON DELEGATED LEGISLATION HELD ON THURSDAY, 2ND APRIL, 2026 IN COMMITTEE ROOM 21, 5TH FLOOR, BUNGE TOWER AT 11.00AM

PRESENT

1. The Hon. Samuel Kiprono Chepkong'a, CBS, M.P. – Chairperson
2. The Hon. Robert Mbui, CBS, M.P
3. The Hon. Julius Lekakeny Ole Sunkuli, EGH, EBS M.P
4. The Hon. Anthony Oluoch, M.P.
5. The Hon. Mwirigi, John Paul, M.P
6. The Hon. Maj. (Rtd) Dekow Barrow Mohamed, M.P
7. The Hon. Omondi, Moses Okoth, M.P
8. The Hon. (Dr) Kimaiyo, Gideon Kipkoech, M.P
9. The Hon. Paul Chebor, M.P.
10. The Hon. Joseph Kamau Munyoro, M.P.
11. The Hon. (Dr.) Mamwacha Onchoke Charles, M.P
12. The Hon. Lenguris Pauline, M.P
13. The Hon. Laura Amina Mnyazi, M.P
14. The Hon. Yakub Adow Kuno, M.P.
15. The Hon. Innocent Mugabe, M.P.

APOLOGIES

1. The Hon. Robert Gichimu Githinji, M.P. - Vice-Chairperson
2. The Hon. Oduyo, Jared Okello, M.P
3. The Hon. Kameme Joyce, M.P
4. The Hon. Maj. (Rtd). Abdullahi Bashir Sheikh, M.P.
5. The Hon. Waithaka John Machua, M.P.
6. The Hon. Chepkorir, Linet, M.P

IN ATTENDANCE
SECRETARIAT

- | | | |
|-------------------------|---|----------------------|
| 1. Mr. Wilson Dima Dima | - | Deputy Director, DLS |
| 2. Mr. Brian Langwech | - | Clerk Assistant III |
| 3. Ms. Grace Odedere | - | Clerk Assistant III |
| 4. Mr. Peter Barasa | - | Legal Counsel II |
| 5. Ms. Fiona Wanjiru | - | Legal Counsel II |
| 6. Ms. Brendah Michira | - | Research Officer III |
| 7. Mr. Rodgers Kilungya | - | Hansard Officer II |
| 8. Mr. Noah Chemweno | - | Sergeant at Arms |

THE MINISTRY OF ROADS AND TRANSPORT

- | | | |
|-----------------------|---|----------------------------|
| 1. Mr. Davis Chirchir | - | Cabinet Secretary, MOR&T |
| 2. Eng Joseph Mbugua | - | Principal Secretary, Roads |

- | | | |
|-------------------------|---|-----------------------------|
| 3. Ms. Judith Otsuya | - | DG, KRB |
| 4. Eng. Silas Kinoti | - | DG, KURA |
| 5. Eng. Victor Odula | - | Deputy Director, P&R |
| 6. Mr. Alex Mbuvi | - | C.S.C., MOR&T |
| 7. Mr. Martin Agumbi | - | DFF, KRB |
| 8. Mr. Isaac m. Maina | - | D-UPR, KRB |
| 9. Ms. Catherine Kassim | - | Deputy Director, Legal, KRB |
| 10. Ms. Amira Malyne | - | Principal Legal, KRB |
| 11. Mr. Michael Labbot | - | PLO, SDOR |

MINISTRY OF EDUCATION / KENYA MEDICAL RESEARCH INSTITUTE

- | | | |
|------------------------------|---|-------------------|
| 1. Dr. Beatrice M Inyangala, | - | PS, MOE |
| 2. Dr. Abdullahi Ali | - | Chairman, KEMRI |
| 3. Prof. Elijah Songok | - | Ag. CEO, KEMRI |
| 4. Mr. Barnabas kimato | - | Chairperson, AIST |
| 5. Dr. Eunice marete | - | DCS-SQA, KEMRI |
| 6. Mr. Isaac Gathirwa | - | SACS, CUE |
| 7. Mr. Joseph Munyoki | - | SACS, CUE |
| 8. Dr. Martin Bundi | - | Ag. Dir, KEMRI |
| 9. Ms. Margaret Rigoro | - | Ag. CS, KEMRI |

AGENDA

1. Prayers
2. Preliminaries
3. Adoption of the Agenda
4. Confirmation of minutes
5. Matters arising
6. **Meeting with the Cabinet Secretary, Ministry of Roads and Transport regarding the Kenya Roads Board (Kenya Roads Board Fund)(Additional Funding) Regulations, 2025**
7. **Meeting with the Cabinet Secretary Ministry of Education regarding the Draft Kenya Medical Research Institute Charter, 2025.**
8. Any Other Business; and
9. Adjournment.

MIN. DAA&GPC/CDL/071/2026: PRELIMINARIES

The Chairperson called the meeting to order at 10.10 a.m., after which he said a word of prayer. He then welcomed all to the meeting followed by a round of introductions.

MIN. DAA&GPC/CDL/072/2026: ADOPTION OF THE AGENDA

The agenda of the meeting was adopted, having been proposed by the Hon. Joseph Kamau Munyoro, M.P, and seconded by the Hon. (Dr.) Mamwacha Onchoke Charles, M.P.

MIN. DAA&GPC/CDL/073/2026: CONFIRMATION OF MINUTES

The Minutes of the 12th Sitting held on Tuesday, 31st March, 2026 were confirmed as an accurate record of the proceedings having been proposed by the Hon. Joseph Kamau Munyoro, M.P. and seconded by the Hon (Dr.) Mamwacha Onchoke Charles M.P

MIN. DAA&GPC/CDL/073/2026: MATTERS ARISING

1. The Committee took note of the Tax Procedures (Unassembled Motor Vehicles and Trailers (No 2) (Amendment) Regulations, 2025 that was pending before the Committee awaiting its decision having been considered in the previous meeting under MIN. DAA&GPC/CDL/010/2026;
2. Having scrutinized the Tax Procedures (Unassembled Motor Vehicles and Trailers (No 2) (Amendment) Regulations, 2025 against the Constitution, the Statutory Instruments Act (*Cap. 2A*), section 112 of the Tax Procedure Act, 2015 and the Interpretation and General Provisions Act (*Cap. 2*), the Committee resolved to **approve and accede** to the *Legal Notice No. 170 Of 2025* having been proposed by the Hon. Omondi, Moses Okoth, M.P and seconded by the Hon. (Dr) Kimaiyo, Gideon Kipkoech, M.P.

MIN.DAA&GPC/CDL/074/2026: MEETING WITH THE CABINET SECRETARY, MINISTRY OF ROADS AND TRANSPORT REGARDING THE KENYA ROADS BOARD (KENYA ROADS BOARD FUND) (ADDITIONAL FUNDING) REGULATIONS, 2025

The Cabinet Secretary, Ministry of Roads and Transport, Mr. Davis Chirchir presented a brief overview of the Kenya Roads Board (Kenya Roads Board Fund)(Additional Funding) Regulations, 2025 and thereafter invited Mr. Alex Mbuvi to make a detailed presentation on the subject as follows;

1. **Part I** of the regulations provide for preliminary provisions which is the citation, interpretation of the various terminologies used in the text of the regulations, Object, purpose and the scope of these regulations.
2. **Part II** of the regulations provides for review programs by the Board and provisions on participation by road agencies.
3. **Part III** of the regulations provide for a proposal for additional funds. Under this part the regulations provide for apportion of the fund to be set aside, proposals for additional funding, contents for additional funding proposal and approval for additional funding proposal.
4. **Part VI** of the regulations provide for securing and disbursement additional funds. Under this part the regulations provide for provision on clearance by the National

Treasury and the Attorney General, Remittance of additional funds by advisor and disbursement.

5. **Part V** of the regulations provides for miscellaneous provisions. Under this part the regulations provide for a register of road agencies to which additional funds have been disbursed, compliance, books and records of account annual reports and transitional matters.
6. Upon deliberations, the Committee made the following observations:
 - i. The Regulations were published in the Kenya Gazette supplement no. 156 dated 16th September 2025, received by the Clerk of the National Assembly on the 24th September 2025 and tabled by the Leader of Majority on the 30th September 2025, a period which is within the statutory timelines contemplated under section 11(1) of the Statutory Instruments Act, Cap. 2A.
 - ii. The regulations were made pursuant to the provisions of section 32A (3) of The Kenya Roads Board Act, Cap. 408A, which is the enabling provision which empowers the Cabinet Secretary to make such regulations.
 - iii. Legal Notice 156 of 2025 is a statutory instrument and has the force of law within the meaning of section 2 of the Statutory Instruments Act, Cap 2A.
 - iv. The Legal Notice No.156 of 2025 is accompanied by a detailed Explanatory Memorandum as required under section 5A of the Statutory Instruments Act, Cap 2A.
 - v. There is attached evidence of consultation with stakeholders, as required under section 5 of the Statutory Instruments Act, Cap 2A.
 - vi. The regulatory impact statement has been attached as required by section 6 of the Statutory Instruments Act.
 - vii. The Committee also noted that the Regulations Making Authority had incorporated all the Comments raised by Members during Pre-Publication scrutiny engagement.
7. **In view of the findings above, the Committee resolved to Approve the Kenya Roads Board (Kenya Roads Board Fund)(Additional Funding) Regulations, 2025 (Legal Notice No. 156 of 2025) having been proposed by the Hon. Julius Lekakeny Ole Sunkuli, EGH, EBS M.P., and seconded by the Hon. (Dr.) Mamwacha Onchoke Charles, M.P**

**MIN.DAA&GPC/CDL/075/2026: MEETING WITH THE CABINET SECRETARY
MINISTRY OF EDUCATION REGARDING THE
DRAFT KENYA MEDICAL RESEARCH
INSTITUTE CHARTER, 2025**

The Principal Secretary, Ministry of Education, State Department for Higher Education, Ms Beatrice Muganda Inyangala appeared before the Committee and briefed it on the Draft Kenya Medical Research Institute Charter, 2026 as follows:

1. **PART I** provides for Short title and Interpretation.
2. **PART II** provides for Establishment of the Institute, Vision, Mission, Philosophy, Functions of the Institute, Admission of students to the Institute, Establishment of Regional offices, Conferment, granting, cancellation and withdrawal of specialized degrees and other awards, and Award of Scholarships.

3. **PART III** provides for Membership of the Institute, The Chancellor, The Chairperson of the Board, The Board, The Vice-Chancellor, The Research and Academic Board, Student's association, Alumni Association.
4. **PART IV** provides for The Management Board, The Directors of Directorates, The Heads of Regional Offices, and Staff of the Institute.
5. **PART V** provides for Research for human health, Research priorities and agenda, Initiation of research, Ethical considerations, Establishment of the Scientific and Ethics Review Unit, Membership to the Scientific and Ethics Review Unit committees, Code of conduct for members, Engagement in research, Research Data, Quality assurance in research, Management of research data, Data management, analysis and dissemination, and Monitoring and evaluation.
6. **PART VI** provides for Medical Services, Conduct of clinical trials, and Clinical trial research in public health emergencies.
7. **PART VII** provides for Responsibility of government in traditional and alternative medicine, Assessment of quality, efficacy, and safety, Capacity building for practitioners, Offences related to traditional medicinal products, and Management of traditional and alternative medicine knowledge.
8. **PART VIII** National Biosecurity and Bio surveillance platform, Biobanks, Designation of biobanks, Research data banks, Regulatory Sandbox, Establishment of research hospitals and clinics.
9. **PART IX** Rights to vest in the Institute, Withholding intellectual property information, Registration of intellectual property, Ownership of intellectual property, Commercialization of intellectual property, and Benefits.
10. **PART X** Financial year, Funds of the Institute, Investments of Funds, Annual estimates, Utilization of grants and donations, Unexpended monies, and Accounts and audit
11. **PART XI** Associations, collaborations or linkages, Instruments of governance, Statutes, Instruments of authority, Protection of name, Performance of functions in the absence of office holder, Convocation, Transition, and Variation and revocation.
12. Upon deliberations, the committee made the following observations;
 - i. There was need for the citation section to be properly drafted to provide the use of the word "may" instead of "shall".
 - ii. The Committee observed that there was need to properly define the term "Alumni" as it is improperly framed as a body rather than a person.
 - iii. The Committee observed that there was need to define the term "Convocation" in the interpretation section rather than than the clauses in the Charter.
 - iv. The Committee observed that the term "student" should be properly defined to align with the postgraduate focus of the institution.
 - v. The Committee observed that the term "Variable Pay" should be replaced with the term "additional pay" as having it within Charter, is unnecessary and not aligned with the core purpose of a university charter.

- vi. The Committee observed that there was need to align the Charter with the Universities Act, 2012, particularly regarding the composition of the governing body the Charter proposes twelve (12) members while the Act provides for nine (9) members.
- vii. The Committee observed there was wrong designation of appointing powers to the President instead of the Cabinet Secretary as provided in the Universities Act, 2012.
- viii. The Committee noted that the Charter lacks clear delegation provisions, regarding the development and approval of statutes, which should be subjected to Parliamentary oversight.
- ix. The Committee noted that there was incorrect and inconsistent clause referencing, on management structures (page 20).
- x. The Committee observed that Clause 2(d) lacks specificity and should be revised to provide clear and enforceable provisions.
- xi. The Committee noted that the Charter provides for the award of degrees, yet the Institute is intended to focus primarily on postgraduate specialized research training.
- xii. The Committee observed that the requirement of twelve (12) years' experience for the position of Corporation Secretary is restrictive and may limit eligible candidates.

1) In view of the findings above, the committee resolved to recommend that the House APPROVES the award of the Charter for the establishment of the Kenya Medical Research Institute in accordance with section 24(1) of the Public Universities Act, No. 42 of 2012 subject to correction of the above comments.

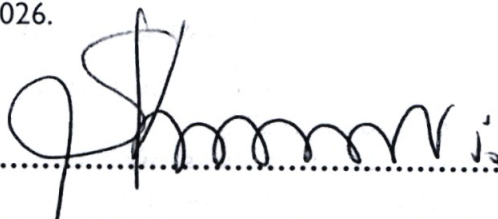
MIN. DAA&GPC/CDL/076/2026: ANY OTHER BUSINESS

There were no deliberations on this agenda item.

MIN. DAA&GPC/CDL/077/2026: ADJOURNMENT

The meeting was adjourned at twenty minutes to two o'clock. The next meeting will be held on Tuesday, 7th April 2026.

SIGNED:



**THE HON. SAMUEL CHEPKONG'A, CBS, M.P.
CHAIRPERSON, COMMITTEE ON DELEGATED LEGISLATION**

DATE:

7/04/2026



Commission for University Education

Office of the Chief Executive

REF: CUE/C/6/20 Vol .9 (20)

5th February 2026

Hon. Julius Migos Ogamba
Cabinet Secretary,
Ministry of Education, Science and Technology
Jogoo House "B"
Harambee Avenue
P.O. BOX 300400-00100
NAIROBI

Thro'

Dr. Beatrice Inyagala Muganda
The Principal Secretary
State Department of University Education
Ministry of Education, Science and Technology
Jogoo House "B"
Harambee Avenue
P.O. BOX 300400-00100
NAIROBI

Dear Hon. Ogamba

RE: CHARTER AND LETTER OF INTERIM AUTHORITY FOR UNIVERSITIES

The Commission for University Education is mandated by the Universities Act Cap 210 to evaluate universities in Kenya for accreditation. In this regard, the Commission in its 51st meeting of 3rd February 2026 approved a recommendation for award of Charter to **Kenya Medical Research Institute**, as a Specialized Degree Awarding Institution, pursuant to Section 24(1)(a) of the Act. In the same meeting, the Commission also approved a recommendation for grant of Letter of Interim Authority to the **African Talent University**, in Kisumu, pursuant to Section 14(1) of the Act. The recommendations were based on a comprehensive technical evaluation of the two institutions by the Commission on diverse dates between August and December 2025. Subsequent to the evaluations, the Commission was satisfied that the two institutions had respectively met minimum requirements for the accreditation status sought.

The purpose of this letter is therefore to convey the resolutions of the Commission to your esteemed office and to request you, upon your satisfaction, to grant a Letter of Interim Authority

Redhill Rd. off Limuru Rd., Gigiri P.O. Box 54999-00200, Nairobi, Kenya.

Tel: 254 (020) 7205000

E-mail: ceo@cue.or.ke/info@cue.or.ke, Website: <http://www.cue.or.ke>

to the African Talent University. We also request you to convey the recommendation for award of charter, to the Kenya Medical Research Institute, to Parliament and then to His Excellency the President for consideration.

Yours sincerely

A handwritten signature in black ink, appearing to be 'MK', enclosed within a circular scribble.

PROF. MIKE KURIA, PHD
COMMISSION SECRETARY/CEO

Mk/Jmm



REPUBLIC OF KENYA

OFFICE OF THE ATTORNEY GENERAL
&
DEPARTMENT OF JUSTICE

Our Ref: AG/LDD/674/2/ VOL. X

25th September, 2024

Dr. Deborah M. Barasa

Cabinet Secretary

Ministry of Health

P.O. Box 30016-00100

NAIROBI

**RE: ADVISORY ON KENYA MEDICAL RESEARCH INSTITUTE SPECIAL
DEGREE AWARDING STATUS**

This has reference to your letter dated 28th May, 2024, under Ref. MCH/MM/1/1/61 vol. 1 in which you requested this Office for an advisory on whether the Kenya Medical Research Institute shall remain domiciled in the Ministry of Health *or* awarded a Charter as a specialized degree-awarding or research institution *where* mandate shall be of strategic national importance.

As requested, we have reviewed the contents of the letter and the proposal to Charter the Institute in line with the Constitution, the Universities Act (Cap. 210), the State Corporations Act (Cap. 446), the Kenya Medical Research Institute Order, 2021 and all other relevant laws and our views are as follows:

The Law

The Kenya Medical Research Institute is a state corporation established by His Excellency the President under Legal Notice No. 35 of 2021 pursuant to the provisions of section 3(1) of the State Corporations Act (Cap. 446). The functions of the Institute are to—

- (a) conduct health, biomedical and public health research for human health;
- (b) build human health research capacity;
- (c) collaborate and partner with other local and international research bodies and institutions in carrying out human health research and capacity building;

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DEPARTMENT OF JUSTICE
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E-MAIL: legal@justice.go.ke WEBSITE: www.justice.go.ke

ISO 9001:2008 Certified



- (d) advice the responsible Ministry in matters pertaining to health research policies and priorities;
- (e) undertake scientific and technological innovation as well as in the discovery, transmission and enhancement of knowledge and stimulate the intellectual life in the economic, social, cultural, scientific, and technological development;
- (f) establish incubation centres for innovation, and link research, policymakers, academia and industry in the health products value chain; and
- (g) do all such things that are necessary or desirable to carry out its functions.

From the foregoing, we note that these are specialised functions related to health research, policies and priorities. Further, the Cabinet Secretary for Health administers the Institute under the Legal Notice.

The Kenya Medical Research Institute has applied for a Charter in accordance with the provisions of section 24(1)(a) of the Universities Act to be declared as a specialized degree-awarding or research institution whose mandate shall be of strategic national importance. The application is currently awaiting approval by the Cabinet and Parliament in accordance with section 24 of the Universities Act.

Section 24(1)(a) of the Universities Act provides that the President, on the recommendation of the Commission, through the Cabinet Secretary, and with the approval of Parliament, may award a Charter for specialized degree awarding or research institutions whose mandate shall be of strategic national importance.

An institution that wishes to be declared as an institution of strategic national importance under section 24(1)(a) of the Universities Act, shall apply to the Commission for University Education and submit information which includes governance structures and financial management systems. Under section 24(2) of the Universities Act, the Commission is required to prioritize the accreditation and development of the governing instruments of an institution that has applied for a Charter under section 24(1)(a) of the Act.

Section 24(4) of the Universities Act states that the provisions of Part V of the Universities Act on governance and management of universities shall apply with such necessary modifications as the Cabinet Secretary and the Commission may approve. Where the Commission is satisfied with the information submitted, it shall recommend the establishment of a specialized degree-awarding or research institution whose mandate shall be of strategic national importance to the Cabinet Secretary in accordance with the provisions of section 24 of the Universities Act. The Cabinet Secretary shall then submit the draft Charter to Parliament for its consideration. Where Parliament approves the establishment of a specialized degree-awarding or research institution whose mandate shall be of strategic national importance, the institution shall be awarded a Charter by His Excellency the President.

From the foregoing, the Cabinet Secretary for Education administers the Universities Act under which the Kenya Medical Research Institute is seeking to be awarded a Charter under section 24(1). This means that the Kenya Medical Research Institute shall be under the Ministry responsible for university education as pursuant to the provisions of the Universities Act, the establishment and regulation of specialized degree-awarding or research institutions whose mandate shall be of strategic national importance is the mandate of the Commission for University Education and the Ministry of Education.

Further, section 16 of the Science, Technology and Innovation Act (Cap. 511) provides for the establishment of research institutions. Section 16(2) of the Act states that research institutes set out in the Fourth Schedule and any other research institute established under any other law shall be deemed to be established under the section. The Kenya Medical Research Institute is listed under the Fourth Schedule of the Science, Technology and Innovation Act as a research institute under the National Commission for Science, Technology and Innovation.

Paragraph 3 of the Kenya Medical Research Institute Order, 2021, states that the Institute is established within the meaning of section 16(2) and 53 as read with the Fourth Schedule of the Science, Technology and Innovation Act.

The Executive Order No. 2 of 2023 has placed the National Commission for Science, Technology and Innovation under the State Department for Higher Education and Research in the Ministry of Education. On the other hand, the Kenya Medical Research Institute has been placed under the State Department for Medical Services in the Ministry of Health. This means that the Kenya Medical Research Institute is administered by both the Ministry of Education under the Science, Technology and Innovation Act and the Ministry of Health under the Kenya Medical Research Institute Order, 2021.


In our considered opinion, and in light of the specialised nature of the human health related research services offered by the Institute and the aforementioned legal framework regulating the Institute, we propose that there be incorporated a provision in the proposed Charter that the overall management of the proposed institution of strategic national importance shall be vested in the Ministry of Health in collaboration with the Ministry of Education. The proposed provision to be incorporated in the proposed Charter is similar to paragraph 3(4) of the National Defence University-Kenya Charter, 2021, which states that the overall management of the University shall be vested in the Ministry responsible for Defence in collaboration with the Ministry responsible for University Education. *(The Charter is attached for ease of reference).*

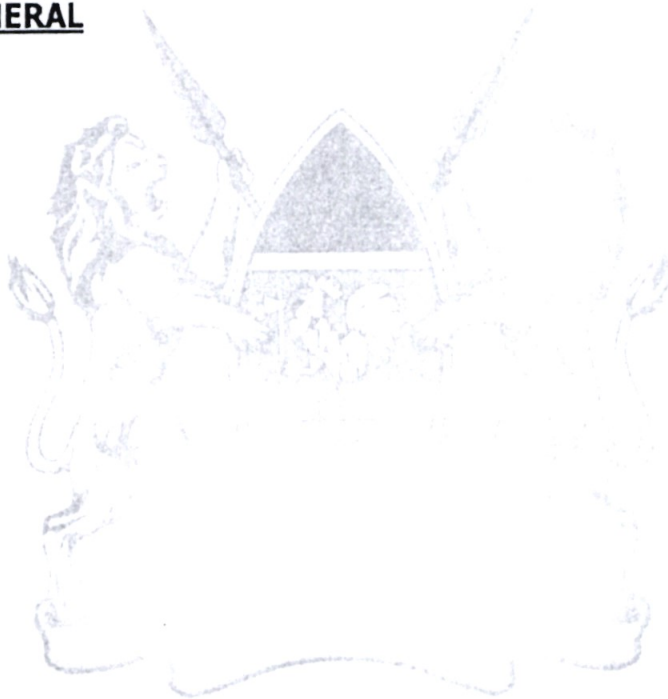
We note the National Defence University-Kenya is also established under section 24(3) of the Universities Act as a specialized degree awarding institution specializing in national security issues. The proposed provision to be incorporated in the proposed Charter shall therefore address issues related to the specialised nature of

the proposed institution *vis a viz* the legal framework related to establishment and operationalisation of specialized degree awarding institutions in Kenya.

Conclusion

From the foregoing, the Kenya Medical Research Institute shall, on award of the Charter as a specialized degree-awarding or research institution whose mandate shall be of strategic national importance, be under the Ministry of Education in accordance with section 24(1) of the Universities Act. However, we propose that there be incorporated a provision in the proposed Charter that the overall management of the proposed institution shall be vested in the Ministry of Health in collaboration with the Ministry of Education.


Dorcas A. Oduor, SC, OGW, EBS
ATTORNEY-GENERAL


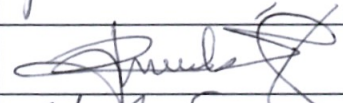
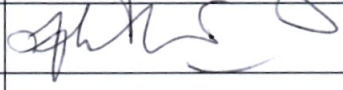



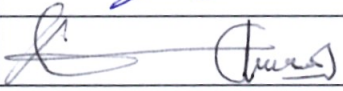

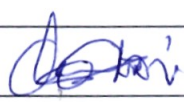



COMMITTEE ON DELEGATED LEGISLATION ADOPTION LIST

DATE: 22/04/2016 VENUE: BUNGEE TOWN STARTING TIME: 12:00 P.M.....

ENDING TIME:

AGENDA: CONSIDERATION OF THE KENYA INSTITUTE OF RESORT CHARTER

	NAME	SIGNATURE
1.	The Hon. Chepkong'a Kiprono Samuel, CBS, M.P, Chairperson	
2.	The Hon. Githinji, Robert Gichumi, M.P. Vice-Chairperson	
3.	The Hon. Mbui, Robert, CBS, M.P.	
4.	The Hon. Sunkuli Julius Lekakeny, EGH, EBS, MP	
5.	The Hon. Maj. (Rtd) Abdullahi Bashir Sheikh, M.P.	
6.	The Hon. Mwirigi, John Paul, M.P.	
7.	The Hon. Kamene, Joyce, M.P.	
8.	The Hon. Omondi, Moses Okoth M.P.	
9.	The Hon. Odoyo, Jared Okello, M.P.	
10.	The Hon. Anthony, Oluoch, M.P.	
11.	The Hon. Maj. (Rtd.) Dekow Barrow Mohamed, M.P.	
12.	The Hon. Munyoro, Joseph Kamau, M.P.	
13.	The Hon. (Dr.) Kimaiyo, Gideon Kipkoech, M.P.	
14.	The Hon. Waitaka, John Machua, M.P.	
15.	The Hon. Chepkorir, Linet, M.P.	
16.	The Hon. Chebor, Paul, M.P.	
17.	The Hon. Lenguris, Pauline, M.P.	
18.	The Hon. (Dr.) Mamwacha Onchoke Charles, M.P.	
19.	The Hon. Yakub, Adow Kuno, M.P.	
20.	The Hon. Mnyazi, Amina Laura, M.P.	
21.	The Hon. Mugabe, Innocent Maino, M.P.	