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NATIONAL ASSEMBLY

THIRTEENTH PARLIAMENT - FOURTH SESSION - 2025

DEPARTMENTAL COMMITTEE ON HEALTH

REPORT ON THE KENYA INSTITUTE OF PRIMATES RESEARCH BILL, 2024 (NATIONAL ASSEMBLY BILL NO. 52 OF 2024)



CLERK'S CHAMBERS DIRECTORATE OF DEPARTMENTAL COMMITTEES PARLIAMENT BUILDINGS NAIROBI

APRIL 2025

THE NATIONAL ASSEMBLY PAPERS LAID DAY. 20 APR 2025 DATE: 30.04.25 (hair Person, Health (em. Hon (Dr.) James Mikal MP (Du -TABLED BY: M. Modo CLERK-AT THE-TABLE:

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LIST OF ABBREVIATIONS AND ACRONYMS

- COG Council of Governors
- HQ Headquarters
- KEMRI Kenya Medical Research Institute
- KIPRE Kenya Institute of Primate Research
- KLRC Kenya Law Reform Commission
- KeNIA Kenya National Innovation Agency

MOALD - Ministry of Agriculture and Livestock Development

- MOH Ministry of Health
- $\mathbf{MP}-\mathbf{Member}$ of Parliament
- NACOSTI National Commission for Science, Technology and Innovation
- NGO Non-Governmental Organization
- $\mathbf{OAG}\ \mathbf{and}\ \mathbf{DOJ}$ Office of the Attorney General and Department of Justice
- **ODM** Orange Democratic Movement
- PhD Doctor of Philosophy
- UDA United Democratic Alliance

CHAIRPERSON'S FOREWORD

This report contains proceedings of the Departmental Committee on Health on its consideration of the Kenya Institute of Primate Research Bill, 2024 (National Assembly Bill No. 52 of 2024) which was published on 26th November 2024. The Bill was read the First Time in the House on Thursday, 5th December 2024, and thereafter committed to the Departmental Committee on Health for consideration and reporting to the House pursuant to the provisions of Standing Order 127.

The principal object of this Bill is to make provision for the establishment, powers, and functions of the Kenya Institute of Primate Research. The Bill also makes provision for the effective conduct of research using non-human primates and other experimental animals for the improvement of human health through innovative pre-clinical research, biomedical research, and translational research while conserving non-human primates for biodiversity.

Following the placement of an advertisement in the print media on Friday, 6th December, 2024 seeking public and stakeholder views on the Bill pursuant to Article 118(1) (b) of the Constitution and Standing Order 127(3), the Committee received submissions from three(3) stakeholders including; the Ministry of Health (MOH), State Department for Public Health and Professional Standards, the Ministry of Agriculture and Livestock Development (State Department for Livestock Development) and the Kenya Institute of Primate Research (KIPRE)

The Committee also engaged various stakeholders, including the Ministry of Health (MOH) – State Department for Public Health and Professional Standards; the Ministry of Agriculture and Livestock Development – State Department for Livestock Development; the Kenya National Innovation Agency (KeNIA); the International Livestock Research Institute (ILRI); the Kenya Medical Research Institute (KEMRI); the Office of the Attorney General and Department of Justice (OAG and DOJ); the Kenya Law Reform Commission (KLRC); and the Kenya Institute of Primate Research (KIPRE); to make submissions on the Bill. The meeting was held on Saturday, 12th April 2025, at the Hilton Garden Inn Hotel, Machakos County.

The Committee is grateful to the Offices of the Speaker and the Clerk of the National Assembly for the logistical and technical support accorded to it during its sittings. The Committee further wishes to thank all stakeholders who submitted memoranda on the Bill. Finally, I wish to express my appreciation to the Honourable Members of the Committee and the Committee Secretariat for their valuable contributions towards the consideration of the Bill and the production of this Report

On behalf of the Departmental Committee on Health and pursuant to the provisions of Standing Order 199 (6), it is my pleasant privilege and honour to present to this House the Report of the Committee on its consideration of the Kenya Institute of Primate Research Bill, 2024 (National Assembly Bill No. 52 of 2024).

It is my pleasure to report that the Committee has considered the Kenya Institute of Primate Research Bill, 2024 (National Assembly Bill No. 52 of 2024) and has the honour to report back to the National Assembly with the recommendation that the Bill be **approved with amendments as reported by the Committee**.

HON. DR. NYIKAL JAMES WAMBURA, MP. <u>CHAIRPERSON, DEPARTMENTAL COMMITTEE ON HEALTH</u>

CHAPTER ONE

1.0 PREFACE

1.1 ESTABLISHMENT AND MANDATE OF THE COMMITTEE

- 1. The Departmental Committee on Health is established pursuant to the provisions of Standing Order 216 of the National Assembly Standing Orders and in line with Article 124 of the Constitution which provides for the establishment of the Committees by Parliament. The mandate and functions of the Committee include:
 - a) To investigate, inquire into, and report on all matters relating to the mandate, management, activities, administration, operations and estimates of the assigned ministries and departments;
 - b) To study the programme and policy objectives of ministries and departments and the effectiveness of the implementation;

ba) on a quarterly basis, monitor and report on the implementation of the national budget in respect of its mandate;

- c) To study and review all legislation referred to it;
- d) To study, assess and analyse the relative success of the ministries and departments as measured by the results obtained as compared with their stated objectives;
- e) To investigate and inquire into all matters relating to the assigned ministries and departments as they may deem necessary, and as may be referred to them by the House;
- f) Vet and report on all appointments where the constitution or any other law requires the national Assembly to approve, except those understanding Order 204 (Committee on appointments);
- g) To examine treaties, agreements and conventions;
- *h)* To make reports and recommendations to the House as often as possible, including recommendation of proposed legislation;
- i) To consider reports of Commissions and Independent Offices submitted to the House pursuant to the provisions of Article 254 of the Constitution; and
- j) To examine any questions raised by Members on a matter within its mandate.
- 2. In accordance with the Second Schedule of the Standing Orders, the Committee is mandated to consider matters related to health, medical care and health insurance, including universal health coverage.
- 3. In executing its mandate, the Committee oversights the Ministry of Health with its two State Departments namely the State Department for Medical Services and the State Department for Public Health and Professional Standards.

1.2 COMMITTEE MEMBERSHIP

 The Departmental Committee on Health was constituted by the House on 27th October 2022 and comprises the following Members:

> Chairperson Hon. Dr. Nyikal James Wambura, MP Seme Constituency <u>ODM Party</u>

Vice-Chairperson Hon. Ntwiga, Patrick Munene MP Chuka/Igambang'ombe Constituency UDA Party

Hon. Owino Martin Peters, MP Ndhiwa Constituency **ODM Party**

Hon. Muge Cynthia Jepkosgei, MP Nandi (CWR) <u>UDA Party</u>

Hon. Wanyonyi Martin Pepela, MP Webuye East Constituency Ford Kenya Party

Hon. Kipngok Reuben Kiborek , MP Mogotio Constituency <u>UDA Party</u>

Hon. (Dr.) Robert Pukose, MP Endebes Constituency <u>UDA Party</u>

Hon. Kibagendi Antoney, MP Kitutu Chache South Constituency **ODM Party**

Hon. Julius Ole Sunkuli Lekakeny, MP Kilgoris Constituency KANU Hon. Maingi Mary, MP Mwea Constituency <u>UDA Party</u>

Hon. Mathenge Duncan Maina, MP Nyeri Town Constituency **UDA Party**

Hon. Lenguris Pauline, MP Samburu (CWR) <u>UDA Party</u>

Hon. Oron Joshua Odongo, MP Kisumu Central Constituency **ODM Party**

Hon. (Prof.) Jaldesa GuyoWaqo, MP Moyale Constituency <u>UPIA Party</u>

Hon. Mukhwana Titus Khamala, MP Lurambi Constituency <u>ODM Party</u>

1.3 COMMITTEE SECRETARIAT

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5. The Committee is supported by the following secretariat:

Mr. Hassan Abdullahi Arale Clerk Assistant I/Head of Secretariat

> Timothy Kimathi Samson Clerk Assistant III

Ms. Gladys Jepkoech Kiprotich Clerk Assistant III

Ms. Marlene Ayiro Principal Legal Counsel I

Ms. Faith Chepkemoi Legal Counsel II

Ms. Rahab Chepkilim Audio Recording Officer II

Mr. Hiram Kimuhu Fiscal Analyst III

Mr. Eric Lungai Hansard Officer II Mr. Hillary Mageka Media Relations Officer

Ms. Abigael Muinde Research Officer III

Ms. Sheila Chebotibin Principal Serjeant-At-Arms II

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CHAPTER TWO

2.0 THE KENYA INSTITUTE OF PRIMATES RESEARCH BILL, 2024 (NATIONAL ASSEMBLY BILL NO. 52 OF 2024)

- 6. The Kenya Institute of Primate Research Bill, 2024 (National Assembly Bill No. 52 of 2024) was published on 26th November 2024. The Bill is sponsored by the Departmental Committee on Health in the National Assembly.
- 7. The principal object of this Bill is to make provision for the establishment, powers, and functions of the Kenya Institute of Primate Research. The Bill also makes provision for the effective conduct of research using non-human primates and other experimental animals for the improvement of human health through innovative pre-clinical research, biomedical research, and translational research while conserving non-human primates for biodiversity.
- 8. The Kenya Institute of Primate Research (as currently established vide a Legal Order pursuant to sections 16 and 17 of the Science, Technology and Innovation Act, (Cap. 511) needs to be properly anchored in an Act of Parliament so as to ensure efficiency and effectiveness in the performance of its functions.

2.1 OVERVIEW OF THE BILL

- 9. **Part I (clause 1 to 4)** provides for preliminary matters including the short title, the objects of the Act, and guiding principles in relation to the implementation of the law, which include scientific integrity, ethics and professional standards, quality animal care, and openness and accountability. It further provides various definitions, such as biomedical research and primatology, among others. Under clause 3, the objects of the law are to: establish KIPRE as a national centre undertaking biomedical and preclinical research using primates for the development of health products and services that comply with local and international standards to improve human health, improve human health and biodiversity through biomedical research and non-human primate conservation, ensure the protection of animal species and their habitats from extinction and establish a training centre for biomedical research, preclinical and clinical research using non-human primates and other experimental animals
- 10. **Part II (clause 5 to 22)** provides for the establishment of the Kenya Institute of Primate Research as a body corporate, its functions, powers; the composition, term of office, functions and qualifications of the Board of Directors of the Institute. It further provides for the appointment of a Director-General and the staff of the Institute.
- 11. **Part III (clause 23-31)** provides for the conduct of research by the Institute in relation to the considerations to be taken into account by the Institute which include respect for the care and welfare of animals and non-human primates. The Part also sets out the type of research to be undertaken using non-human primates and other experimental animals among others. This includes basic research, biomedical research, pre-clinical research and translational research. The KIPRE Board is further given power to establish research infrastructure,

biobanks for the collection, storage and management of biologicals used in pre-clinical research and a centralized research data bank.

- 12. PART IV (clause 32-37) makes provision for the certification of animal care and use of programs or facilities for experimental animals and experimental animal facilities including how applications for certifications are to be made. The Institute is also required to maintain a register of the certified animal care and use programs and facilities for experimental animals. The KIPRE Board is further given power to undertake periodic audits of the processes and systems of the managers of animal care and use programs and facilities for experimental animals.
- 13. **PART V (clause 38-39)** provides for capacity building by the Institute through the conduct of biomedical and pre-clinical research, providing training in the areas set out in the Second Schedule to the Act and providing scientific and technical advice on the care and use of experimental animals. The training centre of the Institute shall further provide specialized short course training programmes.
- 14. Part VI (clause 40-45) provides for the management of intellectual property over innovations and inventions on health products made by the Institute. Under this Part, the rights to an invention or innovation made by the Institute shall vest in the Institute unless there is an agreement to the contrary. The Part also enables the Institute to own and commercialize intellectual property as well as to handle the benefits arising from the intellectual property owned by the Institute.
- 15. Part VII (clause 46-51) provides the sources of funds of the Institute which includes the monies appropriated by the National Assembly, the modalities on investments made by the Institute, annual reporting by the Institute and handling of the accounts of the Institute including the audit of its finances.
- 16. **Part VIII (clause 52)** provides for the delegation of power to the Cabinet Secretary for health, in consultation with the Board of Directors of KIPRE, to make regulations for the better carrying into effect of the provisions of the Act.
- 17. Part IX (clause 53-60) provides for the general provisions such as the power to engage experts, maintenance of confidentiality in the performance of the functions of the Institute, disclosure of information by the Institute and protection of personal data in the conduct of research. The Part also sets out offences that may be committed in relation to the functions of KIPRE as well as the general penalty of a fine of Kshs. 5 million or imprisonment for five years for offences where no penalty is expressly provided for. The Part further places an obligation on KIPRE to cooperate with National Commission for Science Technology and Innovation (NACOSTI) in the conduct of research related to non-human primates and other experimental animals and in the review and approval of research proposals.
- 18. Part X (clause 61-73) provides transition provisions where KIPRE is being transitioned from the Kenya Institute of Primate Research Order, 2017 to the new legal framework under the Bill. The Part makes provision for the transition of the staff and Board Members and existing agreements, contracts and other binding instruments, assets and liabilities, directions, orders and such related authorizations or documents, annual estimates and legal

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proceedings from the former Institute to the Institute under the Bill. The staff of the former Institute shall be deemed as the employees of the Institute under the Bill on the same terms and conditions. The Part also makes provision for the revocation of the Kenya Institute of Primate Research Order, 2017 in light of the enactment of the Bill.

CHAPTER THREE

3.0 CONSIDERATION OF THE BILL BY THE COMMITTEE

3.1 LEGAL PROVISION ON PUBLIC PARTICIPATION

19. Article 118 (1) (b) of the Constitution of Kenya provides as follows—

"Parliament shall facilitate public participation and involvement in the legislative and other business of Parliament and its Committees."

20. Standing Order 127(3) provides that-

"The Departmental Committee to which a Bill is committed shall facilitate public participation on the Bill through an appropriate mechanism, including—

- (a) inviting submission of memoranda;
- (b) holding public hearings;
- (c) consulting relevant stakeholders in a sector; and
- (d) consulting experts on technical subjects.
- 21. Standing Order127(3A) further provides that-

"The Departmental Committee shall take into account the views and recommendations of the public under paragraph (3) in its report to the House."

3.2 PUBLIC PARTICIPATION IN THE REVIEW OF THE BILL

- 22. The Kenya Institute of Primate Research Bill, 2024, sponsored by the Departmental Committee on Health, was published on 26th November 2024. Pursuant to Standing Order 127(1), the Bill was referred to the Departmental Committee on Health, having been read the First Time in the House on Thursday, 5th December 2024.
- 23. Pursuant to the aforementioned provisions of the Constitution and the Standing Orders on public participation, the Committee, through local daily newspapers (Nation and Standard) of Friday, 6th December 2024, published an advertisement inviting the public to submit memoranda on the Bill.
- 24. The Committee also sought comments on the Bill from relevant stakeholders, namely the Ministry of Health, the Office of the Attorney General and Department of Justice, the Ministry of Agriculture and Livestock Development, the Kenya Institute of Primate Research, and the Kenya Law Reform Commission, vide letter dated 13th December 2024.
- 25. Further, vide a letter dated 7th April 2025, the Committee invited the following institutions to submit memoranda on the Bill: the Ministry of Health (State Department for Public Health and Professional Standards); Amref Health Africa; the Kenya Law Reform Commission (KLRC); the Kenya National Innovation Agency (KeNIA); the International Livestock

Research Institute (ILRI); the Kenya Medical Research Institute (KEMRI); the Council of Governors (COG); the National Commission for Science, Technology and Innovation (NACOSTI): the Kenya Biovax Institute Limited; and the Ministry of Agriculture and Livestock Development (State Department for Livestock Development). The Committee thereafter convened a stakeholder meeting with these institutions on Saturday, 12th April 2025, at the Hilton Garden Inn Hotel, Machakos County where the Ministry of Health (MOH) – State Department for Public Health and Professional Standards; the Ministry of Agriculture and Livestock Development – State Department for Livestock Development; the Kenya National Innovation Agency (KeNIA); the International Livestock Research Institute (ILRI); the Kenya Medical Research Institute (KEMRI); the Office of the Attorney General and Department of Justice (OAG and DOJ); the Kenya Law Reform Commission (KLRC); and the Kenya Institute of Primate Research (KIPRE) attended and made their submissions on the Bill.

3.3 SUBMISSIONS ON THE BILL

- 26. The Committee received submissions through oral presentations and written memoranda from the following institutions:
 - a) The Ministry of Health (MOH), State Department for Public Health and Professional Standards;
 - b) The Kenya Law Reform Commission (KLRC);
 - c) The Kenya Medical Research Institute (KEMRI);
 - d) The Ministry of Agriculture and Livestock Development, State Department for Livestock Development;
 - e) The Kenya Veterinary Board;
 - f) The Kenya Institute of Primate Research (KIPRE); and
 - g) The Office of the Attorney General and Department of Justice (OAG and DOJ);

27. The Ministry of Agriculture and Livestock Development, State Department for Livestock Development submitted as follows:

a) In Clause 2, any biologicals used in animals comprise veterinary medicine and should assume the same meaning as provided in the Veterinary Surgeons and Para-Professionals Act.

Committee Resolution: Not adopted. The definition is broad and does not distinguish between human and veterinary medicine.

b) In Clause 2, the Cabinet Secretary should be "the Cabinet Secretary responsible for matters primate research.

Committee Resolution: Not adopted. Research by KIPRE is intended for human health.

c) In Clause 3(a), replace the word "primates" with "non-human primates".

Committee Resolution: Adopted with amendments. The clause redrafted to align with KIPRE's functions of conducting research using non-human primates and other experimental animals.

d) In Clause 3(c), redraft clause 3(c) to provide "ensure the protection of non-human primates and other experimental animals used in research and their habitats from extinction".

Committee Resolution: Adopted with amendments. The clause redrafted to align with KIPRE's functions of conducting research using non-human primates and other experimental animals.

e) In Clause 7(p), expunge clause 7(p) and cross-reference the Veterinary Surgeons and Veterinary Para-professionals Act.

Committee Resolution: Adopted. Clause 7(p) was deleted, and the function aligned with the Veterinary Surgeons and Veterinary Para-professionals Act.

f) In Clause 9(1), include the Chief Executive Officer of the Kenya Veterinary Board in the KIPRE Board.

Committee Resolution: Adopted with amendments. The Principal Secretary responsible for veterinary services or a representative designated in writing was included in the Board.

g) In Clause 23(3), amend clause 23(3) to state that "the Institute shall use the Code of Conduct approved by the Kenya Veterinary Board on invasive research on animals."

Committee Resolution: Adopted. To align with the provisions of the Veterinary Surgeons and Veterinary Para-professionals Act.

h) In Clause 26(1), amend clause 26(1) to provide for the role of safe use of medicines in animals.

Committee Resolution: Not adopted. The clause was retained as it relates to human application, not animal health.

i) In Clause 27, insert a new paragraph (k) mandating the Institute to report notifiable diseases to the veterinary authorities.

Committee Resolution: Adopted. To enhance surveillance and control in the management of diseases in the country by the Ministries responsible for health and veterinary services.

j) In Part IV, review Part IV to delineate certification roles by the veterinary experts in line with the veterinary oath and administrative roles by the Institute.

Committee Resolution: Adopted. Certification responsibilities were reassigned to the Kenya Veterinary Board.

28. The Kenya Medical Research Institute (KEMRI) submitted as follows:

a) In Clause 2, the term "bio banks" to be defined to mean specialized institutions or repository that collect, store and manage biological materials.

Committee Resolution: Not adopted. The terms proposed for definition are used in their ordinary sense.

b) In Clause 2, since the Institute will derive materials from animals as specimens, there is need to define "biospecimens" to mean any material derived from a human or animal body for research, diagnostic or therapeutic purposes including blood, tissue, urine, saliva and genetic material.

Committee Resolution: Not adopted. The terms proposed for definition are used in their ordinary sense.

c) In Clause 2, the definition of "incubation centre" seems incomplete/inadequate and should be redefined to mean "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."

Committee Resolution: Not adopted. The terms proposed for definition are used in their ordinary sense.

- d) In Clause 2, qualify the use of the word "health" to mean "human health". **Committee Resolution:** Not adopted. The terms proposed for definition are used in their ordinary sense.
- e) In Clause 2, "traditional and alternative" medicines has been identified as a research area and needs to adopt the definition in the Health Act.

Committee Resolution: Not adopted. The terms proposed for definition are used in their ordinary sense.

f) In Clause 3(c), clause 3(c) is a good object but it may require elucidation.

Committee Resolution: The Committee took note of the observation.

g) In Clause 7(1), insert a clause mandating collaboration between KIPRE and KEMRI and propose a clause that reflects partnership with KEMRI to show the complementary functions of the two government institutions.

Committee Resolution: Not adopted. One of the powers of the Board is to enter into partnerships and collaborations with other relevant government agencies, including KEMRI.

h) In Clause 7(1), combine and harmonize paragraph (b) and (h). The aspect of "zoonotic diseases" appears hanging in paragraph (h).

Committee Resolution: Adopted with amendments. The functions were redrafted to limit KIPRE to the conduct of research using non-human primates and other experimental animals and not to conflict with KEMRI's functions.

i) In Clause 7(1), combine and harmonize paragraph (c), (g) and (h).

Committee Resolution: Adopted with amendments. The functions were redrafted to limit KIPRE to the conduct of research using non-human primates and other experimental animals and not to conflict with KEMRI's functions.

j) In Clause 7(1), review paragraph (h) and locate elsewhere.

Committee Resolution: Adopted with amendments. The functions were redrafted to limit KIPRE to the conduct of research using non-human primates and other experimental animals and not to conflict with KEMRI's functions.

k) In Clause 7(1), justification for the designation as the national centre in paragraph (i) may need to be provided.

Committee Resolution: Adopted with amendments. The functions were redrafted to limit KIPRE to the conduct of research using non-human primates and other experimental animals and not to conflict with KEMRI's functions.

l) In Clause 7(1), locate paragraph (k) in the appropriate section as it is a specification of a research area of interest.

Committee Resolution: Adopted with amendments. The functions were redrafted to limit KIPRE to the conduct of research using non-human primates and other experimental animals and not to conflict with KEMRI's functions.

m) In Clause 9(1), include the Director General of KEMRI in the KIPRE Board of Directors.

Committee Resolution: Not adopted. The KIPRE Board has the appropriate skill mix. The Principal Secretary for Health is already included in the Board. The Principal Secretary responsible for veterinary services or a representative designated in writing was included in the Board.

n) In Clause 9(1), include the representative of the Attorney-General.

Committee Resolution: Not adopted. The KIPRE Board has the appropriate skill mix.

o) In Clause 9(1), include the Director General of Kenya Wildlife Services.

Committee Resolution: Not adopted. The KIPRE Board has the appropriate skill mix.

p) In Clause 23, explicitly define what constitutes a "public health emergency" and align with relevant national legislation; define or reference it in line with the Public Health Act.

Committee Resolution: Not adopted. The provision is aligned with the provisions of the Public Health Act, the primary term public health emergencies. This law adequately deals with issues of data sharing and collaboration between government agencies during public health emergencies.

q) In Clause 23, specify the Institute's role in collaborating with public health agencies in emergency response.

Committee Resolution: Not adopted. The provision is aligned with the provisions of the Public Health Act, the primary term public health emergencies. This law adequately deals with issues of data sharing and collaboration between government agencies during public health emergencies.

r) In Clause 26(1), amend Clause 26(1), to state that for the purpose of evaluating the efficacy of products, dosage and safety "in non-human primates, before use in humans."

Committee Resolution: Not adopted. The clause provides the limitation to non-human primate studies.

s) In Clause 26(1), the partnership with KEMRI be recognized as this will support the transition of products for human use.

Committee Resolution: Not adopted. One of the powers of the Board is to enter into partnerships and collaborations with other relevant government agencies including KEMRI. The Bill is premised on the use of non-human primates by KIPRE.

t) In Clause 31(3), broaden clause 31(3) to include all entities that would legitimately require access, including the Scientists, Collaborators and others.

Committee Resolution: Not adopted. The Bill already makes provision for access to information held by the Institute and includes safeguards on the protection and security of data.

u) In Clause 31(3), amend the Bill to specify adherence to international and national data security standards, such as ISO/IEC 27001.

Committee Resolution: Not adopted. The Bill already makes provision for access to information held by the Institute and includes safeguards on the protection and security of data.

 v) In Clause 31(3), redefine the conditions under which the Board may access data to include specific purposes, such as oversight, compliance reviews, or other explicitly defined reasons.

Committee Resolution: Not adopted. The Bill already makes provision for access to information held by the Institute and includes safeguards on the protection and security of data.

w) In Clause 31(3), include provisions for data integrity and backup by adding clauses that mandate regular data integrity checks and backup procedures to prevent data loss and ensure the reliability of the stored data.

Committee Resolution: Not adopted. The Bill already makes provision for access to information held by the Institute and includes safeguards on the protection and security of data.

x) In Clause 31(3), regulatory bodies might include health and safety regulators, data protection authorities, and other government agencies that require access to oversee compliance with legal and ethical standards.

Committee Resolution: Not adopted. The Bill already makes provision for access to information held by the Institute and includes safeguards on the protection and security of data.

y) In Clause 31(3), authorized personnel can include data managers, IT support staff, and other personnel who need access to manage, maintain, and protect the data infrastructure.

Committee Resolution: Not adopted. The Bill already makes provision for access to information held by the Institute and includes safeguards on the protection and security of data.

29. The Kenya Veterinary Board submitted as follows:

a) In Clause 7(1)(p), all matters relating to ethical and professional matters, including the protection of animal health and welfare, should be left to the Kenya Veterinary Board.

Committee Resolution: Adopted. The function of certification of programs and facilities for the care and use of experimental animals was deleted.

b) In Clause 9(1), include the Registrar of the Kenya Veterinary Board in the KIPRE Board.

Committee Resolution: Adopted with amendments. The Principal Secretary responsible for veterinary services or a representative designated in writing was included in the KIPRE Board.

c) In Clause 28(2)(a), replace "veterinary doctor" with "registered veterinary surgeon".

Committee Resolution: Adopted. For alignment with the terminology used in the Veterinary Surgeons and Veterinary Para-professionals Act.

d) In Clause 28(2)(g), replace "veterinarian" with "registered veterinary surgeon".

Committee Resolution: Adopted. For alignment with the terminology used in the Veterinary Surgeons and Veterinary Para-professionals Act.

e) In Part IV, all matters relating to the ethical and professional matters including the protection of animal health and welfare should be left to the Kenya Veterinary Board.

Committee Resolution: Adopted. The function of certification of programs and facilities for the care and use of experimental animals was deleted.

30. The Kenya Law Reform Commission (KLRC) submitted as follows:

a) In Clause 2, in the definition of "Nairobi Metropolitan Area", delete "of" after comprising.

Committee Resolution: Not adopted. The clause is in order as drafted.

b) In Clause 3, redraft as follows- 'The Object of this Act is to-

(a)establish the Kenya Institute of Primate Research; (b) provide for a mechanism for the improvement of human health and biodiversity;

(c) provide for the protection of animal species and their habitat from extinction; and

(d) provide for the establishment of a training center."

Committee Resolution: Adopted with amendments. The clause was redrafted to align with KIPRE's functions of conducting research using non-human primates and other experimental animals.

c) In Clause 7(q), delete the phrase "by any other written law or as necessary for the promotion of the objects of the Act".

Committee Resolution: Not adopted. The clause is in order as drafted in line with the House Drafting Style.

- d) In Clause 9(2), the number 1 should be in bracket (1). **Committee Resolution:** Adopted. The correction was made to Clause 9(2).
- e) In Clause 12, delete the word "physical" appearing in paragraph (a).

Committee Resolution: Not adopted. The clause was retained in line with the Mwongozo Code for Governance of State Corporations.

f) In Clause 17, delete the word "physical" appearing in Clause 17(1)(a).

Committee Resolution: Not adopted. The clause was retained in line with the Mwongozo Code for Governance of State Corporations.

g) In Clause 18, align with the provisions of the Certified Public Secretaries of Kenya Act, Cap. 534.

Committee Resolution: Adopted. The clause was amended accordingly.

h) In Clause 28, specify the term of service of the Scientific and Ethics Review Unit.

Committee Resolution: Adopted. The term of the members appointed to serve in the Scientific and Ethics Review Unit of the Institute was clarified.

i) In Clause 39(1), Clause 39(1) should first establish the training centre before assigning any functions since this is one of the objects of the Bill under clause 3.

Committee Resolution: Adopted. The clause was amended to legally anchor and establish the training centre of the Institute.

j) In Part X, the Part should start by revoking the Kenya Institute of Primate Research Order, 2017. Use the word "revocation" instead of "repeal" in the title of the Part.

Committee Resolution: Adopted. The Part was amended to use the correct terminology.

- 31. The Office of the Attorney General and the Department of Justice (OAG and DOJ) submitted as follows:
 - a) The Bill be amended in order to merge KIPRE and KEMRI and simultaneously revoke both the Kenya Institute of Primate Research Order, 2017, and the Kenya Medical Research Institute Order, 2021. The Office has sought the policy guidance of the Ministry of Health, which is responsible for the policy contained

in the Bill, and shall share that guidance and its legal opinion thereon, as and when it is provided.

Committee Resolution: Noted. The Committee took note of the submission and the recommendation by Cabinet on the merger during its deliberation.

32. Ministry of Health (State Department for Public Health and Professional Standards) submitted as follows:

- a) Supported the Bill in its entirety.
- b) Highlighted that the Bill is necessary to anchor KIPRE in law so as to enhance its legislative and operational functions. KIPRE has existed under a Legal Notice and was brought under the docket of the MOH through the Executive Order of 2023. KIPRE has achieved numerous successes, particularly in relation to snakebite disease and anti-venom.

Committee Resolution: The Committee acknowledged the support of the Ministry and took note of its justification for anchoring KIPRE in statute.

33. Kenya Institute of Primate Research (KIPRE) submitted as follows:

- a) In support of the Bill in its entirety.
- b) KIPRE to operate as a stand-alone Semi-Autonomous Government Agency (SAGA) to enable seamless research and development with the focus on the production of drugs/vaccines, including snakebite antivenom, and become selfsustaining in the next 5–10 years.

Committee Resolution: The Committee took note of the general comments in its deliberations on the Bill.

3.4 GENERAL COMMENTS ON THE BILL BY STAKEHOLDERS

34. The Kenya Medical Research Institute (KEMRI) submitted as follows:

a) KEMRI recognized the critical role of KIPRE in preclinical research involving non-human primates, its designation as a WHO Collaborating Centre, and its notable contribution to neglected tropical disease research, such as the launch of snakebite antivenom in January 2024. However, KEMRI cautioned that establishing KIPRE as a stand-alone State Corporation could fragment Kenya's health research ecosystem. KEMRI proposed a strategic integration framework that would align both institutions and optimize resource utilization while maintaining KIPRE's focus on non-human primate research.

Committee Resolution: Noted. The Committee acknowledged KEMRI's concerns and recognized the complementarity of the mandates between the two institutions but resolved to proceed with the legislative anchoring of KIPRE as a statutory body.

35. The Ministry of Agriculture and Livestock Development submitted as follows:

a) The Ministry emphasized that the Bill should confine its scope to research involving non-human primates and experimental animals only. It further proposed that all regulatory roles currently performed by the Ministry through the Kenya Veterinary Board and the Veterinary Medicines Directorate be excluded from the Bill. The Ministry recommended that ethical and professional interventions involving animal health and welfare be managed by registered veterinary professionals in accordance with the Veterinary Surgeons and Veterinary Para-professionals Act.

Committee Resolution: Noted. The Committee adopted several proposals from the Ministry, including deletion of regulatory functions from KIPRE and reassignment to the Kenya Veterinary Board.

36. Kenya Veterinary Board submitted as follows:

a) The Board supported the Ministry of Agriculture and Livestock Development's position and reiterated that all matters relating to the care, certification, and welfare of experimental animals should be handled exclusively by the Kenya Veterinary Board.

Committee Resolution: Noted. The Committee adopted the proposal and transferred the functions of certification of animal care and use programs and facilities to the Kenya Veterinary Board.

CHAPTER FOUR

4.0 COMMITTEE OBSERVATIONS

- 37. The Committee, having considered the Kenya Institute of Primate Research Bill (National Assembly Bill No. 52 of 2024) and submissions from stakeholders, made the following observations:
- a. The Kenya Institute of Primate Research (KIPRE; formerly the Institute of Primate Research-IPR is a biomedical pre-clinical research facility which has existed since 1958. KIPRE ethically utilizes non-human primates and other experimental animals for research resulting in the production and commercialization of vaccines, drugs, medical interventions, and services for reproductive health, infectious diseases, and non-communicable diseases to improve human health;
- b. KIPRE's strong research capacity and compliance with international standards have earned it multiple recognitions and international accreditation, and designation as a WHO Collaborating Centre;
- c. The Bill seeks to transition the Kenya Institute of Primate Research (KIPRE) from its current status as a legal entity established under Legal Notice No. 273 of 2017 to a fully-fledged statutory body through an Act of Parliament. Doing this will enhance its institutional autonomy, accountability, and operational capacity;
- d. The Bill incorporates ethical, scientific, and institutional provisions that align Kenya's nonhuman primate research framework with international best practices by promoting adherence to animal welfare and conservation principles;
- e. The Bill places strategic emphasis on advancing Kenya's public health priorities through biomedical research. It provides for the development of essential health products such as vaccines, antivenoms, and diagnostics. Additionally, the Bill contains robust provisions for the protection, registration, and commercialization of intellectual property, thereby encouraging innovation while safeguarding public interest and incentivizing inventors;
- f. The establishment of a dedicated training centre to provide specialized short course training programmes based on the training needs of the country including on biomedical research, primatology, biodiversity, and disease ecology, will enhance Kenya's scientific capacity and ensure sustainability in the field of biomedical research;
- g. The Bill recognizes the ecological importance of non-human primates and includes provisions for conservation and sustainable utilization of biodiversity. This aligns with Article 69 of the Constitution and the Wildlife Conservation and Management Act, Cap. 376;

CHAPTER FIVE

5.0 COMMITTEE RECOMMENDATION

38. The Committee recommends that the National Assembly consider and **approve** the Kenya Institute of Primate Research Bill, 2024 (National Assembly Bill No. 52 of 2024) with the following amendments:

CLAUSE 2

THAT, Clause 2 of the Bill be amended by inserting the following new definition in the proper alphabetical sequence—

"notifiable disease" has the meaning assigned to it under section 2 of the Animal Diseases Act;

Cap. 364.

Justification: To adopt the definition of the term "notifiable disease" as defined in the Animal Diseases Act, Cap. 364 in light of the fact that the Kenya Institute of Primate Research is to be obligated to report notifiable diseases that it identifies in the course of the conduct of research using non-human primates and other experimental animals.

CLAUSE 3

THAT, Clause 3 of the Bill be amended —

- (a) in paragraph (a) by deleting the words " primates for the development of health products and services that comply with local and international standards to improve human health" and substituting therefor the words "non-human primates and other experimental animals";
- (b) in paragraph (c) by deleting the words "animal species" and substituting therefor the words "non-human primates and other experimental animals used in research"; and

Justification: To specify that the Kenya Institute of Primate Research conducts research using non-human primates and other experimental animals.

(c) by inserting the following new paragraph immediately after paragraph (d)—

"(e) provide a mechanism for the development and testing of health products and services".

Justification: To buttress that the Bill is intended to provide a mechanism for the development and testing of health products and services towards the improvement of human health.

CLAUSE 7

THAT, Clause 7 of the Bill be amended in subclause (1) by-

 (a) by deleting the words "and translational research, as may be appropriate using nonhuman primates and, in collaboration with other relevant government agencies" appearing in paragraph (a) and substituting therefor the words "biomedical and translational research using non-human primates and";

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Justification: To include the conduct of biomedical research and to specify that the research conducted by the Institute is limited to the use of non-human primates and other experimental animals

(b) deleting paragraph (p).

Justification: To allow the Kenya Veterinary Board to be responsible for the certification animal care and use programs and facilities for experimental animals in accordance with the provisions of the Veterinary Surgeons and Veterinary Para-professionals Act, Cap. 366.

CLAUSE 9

THAT, Clause 9 of the Bill be amended in sub-clause (1) by-

(a) inserting the following new paragraph immediately after paragraph (c)—

"(ca) the Principal Secretary in the Ministry responsible for matters relating to veterinary services or a representative designated in writing";

(b) deleting the word "six" appearing in paragraph (d) and substituting therefor the word "five".

Justification: To make provision for the representation of the Ministry responsible for veterinary services which is entity responsible for the regulation of animal care and use in the country.

CLAUSE 18

THAT, Clause 18 of the Bill be amended in sub-clause (2) by-

- (a) inserting the words " or any other relevant field" immediately after the word "law" appearing in paragraph (b); and
- (b) deleting paragraph (c).

Justification: To align with the provisions of the Certified Public Secretaries of Kenya Act, Cap. 534.

CLAUSE 23

THAT, Clause 23 of the Bill be amended in sub-clause (3) by inserting the words "and other experimental animals in accordance with the Veterinary Surgeons and Veterinary Paraprofessionals Act and the Prevention of Cruelty to Animals Act" immediately after the words "non-human primates".

Justification: To ensure that the code of conduct for research to be used by the Institute shall comply with the provisions of the Veterinary Surgeons and Veterinary Para-professionals Act, Cap. 366 and the Prevention of Cruelty to Animals Act, Cap. 360.

CLAUSE 27

THAT, Clause 27 of the Bill be amended by inserting the following new paragraph immediately after paragraph (j)—

"(k) the reporting of notifiable diseases to the Cabinet Secretary and the Ministry responsible for veterinary services".

Justification: To enhance surveillance and control in the management of diseases in the country by the Ministries responsible for health and veterinary services.

CLAUSE 28

THAT, Clause 28 of the Bill be amended —

- (a) in sub-clause (2) by—
 - (i) deleting the words "veterinary doctor" appearing in paragraph (a) and substituting therefor the words "registered veterinary surgeon";
 - (ii) deleting paragraph (g) and substituting therefor the following new paragraph (g)—

"(g) a registered veterinary surgeon, not serving at the Institute, from the Division of Veterinary Services at the Ministry responsible for matters relating to veterinary services"; and

Justification: For alignment with the terminology used in the Veterinary Surgeons and Veterinary Para-professionals Act, Cap. 366.

(b) by inserting the following new sub-clauses immediately after sub-clause (3)—

"(4)The members appointed under subsection (2)(a), (d),(e),(f) and (g) shall serve for a term of three years and shall be eligible for re-appointment for one further term of three years.

(5) The members appointed under subsection (2)(b) and (c) shall serve by virtue of their position at the Institute unless removed from the position by the Board."

Justification: To clarify the term of the members appointed to serve in the Scientific and Ethics Review Unit of the Institute.

CLAUSE 32

THAT, the Bill be amended by deleting Clause 32.

Justification: To allow the Kenya Veterinary Board to be responsible for the certification animal care and use programs and facilities for experimental animals in accordance with the provisions of the Veterinary Surgeons and Veterinary Para-professionals Act, Cap. 366.

CLAUSE 33

THAT, the Bill be amended by deleting Clause 33

Justification: To allow the Kenya Veterinary Board to be responsible for the certification animal care and use programs and facilities for experimental animals in accordance with the provisions of the Veterinary Surgeons and Veterinary Para-professionals Act, Cap. 366.

CLAUSE 34

THAT, the Bill be amended by deleting Clause 34.

Justification: To allow the Kenya Veterinary Board to be responsible for the certification animal care and use programs and facilities for experimental animals in accordance with the provisions of the Veterinary Surgeons and Veterinary Para-professionals Act, Cap. 366.

CLAUSE 35

THAT, the Bill be amended by deleting Clause 35.

Justification: To allow the Kenya Veterinary Board to be responsible for the certification animal care and use programs and facilities for experimental animals in accordance with the provisions of the Veterinary Surgeons and Veterinary Para-professionals Act, Cap. 366.

CLAUSE 36 THAT, the Bill be amended by deleting Clause 36.

Justification: To allow the Kenya Veterinary Board to be responsible for the certification animal care and use programs and facilities for experimental animals in accordance with the provisions of the Veterinary Surgeons and Veterinary Para-professionals Act, Cap. 366.

CLAUSE 37

THAT, the Bill be amended by deleting Clause 37.

Justification: To allow the Kenya Veterinary Board to be responsible for the certification animal care and use programs and facilities for experimental animals in accordance with the provisions of the Veterinary Surgeons and Veterinary Para-professionals Act, Cap. 366.

CLAUSE 39

THAT, Clause 39 of the Bill be amended in sub-clause (1) by deleting the words "The training centre of the Institute" and substituting therefor the words "There is established a training centre of the Institute which".

Justification: To legally anchor and establish the training centre of the Institute as contemplated under Clause 3 of the Bill.

SIGNED..... 4 Č

DATE 2914/2025

HON. DR. JAMES NYIKAL WAMBURA, M.P. CHAIRPERSON, DEPARTMENTAL COMMITTEE ON HEALTH

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ANNEXURE 1:MINUTES OF COMMITTEE SITTINGS

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THE NATIONAL ASSEMBLY

13TH PARLIAMENT – FOURTH SESSION (2025)

DIRECTORATE OF DEPARTMENTAL COMMITTEES

DEPARTMENTAL COMMITTEE ON HEALTH

REPORT ON THE CONSIDERATION OF THE KENYA INSTITUTE OF PRIMATES RESEARCH BILL, 2024 (NATIONAL ASSEMBLY BILL NO. 52 OF 2024)

We, the undersigned Members of the Departmental Committee on Health do hereby append our signatures to adopt this Report Date: 28442025

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