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29/4/25

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	
DATE: 30 APR 2025	
DAY: 30-04-25	
TABLED BY:	Chair Person, Health Com- Hon (Dr) James Nyika MP
CLERK-AT THE-TABLE:	M. Mado

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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

MP – Member of Parliament

NACOSTI – National Commission for Science, Technology and Innovation

NGO – Non-Governmental Organization

OAG and 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.
CHAIRPERSON, DEPARTMENTAL COMMITTEE ON HEALTH

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 oversees 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

- 4 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
ODM Party

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)
UDA Party

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

Hon Kipngok Reuben Kiborek , MP
Mogotio Constituency
UDA Party

Hon (Dr) Robert Pukose, MP
Endebes Constituency
UDA Party

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
UDA Party

Hon Mathenge Duncan Maina, MP
Nyeri Town Constituency
UDA Party

Hon Lenguris Pauline, MP
Samburu (CWR)
UDA Party

Hon Oron Joshua Odongo, MP
Kisumu Central Constituency
ODM Party

Hon (Prof) Jaldesa GuyoWaqo, MP
Moyale Constituency
UPIA Party

Hon Mukhwana Titus Khamala, MP
Luiambi Constituency
ODM Party

1.3 COMMITTEE SECRETARIAT

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 Chepkemai
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. Abigail Muinde
Research Officer III

Ms. Sheila Chebotibin
Principal Serjeant-At-Arms II

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 to ensure compliance with the law.
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

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 Order 127(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 self-sustaining 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 2021) 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 non-human 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—

Cap.
364.
“notifiable disease” has the meaning assigned to it under section 2 of the Animal Diseases Act;

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 non-human 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”;

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 Para-professionals 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.

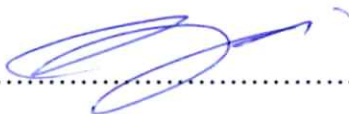
Justification: To allow the Kenya Veterinary Board to be responsible for the certification animal care and use programs and facilities for experimental animals in accordance with the provisions of the Veterinary Surgeons and Veterinary Para-professionals Act, Cap. 366.

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.....



DATE.....

29/4/2025

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

ANNEXURE 1:MINUTES OF COMMITTEE SITTINGS

ANNEXURE 2: REPORT ADOPTION SCHEDULE

MIN. NO. NA/DC-H/2025/271: CONSIDERATION AND ADOPTION OF THE REPORT ON THE KENYA INSTITUTE OF PRIMATES RESEARCH BILL, 2024(NATIONAL ASSEMBLY BILL NO. 52 OF 2024)

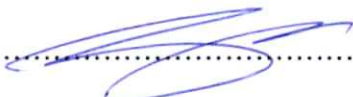
The report on the Kenya Institute of Primate Research Bill, 2024 (National Assembly Bill No. 52 of 2024) was adopted by the committee, having been proposed by the Hon. Dr. Robert Pukose, MP, and seconded by the Hon. Julius Sunkuli Lekakeny Ole, EGH, EBS, MP as the true record of the Committee proceedings.

MIN. NO. NA/DC-H/2025/272: ANY OTHER BUSINESS

There were no matters arising.

MIN. NO. NA/DC-H/2025/273: ADJOURNMENT

There being no other business, the meeting was adjourned at thirty minutes past one o'clock. The next meeting will be held by notice.

Sign.......... Date.....29/4/2025.....

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

 THE NATIONAL ASSEMBLY PAPERS LAID	
DATE: 29 APR 2025	
DAY: 	
TABLED BY:	
CLERK-AT THE-TABLE:	

Members Concerns

1. On why Out of the 20 million members registered, only 4 Million registered members are paying yet 9 million migrated from NHIF. The Ag. CEO Mr. Lenaiyara clarified that many of the 9 million NHIF members were dormant or non-contributing, and some NHIF members had defaulted, stopped paying, or only paid occasionally common among informal sector members. He further indicated that many of the 20 million are newly registered but have not yet started paying, especially informal workers who are difficult to enroll in regular contributions.
2. On whether the critical ICU is sh. 28,000 per day on selected facilities or across all the facilities; the CEO indicated that the Ksh 28,000 / day tariff for ICU (and HDU) under the Emergency, Chronic and Critical Illness Fund is not limited to a selected hospitals it is a uniform rate paid to all empanelled SHA facilities.
3. On the digitalization of health facilities; the CEO informed the meeting that, they are currently rolling out digitalization across public health facilities and the aim is to ensure that hospitals can manage claims and patient records electronically under the new Social Health Authority (SHA) system, he further indicated that they are also providing training to the health facility staff and users and the training will continue until staff can competently use the new digital systems for registration, service delivery, and claims processing.
4. On claim processing, the CEO informed the meeting that claim processing under the SHA system is fully automated for most services, except that surgical cases still require manual review before payment is approved. This means that for outpatient, inpatient (non-surgical), maternity, and other routine services, claims are automatically processed through the digital system once the service is entered and verified and for surgical procedures, additional manual checks and approvals are needed likely due to the complexity and higher cost of surgical claims, requiring extra validation to avoid fraud or errors.
5. The committee recommended that the agency obtain detailed records directly from the National Social Protection Registry maintained by the Ministry of Labour and Social Protection for all indigent groups fully subsidized by the SHA, including: Orphans, Elderly individuals without caregivers, and Street families.
6. In cybersecurity, the Committee was informed on the Health Cloud solutions, which are highly secure cloud platforms designed to protect healthcare information with strong encryption, compliance, monitoring, and disaster recovery features built in.

MIN. NO. NA/DC-H/2025/270: CONSIDERATION AND ADOPTION OF THE REPORT ON THE MATERNAL, NEWBORN AND CHILD HEALTH BILL, 2023 (SENATE BILL NO. 17 OF 2023)

The report on Maternal, Newborn and Child Health Bill, 2023 (Senate Bill No. 17 of 2023) was adopted by the committee, having been proposed by the Hon. Oron Joshua Odongo, MP, and seconded by the Hon. Prof. Jaldesa Guyo Waqo, MP as the true record of the Committee proceedings.

- c. Manipulation of the means testing system resulting in inaccurate premiums which could threaten the sustainability of the fund. The agency has developed an improved big data driven means testing system that is more accurate to support SHA in its roll out
- d. Payment reconciliation – Payment reconciliation using RTGS channel of payment due to users submitting mismatch PRNs (Payment Reference Number) and receiving payments delaying the provision of services

MIN. NO. NA/DC-H/2025/268: THE SYSTEM EFFECTIVENESS IN REGISTERING MEMBERS AND MANAGING CLAIMS.

These system is effective in registration and managing claims. The System runs on advanced high tech big data & AI driven technology to provide service. The system uses several integrated systems to effectively register members and manage claims, eliminating possibility of collision and fraud: Some of the systems benefits so far are:

- a. Ease of Registration – SHA members are now able to register from the comfort of their home, office or place of comfort. Reducing need for Kenyans to walk for long distance to register as members of SHA. An average of 50,000 Kenyans registers every day.
- b. Identity Verification –All members are now verified with the National Registration Bureau (NRB), eliminating fraud. 3M fake records were removed from the system by this system
- c. Automated pre-authorization approval – The system has reduced waiting time at facility for Kenyans from initial 3 days to Minutes
- d. Efficient Claims Processing – The system has automated most claim processing and reduced manual verification. This has improved efficiency at SHA, making it possible for SHA to make claims payments monthly
- e. Improved visibility and enhancing transparency: This system has enabled real-time tracking of claims status by the facility, enhancing transparency
- f. Elimination of Fraud –The system is integrated to many other systems to support it in Fraud detection e, g. Using KMPDC data, the system only allows licensed facilities & Health Workers to provide services as per their license, eliminating fraud that was with NHIF.

MIN. NO. NA/DC-H/2025/269: SIGNIFICANT ACCOMPLISHMENTS REALIZED THROUGH THE DEPLOYMENT OF THE DIGITAL HEALTH SYSTEM.

There has been significant accomplishment realized through deployment of the digital health system as below:

- a. A total of 21,755,721 Members have registered through the digital system with an average of 50,000 members registering everyday
- b. Automated Pre-Authorization & Claims verification -improving provision of services. 2.435 Million Claims worth 48.55B has been processed through the system
- c. 6,000 devices have been distributed across the country to support digitalization and claims in public facilities
- d. Digitalization of Public facilities ongoing in 6 counties .8 more counties to start next week.
- e. 24/7 Taifa care center call center established. With less than 20 seconds waiting time
- f. The Health Information Exchange has been completed, providing centralized services through unique identification registries
- g. Continued training and support of health workers on digitalization

The Digital System is an enabler of the other three pillars of the Universal Health Coverage. It is a combination of 38 Systems & Hardware that support the delivery of Universal Health Coverage. All this system is integrated and support each other in delivery.

The implementation of the Digital Health System has been phased into two key phases namely:

1. Phase 1: Focusing on the Health Financing Pillar and supporting the Social Health Authority operations
2. Phase 2: Focusing on Public Facility digitalization, Human Resource for Health and Health Products and Technologies Pillars

The agency has made great progress in supporting the roll-out of the Social Health Authority, including SHA registration, SHIF Contribution System, and Claims Systems.

a) SHA registration

The Registration Systems are complete and integrated to the National Registration Bureau with multiple channels:

- i. **Self-registration** – Afya yangu portal to support all online registrations
- ii. **Short Mobile Codes *147#** - To support registration of all Kenyans without smart phones but with Simple USSD phone.
- iii. **Community Health Promoters & SHA branch offices Assisted Registration System-** To support the registration of Kenyans without Phones or internet in the villages
- iv. **Smart Afyangu App** –The Afya yangu app is now available in android and will soon be available in apple store to support registration
- v. **The Agency also supported in:** Migrated of 9M NHIF Members that had clean records to SHA Members Database and Integration of SHA registration system to NEMIS school's database to support addition of dependents

b) SHIF Contribution System

The SHIF contribution system are complete as below:

- i. **SHA Means Testing System** – Gives the ability for SHA members to calculate the annual contribution for self-employed/ unemployed Kenyans
- ii. **SHA Employer Portal-** Gives ability to employers to declare employees and make returns to SHA
- iii. **Payment's contribution Options** – There are multiple contribution Channels such as M-Pesa, RTGS, online banking, and OTC.
- c) **Claims Systems** –These systems manage healthcare benefits and ensure efficiency and transparency in claims management and processing. The systems are integrated with multiple other systems, such as the health workers' registry (For identification of Health workers), the Facility registry (for identification of facilities, the Terminology system, and Shared Health Records, among others

Some of the Challenges faced during the implementation of the systems include:

- a. **System Stability issues** –In the initial stage of implementation, the Systems had some downtime. The agency has improved the stability of the system with very minimal downtime now.
- b. **OTP delays** -The OTP delays were caused by network availability in some areas as well as initial system capacity. The agency has improved the system capacity and has worked with internet providers to optimize connectivity network. The availability for OTP has improved and now stands at 99.67%

AGENDA

1. Prayers;
2. Adoption of the Agenda;
3. Confirmation of Minutes of the previous meetings;
4. Matters Arising;
5. **The Operational Dynamics of the Digital Health System, including any Challenges encountered in its Implementation and Daily Use.**
6. **The System's effectiveness in Registering Members and Managing Claims**
7. **Significant accomplishments realized through the Deployment of the Digital Health System.**
8. **Consideration and adoption of the Report on Maternal, Newborn And Child Health Bill, 2023 (Senate Bill No. 17 Of 2023)**
9. **Consideration and adoption of the Report on The Kenya Institute of Primates Research Bill, 2024(National Assembly Bill No. 52 Of 2024)**
10. Any other business; and;
11. Adjournment/Date of the Next Meeting.

MIN. NO. NA/DC-H/2025/263: PRELIMINARIES/INTRODUCTION

The meeting was called to order at ten minutes past ten o'clock, followed by the Prayer and self-introductions.

MIN. NO. NA/DC-H/2025/264: ADOPTION OF AGENDA

The agenda of the meeting was adopted, having been proposed by Hon. Prof. Guyo Jaldesa Peters, MP, and seconded by Hon. Sunkuli Julius Lekakeny Ole, EGH, EBS, MP

MIN. NO. NA/DC-H/2025/265:CONFIRMATION OF MINUTES OF THE PREVIOUS MEETINGS

MIN. NO. NA/DC-H/2025/266: MATTERS ARISING

There were no matters arising.

MIN. NO. NA/DC-H/2025/267:THE OPERATIONAL DYNAMICS OF THE DIGITAL HEALTH SYSTEM, INCLUDING ANY CHALLENGES ENCOUNTERED IN ITS IMPLEMENTATION AND DAILY USE.

The Digital Health System (The Digital Health Superhighway/Integrated Health Information Management System) is one of the Pillars of the Universal Health Coverage as below:

- i. Health Financing (Commonly known as SHA)
- ii. Health Products and Technologies
- iii. Human Resource for Health
- iv. Integrated Health Information Management Ecosystem



MINUTES OF THE 34th SITTING OF THE DEPARTMENTAL COMMITTEE ON HEALTH HELD IN SOCIAL HEALTH AUTHORITY (SHA) BUILDING 10TH FLOOR WITH THE DIGITAL HEALTH AGENCY ON MONDAY, 28TH APRIL 2025, AT 9:40 AM

PRESENT

- | | |
|---|-----------------|
| 1. The Hon. Dr. Nyikal James Wambura, MP | -Chairperson |
| 2. The Hon. Ntwiga Patrick Munene, MP | - Vice Chairman |
| 3. The Hon. Dr. Pukose Robert, MP | -Member |
| 4. The Hon. Sunkuli Julius Lekakeny Ole, EGH, EBS, MP | -Member |
| 5. The Hon. Prof. Jaldesa Guyo Waqo, MP | -Member |
| 6. The Hon. Owino Martin Peters, MP | -Member |
| 7. The Hon. Oron Joshua Odongo, MP | -Member |
| 8. The Hon. Mary Maingi, MP | -Member |
| 9. The Hon Wanyonyi Martin Pepela, MP | -Member |
| 10. The Hon. Cynthia Muge, MP | -Member |

ABSENT WITH APOLOGY

- | | |
|--|----------|
| 1. The Hon. Kipngor Reuben Kiborek, MP | -Member |
| 2. The Hon Kibagendi Antoney, MP | -Member |
| 3. The Hon. Titus Khamala, MP | -Member |
| 4. The Hon. Lenguris Pauline, MP | -Member |
| 5. The Hon. Mathenge Duncan Maina, MP | - Member |

COMMITTEE SECRETARIAT

- | | |
|-------------------------|----------------------|
| 1. Mr. Hassan A. Arale | -Clerk Assistant I |
| 2. Ms. Gladys Kiprotich | -Clerk Assistant III |
| 3. Ms. Faith Chepkemoi | -Legal Counsel |

IN ATTENDANCE-DIGITAL HEALTH AGENCY (ATTACHED)

- | | |
|--------------------------|------------------------------------|
| 1. Mr. Anthony Lenaiyara | -Ag. Chief Executive Officer |
| 2. Mr. Silas Simatwo | -DHA chairman |
| 3. Mr. George Karori | -DHA board members |
| 4. Mr. Pius Cheruiyot | -DHA board members |
| 5. Dr. Greory Ganda | -Director DHA |
| 6. Mr. William Baraza | -Director DHA |
| 7. Mr. Edith Torotich | - DHA |
| 8. Dr. Joyce Wamicwe | -Digital Health & Informatics Lead |



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: 28/4/2025

NO	NAME	SIGNATURE
1.	The Hon. Dr. Nyikal James Wambura, M.P-Chairperson	
2.	The Hon. Ntwiga Patrick Munene, M.P -Vice-Chairperson.	
3.	The Hon. Dr. Pukose Robert, CBS, M.P	
4.	The Hon. Titus Khamala, M.P	
5.	The Hon. Sunkuli Julius Lekakeny Ole, EGH, EBS, M.P.	
6.	The Hon. Prof. Jaldesa Guyo Waqo, M.P.	
7.	The Hon. Owino Martin Peters, M.P.	
8.	The Hon. Wanyonyi Martin Pepela, M.P	
9.	The Hon. Lenguris Pauline, M.P	
10.	The Hon. Mary Maingi, MP	
11.	The Hon. Muge Cynthia Jepkosgei, M.P	
12.	The Hon. Oron Joshua Odongo, M.P.	
13.	The Hon. Kibagendi Antony, M.P.	
14.	The Hon. Mathenge Duncan Maina, M.P	
15.	The Hon. Kipngor Reuben Kiborek, M.P	

ANNEXURE 3: ANALYSIS OF SUBMISSIONS BY STAKEHOLDERS ON THE BILL

**MATRIX ON STAKEHOLDER VIEWS ON THE KENYA INSTITUTE OF PRIMATE RESEARCH BILL, 2024
(NATIONAL ASSEMBLY BILL NO. 52 OF 2024)**

	CLAUSE	STAKEHOLDER	PROPOSED AMENDMENT/ COMMENT	RATIONALE	COMMITTEE RESOLUTION
1	Clause 2	Kenya Law Reform Commission (KLRC)	In the definition of "Nairobi Metropolitan Area", delete "of" after comprising.	Comprise means "consist of", use of "of" after comprise is an unnecessary repetition.	Noted. The clause is in order as drafted.
		Ministry of Agriculture and Livestock Development (State Department for Livestock Development)	(a) In relation to the definition of biologicals, any biologicals used in animals comprise veterinary medicine and should assume the same meaning as provided in the Veterinary Surgeons and Veterinary Para-professionals Act. (b) The Cabinet Secretary should be "the Cabinet Secretary responsible for matters primate research".	No contradictions should be allowed in law since all medicines used on animals are already defined. Each regime should be able to appropriately assign primate research to the relevant Ministry based on focus and effective service delivery.	Not Adopted. The definition is broad and has not distinguished between human and veterinary medicine. Not Adopted. Research by KIPRE is intended for human health.
		Kenya Medical Research Institute (KEMRI)	(a) The term "bio banks" to be defined to mean specialized institutions or repository that collect, store and manage biological materials. (b) 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. (c) The definition of "incubation centre" seems incomplete/inadequate and		Not Adopted. The terms proposed for definition are used in their ordinary sense.

			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. (d) Qualify the use of the word “health” to mean “human health”. (e) “Traditional and alternative” medicines has been identified as a research area and needs to adopt the definition in the Health Act.		
2	Clause 3	KLRC	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.”	The paragraphs are too verbose. The details should form part of the functions of the Institute.	Adopted with amendments. The clause redrafted to align with KIPRE’s functions of conducting research using non-human primates and other experimental animals.

		Ministry of Agriculture and Livestock Development	(a) Replace the word “primates” with “non-human primates” in clause 3(a). (b) 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”.	For consistency as the long title of the Bill uses non-human primates for research. The clause is overly broad and ambiguous for a specialized research institution. Animal species encompass both wild and domestic, across terrestrial, aquatic and aerial ecosystems, and their protection already falls under agencies such as the Kenya Wildlife Service and the State Department for Livestock Development.	
		KEMRI	Clause 3(c) is a good object but it may require elucidation.	There are other institutions that may have this object as their mandate, e.g. Kenya Wildlife Services and Wildlife Research and Training Institute.	
3	Clause 7	KLRC	In Clause 7(q), delete the phrase “by any other written law or as necessary for the promotion of the objects of the Act”.	The use of the phrase is unnecessary repetitive. The Interpretation and General Provisions Act, Cap 2., defines the word “prescribed” as prescribed by the Act in which the word occurs or by subsidiary legislation made thereunder. The use of the words “by any other written law or as necessary for the promotion of the objects of the Act” are	Not Adopted. The clause is in order as drafted in line with the House Drafting Style.

				therefore unnecessary additions.	
		Kenya Veterinary Board	In relation to clause 7(1)(p), 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.	Under the Veterinary Surgeons and Veterinary Professionals Act and the attendant Regulations, the Kenya Veterinary Board is responsible for the licensing of veterinary laboratories and for guaranteeing animal welfare through registration, licensing and regulation of institutions.	Adopted. The function of certification of programs and facilities for the care and use of experimental animals deleted.
		Ministry of Agriculture and Livestock Development	Expunge clause 7(p) and cross reference the Veterinary Surgeons and Veterinary Professionals Act.	Approval and certification of programs and facilities for the care and use of experimental animals for purposes of animal welfare. This is a function of the Kenya Veterinary Board under the Veterinary Surgeons and Veterinary Professionals Act which is responsible for guaranteeing animal welfare through registration, licensing and regulation of institutions.	
		KEMRI	Insert a clause mandating collaboration between KIPRE and KEMRI and propose a clause that reflects partnership with KEMRI to show the complimentary functions of the two government institutions.	The Bill's delineation of KIPRE's mandate in biomedical research, conservation biology and preclinical studies among non-human primates compliments KEMRI's	Not Adopted. One of the powers of the Board is to enter into partnerships and collaborations with other relevant government agencies including KEMRI.

		In clause 7(1): (a) Combine and harmonize paragraph (b) and (h) (b) The aspect of “zoonotic diseases” appears hanging in paragraph (h). (c) Combine and harmonize paragraph (c), (g) and (h). (d) Review paragraph (h) and locate elsewhere. (e) Justification for the designation as the national centre in paragraph (i) may need to be provided. (f) Locate paragraph (k) in the appropriate section as it is a specification of a research area of interest. There is significant overlap in the functions of the institute and those of KEMRI, for example: (a) Paragraph (a) is an elaboration of KEMRI’s function of conducting research for human health (b) Paragraph (b) overlaps with KEMRI’s function in relation to undertaking scientific and technological invention and innovation for human health and service delivery and establishment of incubation centres for invention, innovation and product development for health (c) Paragraph (f), be specific to non-human primates to reflect the differences with KEMRI (d) Paragraph (g) and (h) fits in with KEMRI’s function on establishment	work and mandate among humans. Paragraph (b) and (h) have a similar focus e.g. biodiversity conservation vis-a-vis conservation status and ecosystem health vis-a-vis ecology, population estimates, habitats, spatial distribution, genomic analysis etc, which inform ecosystem health. Systems for research for human health mentioned in paragraph (h). Paragraph (c) and (g) speak to the same function and are part of infrastructure. Quantify if paragraph (i) is exclusive of other institutions. KEMRI also conducts research on snake venom.	Adopted with Amendments. The functions redrafted to limit KIPRE to the conduct of research using non-human primates and other experimental animals and not o conflict with KEMRI’s functions.
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			and maintenance infrastructure and systems for research for human health and the characterization of non-human primates and other experimental animal models both at the population and genomic level constitute infrastructure and systems to support research for human health.		
4	Clause 9	KLRC	(a) In clause 9(1), delete the use of "of" after comprising. (b) In clause 9(2), the number 1 should be in bracket (1).	Comprise means "consist of", the use of "of" after comprise is an unnecessary repetition.	Noted. The clause is in order as drafted. Adopted. The correction made to clause 9(2).
		Kenya Veterinary Board	In clause 9(1), include the Registrar of the Kenya Veterinary Board in the KIPRE Board.	The Kenya Veterinary Board regulates all areas of veterinary practice. The KIPRE Board will oversee the development of standards of the Scientific and Ethics Review Unit which has to be in line with the Kenya Veterinary Board and the Veterinary Surgeons and Veterinary Professionals Guidelines.	Adopted with Amendments. The Principal Secretary responsible for veterinary services or a representative designated in writing included in the KIPRE Board.
		Ministry of Agriculture and Livestock Development	In clause 9(1), include the Chief Executive Officer of the Kenya Veterinary Board in the KIPRE Board.	The Chief Executive Officer of the Kenya Veterinary Board shall support the ethical issues concerning animal health and welfare interventions. The KIPRE Board does not have representation from the livestock sector even though it undertakes research on animals where veterinary	

				expertise is mandatory for any invasive or therapeutic procedures on animals.	
		KEMRI	(a) Include the Director General of KEMRI in the KIPRE Board of Directors. (b) Include the representative of the Attorney-General. (c) Include the Director General of Kenya Wildlife Services. (d) The proposed management Board provides robust oversight but lacks mechanisms to align its activities with broader health research goals.	While the clause indicates six additional members two of whom shall be expertise in biomedical research this is not sufficient on representation.	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 included in the KIPRE Board.
5	Clause 10	KLRC	The Public Service Commission should be mandated to advertise for the positions under paragraph 9(a)(d) and forward the names to the respective appointing authority for appointment.	Under Article 232(1)(g) of the Constitution, fair competition and fair are the basis of appointments and promotions; Article 234 (2)(f) mandates PSC to develop human resources in the public service.	Not Adopted. The appointments of the members of the KIPRE Board to be done in line with Mwongozo Code for Governance of State Corporations.
		Ministry of Agriculture and Livestock Development	Restrict the requirement of clause 10(1)(a) to the persons appointed under clause 10(1)(d). The Chairperson can have post-graduate degree.	The requirements of clause 10(1)(a) will not hold for the position of a Chairperson appointed by the President. Presidential appointees may not necessarily require that level of qualification.	Not Adopted. To professionalize the KIPRE Board since it is highly specialized research entity.
		KEMRI	Re-consider the level of qualification and simply indicate Postgraduate Degree.	While the clause specifies PhD as the chair, this is a position where the Cabinet Secretary has rights on appointment is limiting.	

6	Clause 11	KEMRI	Most statutes work with three (3) years not four (4), but if its allowable, then it can be left as is.		Noted. The term limits are in line with the prevailing KIPRE Legal Notice.
7	Clause 12	KLRC	In clause 12, delete the word "physical" appearing in paragraph (a).	The use of the word physical discriminates against persons with disability contrary to Article 27(4) and (5) of the Constitution.	Not Adopted. The appointments of the members of the KIPRE Board to be done in line with Mwongozo Code for Governance of State Corporations.
8	Clause 16	KLRC	The functions of the Director-General under clause 16(6) should come immediately after the qualifications for appointment.	For purposes of orderliness in the legislation.	Not Adopted. The clause is in order as drafted in line with the House Drafting Style.
9	Clause 17	KLRC	Delete the word "physical" appearing in Clause 17(1)(a).	The use of the word physical discriminates against persons with disability contrary to Article 27(4) and (5) of the Constitution.	Not Adopted. The appointments of the members of the KIPRE Board to be done in line with Mwongozo Code for Governance of State Corporations.
10	Clause 18	KLRC	Align with the provisions of the Certified Public Secretaries of Kenya Act, Cap. 534.	The qualifications under clause 18(2) does not align with the qualifications under section 20 of the CPS Act for appointment as a CPS.	Adopted. To align with the provisions of the Certified Public Secretaries of Kenya Act, Cap. 534.
11	Clause 23	Ministry of Agriculture and Livestock Development	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.	Any interventions on animals whether surgical, medical or otherwise must be complaint with the five freedoms of animals guaranteed by professional veterinary practice. The code of conduct should be recommended by the Kenya Veterinary Board since	Adopted. To align with the provisions of the Veterinary Surgeons and Veterinary Para-professionals Act.

				research by the Institute involves animals.	Not Adopted. The provision is aligned to 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.
	KEMRI	(a) Explicitly define what constitutes a "public health emergency" and align with relevant national legislation; define or reference it in line with Public Health Act. (b) Specify the Institute's role in collaborating with public health agencies in emergency response. (c) KEMRI supports KIPRE's role in emergency response to disease outbreak that traverse human and animals. (d) A provision should be included to ensure data sharing with public health authorities for coordinated response efforts e.g. if there is Ebola among primates, it is important to inform Ministry of Health.			
12	Clause 26	Ministry of Agriculture and Livestock Development	Amend clause 26(1) to provide for the role of safe use of medicines in animals.	The medicines used must be compliant with the Veterinary Medicines Regulations which then ensures efficacy of any medicine used in animals.	Not Adopted. The medicines are being used in humans and not animals under this clause.
	KEMRI	Amend clause 26(1), to state that for purpose of evaluating the efficacy of products, dosage and safety "in non-human primates, before use in humans". The partnership with KEMRI be recognized as this will support the transition of products for human use. KIPRE bridges the gap of studies in		The clause provides the limitation to non-human primate studies.	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

			small animals (done by KEMRI) to primates and back to KEMRI for human studies.		premised on use of non-human primates by KIPRE
13	Clause 27	KLRC	Specific reference to the Prevention to Cruelty of Animals Act should be replaced in clause 27(a) with the laws relating to the protection of animal welfare.	The Prevention to Cruelty of Animals Act, is proposed for repeal (Animal Welfare and Protection Bill).	Not Adopted. The Animal Welfare and Protection Bill is yet to be enacted.
		Ministry of Agriculture and Livestock Development	Insert a new paragraph (k) mandating the Institute to report notifiable diseases to the veterinary authorities.	Zoonoses are diseases that affect both man and animals and therefore any disease detected in research on animals should be reported promptly for remedial action to be take.	Adopted. To enhance surveillance and control in the management of diseases in the country by the Ministries responsible for health and veterinary services.
14	Clause 28	KLRC	Specify the term of service of the Scientific and Ethics Review Unit.	To avoid instances where members may serve in perpetuity.	Adopted. To clarify the term of the members appointed to serve in the Scientific and Ethics Review Unit of the Institute.
		Kenya Veterinary Board	(a) In clause 28(2)(a), replace "veterinary doctor" with "registered veterinary surgeon". (b) In clause 28(2)(g), replace "veterinarian" with "registered veterinary surgeon".		Adopted. For alignment with the terminology used in the Veterinary Surgeons and Veterinary Para-professionals Act.
15	Clause 30	KEMRI	(a) Define "biologicals" clearly to ensure specificity. (b) A clause should specify ownership rights and conditions for third-party access to biologicals, ensuring fair use and benefit-sharing. (c) Include explicit reference to ethical approval from relevant authorities	The term "biologicals" is broad and should be explicitly defined to distinguish between human, animal, and environmental specimens. Reference to national and international ethical and legal frameworks (e.g., WHO guidelines,	Not Adopted. The term biologicals already defined. The Bill in clause 60 cross-references NACOSTI, the Science, Technology and Innovation Act and other relevant laws.

			such as NACOSTI and Institutional Ethics Review Boards.	GCP, and Nagoya Protocol) is necessary for compliance.	
16	Clause 31	KEMRI	(a) Broaden clause 31(3) to include all entities that would legitimately require access including the Scientists, collaborators and name others. Include a clause that allows access of data among research scientists conducting research in human health with relevant regulatory frameworks in place. (b) Amend the Bill to specify adherence to international and national data security standards, such as ISO/IEC 27001. This will ensure that data security measures are not only applied but are also consistent with recognized standards. (c) Redefine the conditions under which the Board may access data to include specific purposes, such as oversight, compliance reviews, or other explicitly defined reasons. Additionally, introduce safeguards like logging access and regular audits to ensure that access is not abused. (d) 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.	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. Authorized personnel can include data managers, IT support staff, and other personnel who need access to manage, maintain, and protect the data infrastructure.	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.
17	PART IV	Kenya Veterinary Board	In relation to PART IV, all matters relating to the ethical and professional	The Kenya Veterinary Board regulates all areas of	Adopted. The function of certification of programs

			matters including the protection of animal health and welfare should be left to the Kenya Veterinary Board.	veterinary practice. The KIPRE Board will oversee the development of standards of the Scientific and Ethics Review Unit which has to be in line with the Kenya Veterinary Board and the Veterinary Surgeons and Veterinary Professionals Guidelines.	and facilities for the care and use of experimental animals deleted.
		Ministry of Agriculture and Livestock Development	Review Part IV to delineate certification roles by the veterinary experts in line with the veterinary oath and administrative roles by the Institute.	Certification of animal care and use programs and facilities for experimental animals is a technical function for veterinary domain regulated by the Kenya Veterinary Board.	
18	Clause 32	KEMRI	KEMRI has an animal house that conducts research on small animals. This clause would limit KEMRI's ability to maintain and be under authority of KIPRE. This may also touch on other institutions that conduct research using animals.		
19	Clause 33	KEMRI	(a) Training for research scientists using or managing the programme or facility should be completed prior to certification. (b) Refer to or mention the need to comply with national and international regulations.		Not Adopted. The function of certification of programs and facilities for the care and use of experimental animals deleted.
20	Clause 38	KEMRI	The clause could be enhanced by specifying more detailed provisions, incorporating broader educational objectives, and emphasizing ethical standards and collaborations.		Not Adopted. The specifics proposed will be handled by the Board and are best

21	Clause 39	KEMRI	Redraft clause 39 as below: 39.(1) The training centre of the Institute shall provide specialized short course training programs tailored to the functions of the Institute and aligned with the training or capacity needs of the country or the region. These programs shall be designed to address current and emerging scientific and research challenges in the field. (2) The training programs in subsection (1) may be provided in collaboration with other accredited institutions of higher learning or research. Such collaborations shall be based on clearly defined criteria that include the strategic goals of the Institute, complementarity of expertise, and the enhancement of the Institute's capabilities. (3) The Board shall: (a) oversee the development and regular review of the curriculum for the training programs to ensure they remain current and scientifically rigorous; (b) approve training manuals and other educational materials that meet international educational standards and are informed by the latest research and technological advancements in the field; (c) ensure that training programs undergo regular quality assurance checks and receive accreditation from recognized educational bodies; (d) establish guidelines for collaboration with external institutions, including frameworks for joint certification and	(a) Expanded to specify the criteria for choosing collaborating institutions, what these collaborations entail, and how they align with the strategic objectives of the Institute. This ensures that collaborations are strategic and beneficial. (b) Introduces a new sub-clause that mandates regular quality assurance reviews and accreditation processes for the training programs to maintain high educational standards. (c) Includes a requirement for consulting with industry stakeholders, academic experts, and potential employers to ensure that the training programs are relevant and meet the current and future needs of the job market. (d) Adds provisions to ensure that training programs are accessible to a diverse range of participants, including provisions for	addressed through subsidiary legislation.
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			academic credit recognition where applicable; (e) develop and implement policies that promote inclusivity and accessibility in training programs, ensuring opportunities for qualified participants from all backgrounds. (4) The Institute shall actively seek and incorporate feedback from program participants, collaborating entities, industry stakeholders and academic experts to continually enhance the relevance and impact of the training programs.	scholarships or reduced fees for participants from underrepresented groups or economically disadvantaged backgrounds.	
		KLRC	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.	To remove the ambiguity in the clause.	Adopted. To legally anchor and establish the training centre of the Institute as contemplated under Clause 3 of the Bill.
22	Clause 46	KLRC	Delete the use of “of” in clause 46(1).	Comprise means “consist of”, the use of “of” after comprise is an unnecessary repetition.	Noted. The clause is in order as drafted.
		KEMRI	Propose allocation of funding for health research from the Science and Technology Innovation Act to include resources both KIPRE and KEMRI.	KIPRE’s reliance on government allocations, grants, and revenue generation mirrors KEMRI’s funding model, potentially straining national resources.	Not Adopted. The allocation of funding for research generally is set under the Science, Technology and Innovation Act. The Health Act then specifies the amount that should be allocated for health research in the country.
23	Part X	KLRC	The Part should start by revoking the Kenya Institute of Primate Research Order, 2017. Use the word “revocation”	Primary legislation are repealed while secondary legislation are revoked.	Adopted. The Part amended as proposed to use the correct terminology.

			instead of “repeal” in the Title of the Part.		
24	Second Schedule	KEMRI	Revise the Second Schedule as follows: ● Biomedical and Pre-Clinical Research: Focus on non-human primates and other experimental animals. Training aims to develop techniques and insights directly applicable to human health advancements. ● Reproductive Health: Cover both human and animal reproductive health issues, exploring intersections and divergences in treatment and research methodologies. ● Primatology: Study primate biology in the context of health research, conservation, and ethical considerations. ● Conservation Ecology: Focus on endangered species, employing modern conservation techniques and policies to promote biodiversity. ● Biodiversity Studies: Explore ecosystem dynamics, species interactions, and conservation strategies to maintain and restore biodiversity. ● Vector-Borne Diseases: Address prevention, treatment, and control strategies, integrating climate change impacts on disease patterns. ● Snakebite Disease Management: Develop antivenom research and	Incorporating emerging technologies and disciplines like genetics, genomics, data science, and artificial intelligence/machine learning (AI/ML) is crucial for maintaining a cutting-edge curriculum in a scientific research institution. These areas are indispensable for modern research environments, offering extensive capabilities in data analysis, predictive modeling, and personalized medicine. Incorporating these disciplines ensures that the training provided by the institute remains relevant and forward-looking, equipping researchers with the skills needed to lead in an increasingly data-driven and technologically advanced scientific landscape.	Not Adopted. The specifics proposed will be handled by the Board through subsidiary legislation as they are dynamic. The new areas proposed such as digital health are cross-cutting and need not be enumerated in the Second Schedule.

			treatment methodologies, emphasizing rapid response and distribution strategies. ● Molecular Biology and Immunology: Include cutting-edge genetic editing technologies and immune response mechanisms. ● Disease Ecology and Zoonosis: Explore the interface between human, animal, and environmental health factors (One Health approach). ● Phage Biology: Study bacteriophage applications in disease control, including antibiotic resistance solutions. ● Scientific Entrepreneurship and Innovation: Training in translating research into viable business opportunities, focusing on market needs, startup creation, and IP management. ● Laboratory Animal Science: Comprehensive training on the care, use, and management of laboratory animals, with a strong focus on ethical standards. ● Ethics in Research: Mandatory ethics training for all researchers and technicians working with non-human primates and other experimental animals, emphasizing welfare and ethical research practices.		
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			Insert the following additional areas of training in the Second Schedule: ● Genetic Sciences and Genomics: Training in genomic technologies, genetic therapies, and their implications for both human and wildlife health. ● Data Science and Bioinformatics: Comprehensive courses on data management, statistical analysis, and bioinformatics applications in biological research. ● Artificial Intelligence and Machine Learning: Application of AI and ML in biomedical research, including algorithm development and disease modeling. ● Advanced Molecular Biology Techniques: Integration of modern genetic editing tools and their applications in research. ● Integrative Omics Technologies: Combining genomics, proteomics, and metabolomics data to enhance understanding of biological and ecological systems. ● Digital Health and Epidemiology: Utilizing digital tools and AI models to improve public health initiatives and epidemiological research. ● Ethical Implications of Emerging Technologies: Addressing the ethical challenges posed by genetics, AI, and large-scale data analytics in research.		
GENERAL COMMENTS ON THE BILL					

26	General	Kenya Institute of Primate Research (KIPRE)	In support of the Bill in its entirety.	KIPRE to operate as a stand-alone SAGA to enable seamless research and development with the focus on production of drugs/ vaccines including snakebite antivenom and become self-sustaining in the next 5-10 years.	Noted. The Committee took note of the general comments in its deliberations on the Bill.
		Ministry of Health (State Department for Public Health and Professional Standards)	In total support of the Bill in its entirety.	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.	
	General	Office of the Attorney General and the Department of Justice	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 policy contained in the Bill and shall share that guidance and its legal opinion thereon, as and when it is provided.	Cabinet at its first meeting of 2025 recommended the merger of the Kenya Institute of Primate Research (KIPRE) and Kenya Medical Research Institute (KEMRI) into one research institute	
	General	Ministry of Agriculture and	The Bill to confine its scope on research on non-human primates and	All invasive interventions on animals are done by	

		Livestock Development	experimental animals and expunge any regulatory roles which are already being undertaken by the Ministry of Agriculture and Livestock Development through the Kenya Veterinary Board and the Veterinary Medicines Directorate. The Kenya Veterinary Board to deal with all matters related to ethical and professional considerations and protection of animal health and welfare for and on behalf of KIPRE. KIPRE can strengthen its veterinary department to address ethical considerations, professional requirements on invasive procedures on non-human primates and other laboratory animals or any other interventions involving animal health and welfare.	registered veterinary surgeons and veterinary paraprofessionals regulated under the Veterinary Surgeons and Veterinary Paraprofessionals Act. The Act is enforced by the Kenya Veterinary Board requiring coordination between agencies involved in activities that affect animal welfare.	
	General	Kenya Veterinary Board	Concurs with the Ministry of Agriculture and Livestock Development's submissions and in particular on leaving certification of care and protection of animals to the Kenya Veterinary Board.		
	General	KIPRE	(a) Support for Biomedical Research Advancement-KEMRI recognizes the critical role of KIPRE in its preclinical research in non-human primates and that KIPRE has name recognition and its research work to inform and develop health solutions. KIPRE 's designation as a World Health Organization Collaborating		

			Centre and its contributions to addressing neglected tropical diseases (e.g., snakebite anti-venom production launched in January 2024) underscore's its strategic importance. KEMRI support the Bill's aim to strengthen this capacity. (b) Common Mandates between KEMRI and KIPRE-While KIPRE's research population is non-human primates, the goal is common to KEMRI's goal to better solutions for human health. The pipeline for product development starts with discovery laboratory bench studies followed by animal studies which includes the non-human primate studies conducted by KIPRE, which is then followed by human studies conducted by KEMRI. KEMRI has a draft KEMRI Bill,2024 and one of its objects is to establish mechanisms for the conduct, coordination, promotion and regulation of research for human health in Kenya. KEMRI aspires to hold the overall framework for the conduct and regulation of human health in Kenya. (c) Concerns over Fragmentation-While KIPRE's autonomy enhances its focus, KEMRI cautions that establishing it as a stand-alone State Corporation may fragment Kenya's health research ecosystem. KEMRI		
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			operates 15 research centers with diverse geographic locations nationwide. The two institutions hold complementary mandates; mutually seek resources from the National government and KEMRI proposes finding a framework for delivery that complements our various resources. (d) Advocacy for Strategic Integration-KEMRI proposes a framework, that encompasses the two institutions and that will offer a more efficient pathway to achieving the mandates of both institutions. Such an approach will leverage the extensive infrastructure, clinical trial networks, and human health research expertise creating a unified research entity capable of tackling Kenya's health challenges holistically. This proposal requires that KIPRE retain its budgetary exchequer budget allocation for research in non-human primates.		
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**ANNEXURE 4: COPY OF THE NEWSPAPER
ADVERTISEMENT ON PUBLIC PARTICIPATION ON
THE BILL**



REPUBLIC OF KENYA THIRTEENTH PARLIAMENT- THIRD SESSION (2024) THE NATIONAL ASSEMBLY

IN THE MATTER OF CONSIDERATION BY THE NATIONAL ASSEMBLY OF:-

1. THE KENYA INSTITUTE OF PRIMATE RESEARCH BILL (NATIONAL ASSEMBLY BILL NO. 52 OF 2024);
2. THE METEOROLOGY BILL (SENATE BILL NO. 45 OF 2023); AND
3. THE ELECTION OFFENCES (AMENDMENT) (NO. 2) BILL (SENATE BILL NO. 28 OF 2024)

INVITATION TO SUBMIT MEMORANDA

WHEREAS, Article 118(1) (b) of the Constitution requires Parliament to facilitate public participation and involvement in the legislative and other business of Parliament and its Committees, and Standing Order 127(3) of the National Assembly Standing Orders requires House Committees considering Bills to facilitate public participation;

AND WHEREAS, the Kenya Institute of Primate Research Bill (National Assembly Bill No. 52 of 2024); the Meteorology Bill (Senate Bill No. 45 of 2023), and the Election Offences (Amendment) (No. 2) Bill (Senate Bill No. 28 of 2024) were Read a First Time and referred to the relevant Departmental Committees for consideration and reporting to the House;

IT IS NOTIFIED that:-

- (1) The Kenya Institute of Primate Research Bill (National Assembly Bill No. 52 of 2024) is sponsored by the Departmental Committee on Health and introduced under the name of its Chairperson, the Hon. (Dr.) Robert Pukose, MP. The Bill seeks to make provisions 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 to improve human health through innovative pre-clinical research, biomedical research and translational research while conserving non-human primates for biodiversity.
- (2) The Meteorology Bill (Senate Bill No. 45 of 2023) is sponsored by the Majority Party and introduced under the name of the Senate Majority Leader, Sen. Aaron Cheruiyot, MP. The Bill seeks to establish a legislative framework to regulate, coordinate, and monitor meteorological services in Kenya. Additionally, the Bill proposes the establishment of the Kenya Meteorological Service Authority, which shall be responsible for the provision, regulation, coordination, and management of meteorological services.
- (3) The Election Offences (Amendment) (No.2) Bill (Senate Bill No. 28 of 2024) is co-sponsored by the Majority Party and the Minority Party. It is introduced under the names of the Senate Majority Leader, Sen. Aaron Cheruiyot, MP and the Senate Minority Leader, Sen. Stewart Madzayo, MP. The Bill seeks to implement part of the resolutions of the National Dialogue Committee (NADCO) by amending section 6 of the Election Offences Act, Cap. 66 to make it an offence for members and staff of the Independent Election and Boundaries Commission to conduct or hold an election in an ungazetted polling station or to unreasonably delay in declaring election results; or to knowingly alter declared election results.

NOW THEREFORE, in compliance with Article 118(1) (b) of the Constitution and National Assembly Standing Order 127(3), the Clerk of the National Assembly hereby invites the public and stakeholders to submit memoranda on the Bills to the Departmental Committees specified below:-

S/NO.	BILL	COMMITTEE
1.	The Kenya Institute of Primate Research Bill (National Assembly Bill No. 52 of 2024)	Health
2.	The Meteorology Bill (Senate Bill No. 45 of 2023)	Environment, Forestry and Mining
3.	The Election Offences (Amendment) (No. 2) Bill (Senate Bill No. 28 of 2024)	Justice and Legal Affairs

Copies of the Bills are available at the National Assembly Table Office, Main Parliament Buildings, and on: www.parliament.go.ke/the-national-assembly/house-business/bills.

The memoranda may be forwarded to the Clerk of the National Assembly, P.O. Box 41842-00100, Nairobi; hand-delivered to the Office of the Clerk, Main Parliament Buildings, Nairobi; or emailed to: cn@parliament.go.ke to be received on or before Friday, 20th December, 2024 at 5.00 p.m.

S. NJOROGE, CBS
CLERK OF THE NATIONAL ASSEMBLY
6th December, 2024

"For the Welfare of Society and the Just Government of the People"



PUBLIC SERVICE COMMISSION

Our Vision
"A citizen-centric public service"

Our Mission
"To reform and transform the public service for efficient and effective service delivery"

RE-ADVERTISEMENT OF VACANCIES

INTELLIGENCE SERVICE COMPLAINTS BOARD - RE-ADVERTISEMENT

Pursuant to the provisions of section 66 of the National Intelligence Service Act, 2012, the Public Service Commission invites applications from suitably qualified persons to be considered for nomination for appointment to the positions of the Chairperson and Member of Intelligence Service Complaints Board as shown below:-

1) VACANCY IN THE POSITION OF CHAIRPERSON, INTELLIGENCE SERVICE COMPLAINTS BOARD - ONE (1) POST

Section 66 (1) (a) of the National Intelligence Service Act, 2012
For appointment to this position, a candidate must:

- (i) be a citizen of Kenya;
- (ii) hold a law degree from a university recognized in Kenya, or is an advocate of the High Court of Kenya, or possess an equivalent qualification in a common-law jurisdiction;
- (iii) (a) have at least ten (10) years experience as a superior court judge or professionally qualified magistrate; or
(b) have at least ten (10) years experience as a distinguished academic or legal practitioner or such experience in other relevant legal field; or
(c) have held the qualifications specified in paragraphs (a) and (b) for a period amounting, in the aggregate, to ten (10) years;
- (iv) be of high moral character, integrity and impartiality; and
- (v) meet the requirements of Chapter Six of the Constitution.

2) VACANCY IN THE POSITION OF MEMBER, INTELLIGENCE SERVICE COMPLAINTS BOARD (ADVOCATE) - ONE (1) POST

Section 66 (1) (b) (i) of the National Intelligence Service Act, 2012
For appointment to this position, a candidate must:

- (i) be a citizen of Kenya;
- (ii) have a Bachelor of Laws (LLB) degree from a university recognized in Kenya;
- (iii) have a Post Graduate Diploma in legal studies from the Kenya School of Law;
- (iv) been admitted as an Advocate of the High Court of Kenya;
- (v) have a minimum of seven (7) years post admission experience; and
- (vi) meet the requirements of Chapter Six of the Constitution.

3) VACANCY IN THE POSITION OF MEMBER, INTELLIGENCE SERVICE COMPLAINTS BOARD (RETIRED SENIOR INTELLIGENCE OFFICER) - ONE (1) POST

Section 66 (1) (b) (ii) of the National Intelligence Service Act, 2012
For appointment to this position, a candidate must:

- (i) be a citizen of Kenya;
- (ii) hold a degree from a university recognized in Kenya;
- (iii) be a retired senior intelligence officer with a distinguished career in the field; and
- (iv) meet the requirements of Chapter Six of the Constitution.

4) VACANCY IN THE POSITION OF MEMBER, INTELLIGENCE SERVICE COMPLAINTS BOARD (PUBLIC SERVICE) - ONE (1) POST

Section 66 (1) (b) (iv) of the National Intelligence Service Act, 2012
For appointment to this position, a candidate must:

- (i) be a citizen of Kenya;
- (ii) hold a degree from a university recognized in Kenya;
- (iii) have had at least seven (7) years experience in the public service;
- (iv) have had a distinguished career in his/her respective field; and
- (v) meet the requirements of Chapter Six of the Constitution.

INTERESTED APPLICANTS ARE REQUESTED TO NOTE THAT:

- (i) The names of shortlisted candidates for each post shall be published on the Commission's website;
- (ii) Shortlisted candidates will be required to present originals of the following documents during the interviews:
 - (a) National Identity Card;
 - (b) Academic and Professional Certificates and transcripts;
 - (c) Any other supporting documents and testimonials; and
 - (d) Current and valid clearances from the following bodies:
 - (i) Kenya Revenue Authority;
 - (ii) Ethics and Anti-Corruption Commission;
 - (iii) Higher Education Loans Board;
 - (iv) Any of the Registered Credit Reference Bureaus;
 - (v) Directorate of Criminal Investigations (Police Clearance Certificate); and
 - (vi) Recommendations from relevant professional bodies (where applicable).
- (iii) The salary and benefits for these positions shall be determined by the Cabinet Secretary on the advice of the Salaries and Remuneration Commission;
- (iv) The Chairperson and Members of the Board shall hold office for a period of three years but shall be eligible for re-appointment for a further term.
- (v) The earlier advert for the same positions is hereby cancelled; and
- (vi) Those who had applied earlier need not re-apply.

MODE OF APPLICATION

- (i) Candidates should submit manual (Hard Copy) applications.
- (ii) All applications should be submitted together with detailed curriculum vitae, a copy of ID/Passport, copies of academic certificates and transcripts, testimonials and any other relevant supporting documents.
- (iii) Applications should be submitted in a sealed envelope clearly marked:
"Application for the position of Chairperson, Intelligence Service Complaints Board"
OR
"Application for the position of Member, Intelligence Service Complaints Board (Advocate)"
OR
"Application for the position of Member, Intelligence Service Complaints Board (Retired Senior Intelligence Officer)"
OR
"Application for the position of Member, Intelligence Service Complaints Board (Public Service)" and delivered to:

THE SECRETARY/CEO
Public Service Commission
Commission House
P.O. Box 30099-00100 NAIROBI

All applications should reach the Public Service Commission on or before 30th December 2024 latest by 5.00 p.m (East African Time).

SECRETARY/CEO
PUBLIC SERVICE COMMISSION

**ANNEXURE 5: LETTER INVITING STAKEHOLDERS
TO SUBMIT VIEWS ON THE BILL**



**THE NATIONAL ASSEMBLY
OFFICE OF THE CLERK**

P. O. Box 41842-00100
Nairobi, Kenya
Main Parliament Buildings

Telephone: +254202848000 ext. 3300
Email: cna@parliament.go.ke
www.parliament.go.ke/the-national-assembly

When replying, please quote
Ref: NA/DDC/DC-II/2024/101

13th December, 2024

Mr. Harry Kimutai, CBS
Principal Secretary
State Department for Medical Services
Ministry of Health
Afya House
NAIROBI

Ms. Mary Muthoni Muriuki, HSC
Principal Secretary
State Department for Public Health and Professional Standards
Ministry of Health
Afya House

Hon. Jonathan Mueke
Principal Secretary
State Department for Livestock Development
Ministry of Agriculture and Livestock Development
Cathedral Road, Nairobi, Kilimo House
NAIROBI
info@kilimo.go.ke

Dr. Peter Gichuhi Mwethera, MBS
Director General
Kenya Institute of Primate Research
End of Karen Road
P.O Box 24481-00502
NAIROBI
ceo@primateresearch.org

Hon. Dorcas A. Oduor, SC, OGW, EBS
Attorney General of the Republic of Kenya
Office of the Attorney General and Department of Justice
Sheria house
Harambee Avenue
NAIROBI
communications@ag.go.ke

Mr. Joash Dache
Secretary /Chief Executive Officer
Kenya Law Reform Commission (K.L.R.C)
P.O BOX 34999-00100.
NAIROBI
info@klrc.go.ke

Dear *Madam,*

RE: **STAKEHOLDER ENGAGEMENT ON THE KENYA INSTITUTE OF PRIMATE RESERACH BILL, 2024 (NATIONAL ASSEMBLY BILL NO. 52 OF 2024)**

The Departmental Committee on Health is established pursuant to Standing Order 216 and is mandated *inter alia* 'to study and review all legislation referred to it'.

Pursuant to the cited mandate, the Committee is considering the **Kenya Institute of Primate Research Bill, 2024 (National Assembly Bills No.52 of 2024)** (copy forwarded herewith). The Bill, sponsored by the Committee, seeks to make provisions for the establishment, powers, and functions of the Kenya Institute of Primate Research, among other issues.

In compliance with the provisions of Article 118 (1) (b) of the Constitution, the Committee invites you to submit your views on the Bill to be received on or before **Friday 17th January, 2025**.

Kindly send an electronic copy of your submission to the Office of the Clerk via email: cna@parliament.go.ke.

Our Liaison Officers on this subject are **Mr. Hassan A. Arale**, who may be contacted on Tel No. 0721480578 or email: hassan.arale@parliament.go.ke and **Mr. Timothy Kimathi**, Tel No. 0725650878 or email: timothy.kimathi@parliament.go.ke.

Yours *sincerely,*



SERAH M. KIOKO, NDOMBI, MBS
For: CLERK OF THE NATIONAL ASSEMBLY

Copy to: **Dr. Deborah Mulongo Barasa**
Cabinet Secretary
Ministry of Health.
Afya House
NAIROBI

Dr. Andrew Mwihia Karanja

Cabinet Secretary

Ministry of Agriculture and Livestock Development

Cathedral Road, Nairobi, Kilimo House

NAIROBI

Prof. Josephat Mulimba

Board Chairman

Kenya Institute of Primate Research

End of Karen Road

P.O Box 24481-00502

NAIROBI

**ANNEXURE 6: LETTER INVITING STAKEHOLDERS
FOR A MEETING WITH THE COMMITTEE ON THE
BILL**



THE NATIONAL ASSEMBLY
OFFICE OF THE CLERK

P. O. Box 41842-00100
Nairobi, Kenya
Main Parliament Buildings

Telephone: +254202848000 ext. 3300
Email: cna@parliament.go.ke
www.parliament.go.ke/the-national-assembly

When replying, please quote

Ref: NA/DDC/DC-H/2025/29

7th April, 2025

Ms. Mary Muthoni Muriuki, CBS
Principal Secretary
State Department for Public Health and
Professional Standards
Ministry of Health
Afya House
NAIROBI
ps.publichealth@health.go.ke

Hon Jonathan Mueke, CBS
State Department for Livestock
Development
Ministry of Agriculture and Livestock
Development
Cathedral Road, Nairobi, Kilimo House
NAIROBI
info@kilimo.go.ke

Mr. Joash Dache, MBS
Secretary /Chief Executive Officer
Kenya Law Reform Commission (K.L.R.C)
P.O BOX 84999-00100.
NAIROBI
info@klrc.go.ke

Hon. Shadrack John Mose
The Solicitor-General
The State Law Office
Sheria House, Harambee Avenue
NAIROBI

Dr. Peter Gichuhi Mwethera, MBS
Director General
Kenya Institute of Primate Research
End Of Karen Road
P. O Box 24481-00502
NAIROBI
ceo@primateresearch.org

Dr. Cecilia Wanjala
Ag. Chief Executive Officer
Kenya BioVax Institute Limited
P. O. Box 30016-00100
NAIROBI

Dr. Tonny K Omwansa
Chief Executive Officer
Kenya National Innovation Agency (KeNIA)
P.O Box 20269-00100
NAIROBI
info@innovationagency.go.ke

Prof. Walter O Oyowa, PhD
Director General
National Commission for Science
Technology & Innovation (NACOSTI)
P.O Box 30623-00100
NAIROBI
info@nacosti.go.ke

Prof. Appolinaire Djikeng
Director General
International Livestock Research Institute
(ILRI) Kenya
P.O Box 30709-00100
NAIROBI
amureithi@cgiar.org

Dr. Meshack Ndirangu
Country Director
Amref Health Africa in Kenya
P O Box 30125, 00100
Wilson Airport
Nairobi, Kenya
info.kenya@amref.org

Prof. Elijah Songok
Ag. Director General
Kenya Medical Research Institute
P.O. Box 54800-00200
NAIROBI
director@kemri.go.ke
Dear

RE: **STAKEHOLDER ENGAGEMENT ON THE KENYA INSTITUTE OF PRIMATE RESERACH BILL, 2024 (NATIONAL ASSEMBLY BILL NO. 52 OF 2024)**

The Departmental Committee on Health is established pursuant to Standing Order 216 and is mandated *inter alia* 'to study and review all legislation referred to it'.

Pursuant to the provisions of Standing Order 127(1), the Kenya Institute of Primate Research Bill, 2024 (National Assembly Bills No. 52 of 2024) was committed to the Committee for consideration.

Copies of the Bill are available at the National Assembly Table Office, Main Parliament Buildings and on www.parliament.go.ke/the-national-assembly/house-business/bills.

In line with the above mandate and in compliance with the provisions of Article 118 (1) (b) of the Constitution, the Committee during its sitting held on Tuesday 1st April, 2025, resolved to invite you for deliberations on the Bill. The Meeting is scheduled for Saturday, 12th April 2025, at 9: 00am, in Argyle Grand Hotel, Machakos County.

Kindly provide fifteen (15) copies of your submission and send a soft copy to the Office of the Clerk via email: cna@parliament.go.ke. In your submission kindly state the specific Clause proposed amendment and the justification

Our Liaison Officers on this subject are Mr. Hassan A. Arale, who may be contacted on Tel No. 0721480578 or email: hassan.arale@parliament.go.ke and Mr. Timothy Kimathi, Tel No. 0725650878 or email: timothy.kimathi@parliament.go.ke. or Ms. Gladys Kiprotich, Tel No. 0718721253 or email: gladys.kiprotich@parliament.go.ke.

Yours

JEREMIAH W. NDOMBI, MBS
For: CLERK OF THE NATIONAL ASSEMBLY

Copy to:

Hon. Aden Barre Duale, E.G.H
Cabinet Secretary
Ministry of Health.
Afya House
NAIROBI

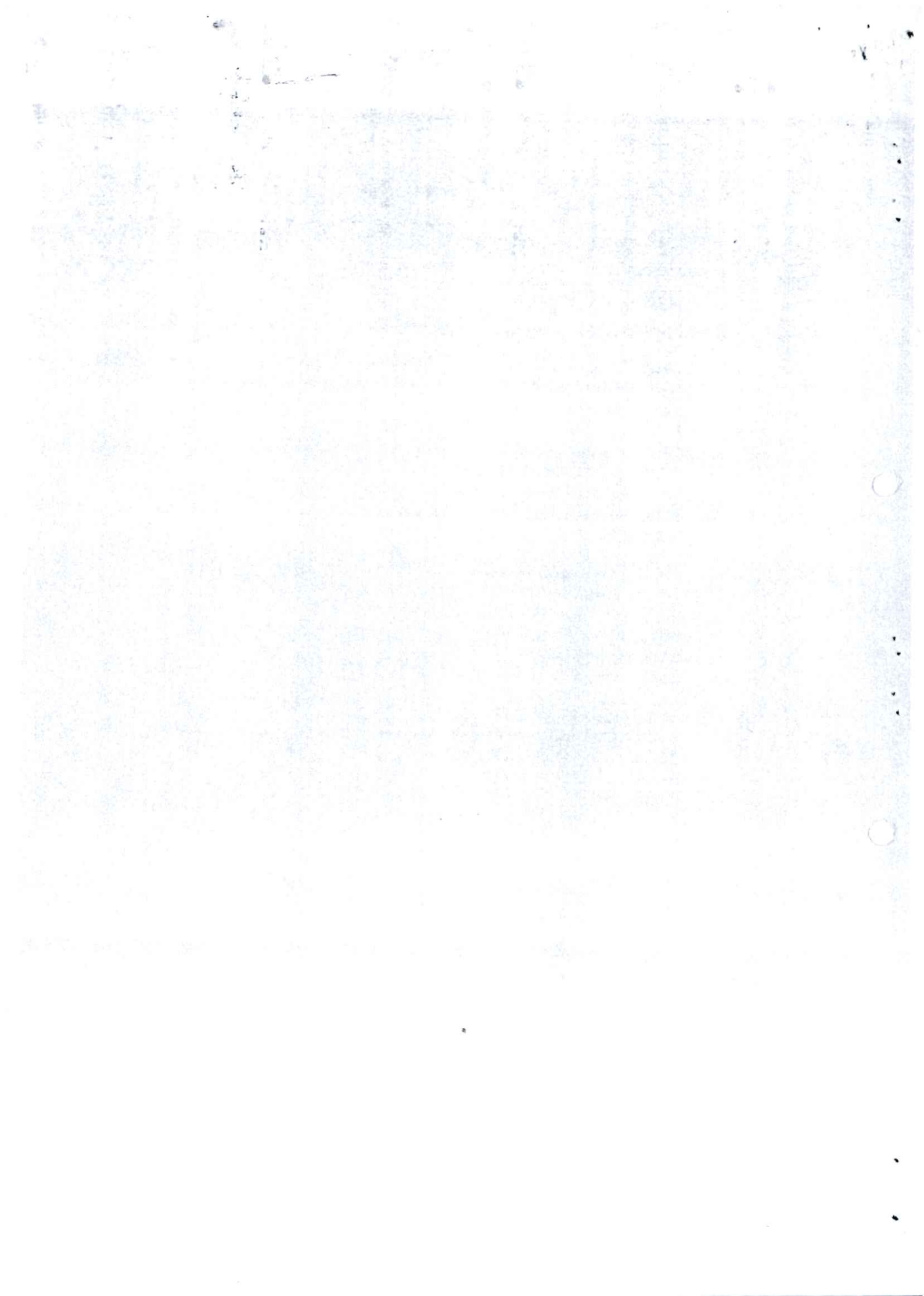
Hon. Mutahi Kagwe, EGH
Cabinet Secretary
Ministry of Agriculture and Livestock Development
Cathedral Road, Nairobi, Kilimo House
NAIROBI

Hon. Dorcas A. Oduor, SC, OGW, EBS
Attorney General of the Republic of Kenya
Office of the Attorney General and Department of Justice
Sheria house
Harambee Avenue
NAIROBI

Hon. Dr. Swarup Mishra
Chairman, Board of Directors
Kenya BioVax Institute Limited
P. O. Box 30016-00100
NAIROBI

Prof. Josephat Mulimba
Board Chairman
Kenya Institute of Primate Research
End of Karen Road
P.O Box 24481-00502
NAIROBI

Hon. Dr. Ali Abudllahi
Board Chairman
Kenya Medical Research Institute
P.O. Box 54800-00200
NAIROBI



ANNEXURE 7:STAKEHOLDER SUBMISSIONS



REPUBLIC OF KENYA

**MINISTRY OF AGRICULTURE AND LIVESTOCK DEVELOPMENT
STATE DEPARTMENT FOR LIVESTOCK DEVELOPMENT**

**MEMORANDUM ON THE KENYA INSTITUTE OF PRIMATE
RESEARCH BILL 2024**

**]BY
HON. JONATHAN MUEKE, CBS
PRINCIPAL SECRETARY**

FEBRUARY 2025

BACKGROUND

The Livestock Policy and the Veterinary Policy provides a definite roadmap for the development of animal resources in Kenya. The animal resources in Kenya comprise of all animals excluding humans and include livestock, wildlife, farmed wildlife, companion, aquatic and other animal species. Provision of animal welfare is central to the physical and psychological wellbeing of animals, including animal health and production and manifests in better performance, improved market access, safe and mutually beneficial companionship. Veterinary Public Health (VPH) is an essential part of public health that links people, animals and the environment. VPH guarantees safety of foods of animal origin. Human health is closely interrelated to animal health with many diseases that affect human beings originating from animals. Optimal human health is one of the essential considerations for sustainable economic development. The "One Health Approach" is based on the realization that diseases that adversely impact the health of humans, animals and the environment can be successfully addressed through collaboration across disciplines and institutions.

Animal research programmes embrace multidisciplinary approaches and integrate education and extension. These programmes are continually changing to respond to emerging challenges and opportunities brought about by rapidly advancing technologies, evolving consumer demands and the need to make positive contributions to human, animal and environmental health. Efficient demand driven animal research translates into affordable and high-quality food for the nation, better livelihoods and economy.

Veterinary Services are classified as a global public good for which the Veterinary Authority takes primary responsibility about good governance and service delivery in accordance with national and international standards and public expectations. The governance must be within an effective, structured national legislative framework supported by appropriate financial and human resources. Animal welfare policies and laws provide for principles of animal welfare; care or use of an animal; animals in captivity or confinement; farm animals; animal accommodation; slaughtering of an animal for human consumption; and aquatic animals.

All invasive interventions on animals are done by registered veterinary surgeons and veterinary paraprofessionals regulated under the Veterinary Surgeons and Veterinary Paraprofessionals Act enforced by the Kenya Veterinary Board requiring coordination between agencies involved in activities that affect animal welfare.

RECOMMENDATIONS

Based on this background, we recommend that all matters related to ethical and professional considerations, and protection of animal health and welfare be addressed by the Kenya Veterinary Board for and on behalf of the Institute in the proposed Bill. The drafters need to capture the spirit and letter.

Signature..........Date.....20/2/2025.....
HON. JONATHAN MUEKE, CBS.



KENYA VETERINARY BOARD

Veterinary Research Laboratories, Upper Kabete
P.O. Box 513 - 00605 Uthiru, Nairobi. Tel: (+254) 722 305253 / 701 581718
Email: info@kenyavetboard.or.ke | Website: www.kenyavetboard.or.ke



Ref: KVB/GEN/Vol.XI/306

Date: 12th April, 2025

The Chairman
Health Committee of Senate
Email: healthcommittee.senate@parliament.go.ke

Dear Sir,

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

Kenya Veterinary Board (KVB) wishes to provide feedback on the proposed Kenya Institute of Primate Research Bill, 2024

KVB is a regulatory Agency mandated to ascertain provision of quality veterinary services through "exercising general supervision and control over the training, business, practice and employment of Veterinary Surgeons and Veterinary Paraprofessionals in Kenya and advice the government in relation to all aspects thereof". KVB established by the Veterinary Surgeons and Veterinary Paraprofessionals (VSVP) Act of 2011.

The Kenya Veterinary Surgeons & Veterinary Paraprofessional Act No 29 of 2011 Section 6 (2) and specifically:

(a) advise the Government on matters relating to veterinary training, research, practice and employment, the use of veterinary medicines, poisons and the pesticides, and **other issues relating to animal welfare;**

(e) register, license, control and regulate veterinary practice and **veterinary laboratories, clinics, animal hospitals, and such other** facilities as provided for in Rules made under this Act;

(f) formulate and publish a code of ethics which shall be binding on all registered persons;

(g) regulate the professional conduct of registered persons and take such disciplinary measures as may be appropriate to maintain proper professional and ethical standards;

(h) ensure the maintenance and improvement of the standards of practice by the registered persons;

(i) assess from time to time human resource and necessary training programmes to guarantee sound and efficient veterinary service delivery and advise the relevant Ministries accordingly.

(n) **guarantee animal welfare through registration, licensing and regulation of institutions and organizations with activities;**

(p) carry out any other function to improve, promote and advance the veterinary profession and practice in Kenya.

KIPR Bill 2024 provides at Section 7 (1)(p) on the core functions of the KIPR that allows KIPR to certify animal care & use programs and facilities for experimental animals and also at Part IV of KIPR Bill, 2024 relating to the Certification of animal care and use programs and facilities for experimental animals

The Board has standards operationalized through the regulation 2013 and code of ethics 2015 which regulates the animal welfare and research animals. The requirement for supervision of animal facilities by a registered and licensed veterinary surgeon in order to guarantee animal welfare within research facilities

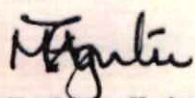
Section 25 (1) of the VSVP Regulations (Code of Ethics 2015) provides for the regulation to manage research animals in line with the World Organization for Animal Health guidelines on use of animals in research which requires strict certification and regulation of the practice of managing animal welfare for research animals.

RECOMMENDATION

While appreciating the functions that can be handled collaboratively with the KVB, we recommend,

1. Section 9 (1) on composition of board of directors should include the Registrar, KVB who regulates all areas of Veterinary practice. The Board will oversee development of standards of the Scientific and ethics Review Unit which has to be in line with the Kenya Veterinary Board and VSVP guidelines.
2. Section 28(2a) Replace veterinary doctor with registered veterinary surgeon and section 28(2g) replace veterinarian with registered veterinary surgeon.
3. All matters related to ethical and professional matters including the protection of animal health and welfare should be left under the Kenya Veterinary Board under its functions stated above.

Yours *Sincerely,*



Dr. Mary T. Agutu

CHIEF EXECUTIVE OFFICER

KENYA VETERINARY BOARD
P. O. Box 513 - 00605 NTHIRU

12 APR 2025

Tel: 0722 305 253 / 0701 581 718
E-mail: info@kenyavetboard.or.ke



COMMENTS ON THE KENYA INSTITUTE OF PRIMATE RESEARCH BILL, 2024

A. INTRODUCTION

The Kenya Law Reform Commission, ("KLRC") is a state corporation established under the Kenya Law Reform Commission Act, Cap. 3 of the laws of Kenya. KLRC has both constitutional and statutory mandate under Section 5(6)(b) of the Sixth Schedule to the Constitution, the Kenya Law Reform Commission Act and the County governments Act, respectively.

The core mandate of the KLRC is to review all the laws and recommend for their reform to ensure that the law conforms to the letter and spirit of the Constitution, taking into account the socio-economic, political and technological developments.

Vide a letter dated 7th April, 2025 and referenced as NA/DDC/DC-H/2025/29, the KLRC received a request from the Clerk of the National Assembly to submit comments on the Kenya Institute of Primate Research Bill, 2024, National Assembly Bill No. 52 of 2024. The broader objects of the Bill as espoused in its long title is to make provisions for the establishment of the Kenya Institute of Primate Research, currently established under the Kenya Institute of Primate Research Order, 2017.

Against this background and pursuant to the KLRC's constitutional and statutory mandate, the KLRC makes the following observations—

B. SPECIFIC COMMENTS

CLAUSE	COMMENT	JUSTIFICATION
Definitions	Delete the use of "of" after comprising.	Comprise means "consist of", the use of "of" after comprise is an unnecessary repetition.
Clause 3	Redraft as follows— The object of this Act is to—	Paragraph too verbose. The details should form part of the functions of the Institute.

	(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.	
Clause 7(q)	Delete the phrase "by any other written law or as necessary for the promotion of the objects of the Act". The use of the phrase is unnecessary repetitive.	The Interpretation and General Provisions Act, Cap 2., defines the word "prescribed" as prescribed by the Act in which the word occurs or by subsidiary legislation made thereunder. The use of the words "by any other written law or as necessary for the promotion of the objects of the Act" are therefore unnecessary additions.
Clause 9	Delete the use of "of" after comprising. The number 1 in subclause (2), should be in bracket (1).	Comprise means "consist of", the use of "of" after comprise is an unnecessary repetition.
Clause 10	The Public Service Commission should be mandated to advertise for the positions under paragraph 9(a)(d) and forward the names to the respective appointing authority for appointment.	Pursuant to Article 232(1)(g) of the Constitution, fair competition and fair are the basis of appointments and promotions. Article 234 (2)(f) mandates the PSC to develop human resources in the public service.
Clause 12.	Delete the word "physical" appearing in paragraph (a).	The use of the word physical discriminates against persons with disability contrary to Article

		27(4) and (5) of the Constitution.
Clause 16	The functions of the Director-General under section 16(6) should come immediately after the qualifications for appointment.	For purposes of orderliness in the legislation.
Clause 17	Delete the word "physical" appearing in paragraph 17(1)(a).	The use of the word physical discriminates against persons with disability contrary to Article 27(4) and (5) of the Constitution.
Clause 18	Align with the provisions of the Certified Public Secretaries of Kenya Act, Cap. 534.	The qualifications under clause 18(2) does not align with the qualifications under section 20 of the CPS Act for appointment as a CPS.
Clause 27(a)	Specific reference to the Prevention to Cruelty of Animals Act should be replaced with the laws relating to the protection of animal welfare.	The Prevention to Cruelty of Animals Act, is proposed for repeal (Animal Welfare and Protection Bill).
Clause 28	Specify the term of service of the Scientific and Ethics Review Unit.	To avoid instances where members may serve in perpetuity.
Clause 37	Clause 37(1) should first establish the training centre before assigning any functions since this is one of the objects of the Bill under clause 3.	To remove the ambiguity in the clause.
Clause 46	Delete the use of "of" in clause 46(1).	Comprise means "consist of", the use of "of" after comprise is an unnecessary repetition.
Part X	The part should start by revoking the Kenya Institute of Primate Research Order, 2017. Use the word "revocation" instead of "repeal".	Primary legislation are repealed while secondary legislation are revoked.



In Search of Better Health

KENYA MEDICAL RESEARCH INSTITUTE

OFFICE OF THE DIRECTOR GENERAL

Tell: +254 020 2722541, 2713349,
0722 205 901, 0709 295 300

P.O. Box 54840-00200, Nairobi

Email: director@kemri.go.ke

Website: www.kemri.go.ke

KEMRI/ADM/1/15

Clerk of National Assembly
P.O. Box 41842-00100
Parliament Buildings
NAIROBI

Dear Sir,

**SUBJECT: MEETING WITH THE DEPARTMENTAL COMMITTEE ON HEALTH ON THE
CONSIDERATION OF THE KENYA INSTITUTE OF PRIMATE RESEARCH
BILL 2024**

We write with respect to your letter Ref. NA/DCC/DC-H/2025/07 of 11th February 2025, to ours of 19th February 2025 and to the meeting of 20th February 2025 whereby the Departmental Committee on Health invited us to make our views regarding the subject Bill.

Following the guidance given in the meeting of 20th February 2025 to submit a written Memorandum, we hereby wish to submit the Kenya Medical Research Institute Memorandum in response to the Kenya Institute of Primate Research Bill 2024, for consideration.

We trust that our input will be valuable in shaping the legislative framework to strengthen health research in Kenya. We look forward to continued collaboration with the Committee and other stakeholders in this legislative process.

Please do not hesitate to contact us for any further clarifications.

Yours faithfully,

Prof. Elijah Songok

Ag. Director General & CEO

KENYA MEDICAL RESEARCH INSTITUTE

Encl.

c.c. **Hon. Aden Duale**, Cabinet Secretary, Ministry of Health
Mr. Harry Kimtai, CBS, Principal Secretary, State Department of Medical Services, MoH



In Search of Better Health

MEMORANDUM TO THE NATIONAL ASSEMBLY DEPARTMENTAL COMMITTEE ON HEALTH ON REVIEW OF THE KENYA INSTITUTE OF PRIMATE RESEARCH BILL 2024

The Kenya Medical Research Institute (KEMRI) memorandum to the National Assembly Departmental Committee on Health on the Kenya Institute of Primate Research Bill 2024

A. Preamble

The Kenya Medical Research Institute (KEMRI), established under the Science and Technology (Amendment) Act of 2013, is Kenya's premier state corporation mandated to conduct human health research to improve the quality of life for Kenyans and contribute to global health advancements. With 15 research centers nationwide and a proud history of innovations such as diagnostic kits, vaccines, and health policy insights, KEMRI welcomes the opportunity to provide input on the Kenya Institute of Primate Research (KIPRE) Bill 2024. This bill seeks to establish KIPRE as an autonomous state corporation under the Ministry of Health, transitioning it from its previous status under the National Museums of Kenya (NMK) to a standalone entity focused on biomedical and preclinical research using non-human primates.

KEMRI acknowledges the bill's intent to strengthen Kenya's biomedical research capacity and applauds efforts to address critical health challenges, such as snakebites, zoonotic diseases, and vaccine development. However, as a key stakeholder in the national health research ecosystem, KEMRI offers the following views, comments, and recommendations to ensure the bill aligns with Kenya's broader health priorities, optimizes resources, and fosters scientific synergy.

B. KEMRI's Views

1. Support for Biomedical Research Advancement

KEMRI recognizes the critical role of KIPRE in its preclinical research in non human primates and that KIPRE has name recognition and its research work to inform and develop health solutions. KIPRE's designation as a World Health Organization (WHO) Collaborating Centre and its contributions to addressing neglected tropical diseases (e.g., snakebite anti-venom production launched in January 2024) underscore its strategic importance. We support the Bill's aim to strengthen this capacity.

2. Common Mandates between KEMRI and KIPRE

While KIPRE's research population is non-human primates, the goal is common to KEMRI's goal to better solutions for human health. The pipeline for product development starts with discovery laboratory bench studies followed by animal studies which includes the non-human primate studies conducted by KIPRE, which is then followed by human studies conducted by KEMRI.

KEMRI has a draft KEMRI Bill 2024 and one of its objects is to establish mechanisms for the conduct, coordination, promotion and regulation of research for human health in Kenya. KEMRI aspires to hold the overall framework for the conduct and regulation of human health in Kenya.

3. Concerns Over Fragmentation

While KIPRE's autonomy enhances its focus, KEMRI cautions that establishing it as a stand-alone State Corporation may fragment Kenya's health research ecosystem. KEMRI operates 15 research centers with diverse geographic locations nationwide. The two institutions hold complementary mandates; mutually seek resources from the National government and we propose finding a framework for delivery that complements our various resources.

4. Advocacy for Strategic Integration

KEMRI proposes a framework, that encompasses the two institutions and that will offer a more efficient pathway to achieving the mandates of both institutions. Such an approach will leverage the extensive infrastructure, clinical trial networks, and human health research expertise creating a unified research entity capable of tackling Kenya's health challenges holistically. This proposal requires that KIPRE retain its budgetary exchequer budget allocation for research in non-human primates.

The table below provides feedback on specific sections of the KIPRE Bill that will need attention: -

PART & SECTION	COMMENTS	PROPOSED CHANGES
I - PRELIMINARIES		
1 -short title		Ok
2 interpretations		
	The use of the word "health" needs to be qualified	should read, "human health"
	While the bill mentions "bio banks" , it has not provided a definition of the term	Definition of Biobank to be considered "biobanks" means specialized institutions or repository that collect, store and manage biological materials;
	Since they will derive materials from animals, as specimens, there is need to define "biospecimens"	"biospecimens" means any material derived from a human or animal body for research, diagnostic or therapeutic purposes including blood, tissue, urine, saliva and genetic material;
	the definition of incubation centre, seems incomplete/inadequate to the meaning "incubation centre" means a designated location for nurturing or mentoring research scientists to move research	to revised, and follow the KEMRI bill definition "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;

	"Traditional and alternative" medicines has been identified as a research area, but has not been defined in preliminaries	"Traditional and Alternative" medicine to be defined as described in the Health ACT	
	3 (c) ensure the protection of animal species and their habitats from extinction: This is a good object but may require elucidation	There are other institutions that may have this object as their mandate (e.g., Kenya Wildlife Services and Wildlife Research & Training Institute)	
5. Establishment of the Institute.		Ok	
6. Headquarters of the Institute.		Ok	
7. Functions of the Institute.	7.(1) (a) – (b) and (h) – similar focus e.g. biodiversity conservation vis a vis conservation status and ecosystem health vis a vis ecology, population estimates, habitats, spatial distribution, genomic analysis etc, which inform ecosystem health. (c) and (g) speak to the same function and are part of infrastructure and systems for research for human health mentioned in (h) (h) The aspect of "zoonotic diseases" appears hanging. (i) National research centre for venom and anti-venom (k) is a specification of a research area of interest. GENERAL COMMENT There is significant overlap in the functions of the institute and those of KEMRI, for example:	Combine and harmonize (b) and (h). Combine and harmonize (c), (g) and (h). Review (h) and locate elsewhere Justification for the designation as the national centre may need to be provided. Quantify if this is exclusive of other institutions. KEMRI also conducts research on snake venom Locate (k) in the appropriate section.	

		7.(1) (a) is an elaboration of KEMRI's function 7.(1) (a): conduct research for human health; 7. (1) (b) Overlaps with KEMRI's function 7.(1): (e) undertake scientific and technological invention and innovation for human health and service delivery and (f): establish incubation centres for invention, innovation and product development for health 7. (1) (f) on research to improve IVF services for human health. To reflect the differences with KEMRI propose that in this section, be specific to non-human primates 7. (1) (g) and (h) fits in with KEMRI's function 7. (1) (c): establish and maintain infrastructure and systems for research for human health; characterization of non-human primates and other experimental animal models both at the population and genomic level constitute infrastructure and systems to support research for human health.		
		The Bill's delineation of KIPRE 's mandate in biomedical research, conservation biology, and preclinical studies among non-human primates compliments KEMRI's work and mandate among humans	- o Insert a clause mandating collaboration between KIPRE and KEMRI, such as - o Propose a clause and a section that reflects partnership with KEMRI to show the complimentary functions of the two government institutions.	
8. Powers of the Institute			Ok	
9. The Board of Directors of the Institute.		while it indicates six additional members two of whom shall be expertise in biomedical research this is not sufficient on representation	We propose amendment to the section as follows: • Include Director General of KEMRI to the KIPRE Board of Directors	

				• Include the representative of the Attorney General • Include the Director General of Kenya Wildlife Services
10. Qualification for appointment as Chairperson or Member of the Board.	While it specifies PhD as the chair, this is a position where the CS has rights on appointment is limiting			Re-consider the level of qualification and simply indicate Postgraduate Degree
11. Term of office.	Most statutes work with three (3) years not four (4), but if its allowable, then it can be left as is			
	Governance Structure o Comment: The proposed management Board provides robust oversight but lacks mechanisms to align its activities with broader health research goals.			
23. Management of research.				Ok
24. Conduct of pre-clinical research.				Ok
25. Public health emergencies.	• The term "public health emergency" should be explicitly defined or referenced in line with Public Health Act. • A provision should be included to ensure data sharing with public health authorities for coordinated response efforts. e.g if there is Ebola among primates, it is important to inform Ministry of Health			• Explicitly define what constitutes a "public health emergency" and align with relevant national legislation. • Specify the Institute's role in collaborating with public health agencies in emergency response. • We support KIPRE role in emergency response to disease outbreak that traverse human and animals
26. Traditional and alternative medicine.	The section provides the limitation to non human primate studies. We propose that the partnership with KEMRI be recognized as this will support the transition of products for human use. KIPRE bridges the gap of studies in small animals (done by KEMRI) to primates and back to KEMRI for human studies.			We propose this statement to be added: For purpose of evaluating the efficacy of products, dosage and safety "in non human primates, before use in humans".

30. Biobanks.	• The term "biologicals" is broad and should be explicitly defined to distinguish between human, animal, and environmental specimens. • Reference to national and international ethical and legal frameworks (e.g., WHO guidelines, GCP, and Nagoya Protocol) is necessary for compliance. • A clause should specify ownership rights and conditions for third-party access to biologicals, ensuring fair use and benefit-sharing.	• Define "biologicals" clearly to ensure specificity. • Include explicit reference to ethical approval from relevant authorities such as NACOSTI and Institutional Ethics Review Boards.
31. Research data banks.	3. Clause 31(3) allows access of the data by the Board alone. This should be broadened to include all entities that would legitimately require access including the Scientists, collaborators and name others.	1. Specify Security Standards: • Amend the bill to specify adherence to international and national data security standards, such as ISO/IEC 27001. This will ensure that data security measures are not only applied but are also consistent with recognized standards. 2. Define Scope and Limitations for Board Access: • Redefine the conditions under which the Board may access data to include specific purposes, such as oversight, compliance reviews, or other explicitly defined reasons. Additionally, introduce safeguards like logging access and regular audits to ensure that access is not abused. Include Provisions for Data Integrity and Backup: • Add clauses that mandate regular data integrity checks and backup procedures to prevent data loss and ensure the reliability of the stored data.

			3. Proposed Revision of Clause 31(3): Explanation and Inclusion of other Stakeholders: 4. Include a clause that allows access of data among research scientists conducting research in human health with relevant regulatory frameworks in place 1. Regulatory Bodies: - These might include health and safety regulators, data protection authorities, and other government agencies that require access to oversee compliance with legal and ethical standards. 2. Authorized Personnel: - This can include data managers, IT support staff, and other personnel who need access to manage, maintain, and protect the data infrastructure	
32. Certification.	KEMRI has an animal house that conducts research on small animals. This clause would limit the Institute's ability to maintain and be under authority of KIPRE	This may also touch on other institutions that conduct research using animals		
33. Application for certification.	This section reads "certification for "no person	Training for research scientists using or managing the programme or facility	Training should be completed prior to certification	Refer to or mention need to comply with national and international regulations.

38. Capacity building.	This section could be enhanced by specifying more detailed provisions, incorporating broader educational objectives, and emphasizing ethical standards and collaborations.	
39. Training centre.	Expand Detail and Clarity: 1. Specificity in Collaboration: ○ Section 39(2) could be expanded to specify the criteria for choosing collaborating institutions, what these collaborations entail, and how they align with the strategic objectives of the Institute. This ensures that collaborations are strategic and beneficial. 2. Quality Assurance and Accreditation: ○ Introduce a new sub-clause that mandates regular quality assurance reviews and accreditation processes for the training programs to maintain high educational standards. 3. Stakeholder Involvement: ○ Include a requirement for consulting with industry stakeholders, academic experts, and potential employers to ensure that the training programs are relevant and meet the current and future needs of the job market. 4. Inclusivity and Accessibility: ○ Add provisions to ensure that training programs are accessible to a diverse range of participants, including provisions for scholarships or reduced fees for	Proposed Revision of Clause 39: 39.(1) The training centre of the Institute shall provide specialized short course training programs tailored to the functions of the Institute and aligned with the training or capacity needs of the country or the region. These programs shall be designed to address current and emerging scientific and research challenges in the field. (2) The training programs in subsection (1) may be provided in collaboration with other accredited institutions of higher learning or research. Such collaborations shall be based on clearly defined criteria that include the strategic goals of the Institute, complementarity of expertise, and the enhancement of the Institute's capabilities. (3) The Board shall: (a) oversee the development and regular review of the curriculum for the training programs to ensure they remain current and scientifically rigorous; (b) approve training manuals and other educational materials that meet international educational standards and are

		participants from underrepresented groups or economically disadvantaged backgrounds.	informed by the latest research and technological advancements in the field; (c) ensure that training programs undergo regular quality assurance checks and receive accreditation from recognized educational bodies, (d) establish guidelines for collaboration with external institutions, including frameworks for joint certification and academic credit recognition where applicable, (e) develop and implement policies that promote inclusivity and accessibility in training programs, ensuring opportunities for qualified participants from all backgrounds. (4) The Institute shall actively seek and incorporate feedback from program participants, collaborating entities, industry stakeholders, and academic experts to continually enhance the relevance and impact of the training programs
	1.	Funding and Resources ○ Comment: KIPRE's reliance on government allocations, grants, and revenue generation mirrors KEMRI's funding model, potentially straining national resources	Recommendation ○ Propose allocation of funding for health research from the science and technology innovation Act to include resources both KIPRE and KEMRI
SECOND SCHEDULE: AREAS OF TRAINING		Incorporating emerging technologies and disciplines like genetics, genomics, data science, and artificial intelligence/machine learning (AI/ML) is crucial for maintaining a cutting-edge curriculum in a scientific research institution. These areas are indispensable for modern research environments, offering extensive capabilities in data analysis, predictive modeling, and personalized medicine.	Revised Schedule: SECOND SCHEDULE: AREAS OF TRAINING ● Biomedical and Pre-Clinical Research ○ Focus on non-human primates and other experimental animals. Training aims to develop

	Incorporating these disciplines ensures that the training provided by the institute remains relevant and forward-looking, equipping researchers with the skills needed to lead in an increasingly data-driven and technologically advanced scientific landscape.	techniques and insights directly applicable to human health advancements. ● Reproductive Health: ○ Cover both human and animal reproductive health issues, exploring intersections and divergences in treatment and research methodologies. ● Primatology: ○ Study primate biology in the context of health research, conservation, and ethical considerations. ● Conservation Ecology: ○ Focus on endangered species, employing modern conservation techniques and policies to promote biodiversity. ● Biodiversity Studies: ○ Explore ecosystem dynamics, species interactions, and conservation strategies to maintain and restore biodiversity. ● Vector-Borne Diseases: ○ Address prevention, treatment, and control strategies, integrating climate change impacts on disease patterns. ● Snakebite Disease Management: ○ Develop antivenom research and treatment methodologies, emphasizing rapid response and distribution strategies. ● Molecular Biology and Immunology: ○ Include cutting-edge genetic editing technologies and immune response mechanisms. ● Disease Ecology and Zoonosis:
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		○ Explore the interface between human, animal, and environmental health factors (One Health approach) ● Phage Biology. ○ Study bacteriophage applications in disease control, including antibiotic resistance solutions. ● Scientific Entrepreneurship and Innovation. ○ Training in translating research into viable business opportunities, focusing on market needs, startup creation, and IP management. ● Laboratory Animal Science: ○ Comprehensive training on the care, use, and management of laboratory animals, with a strong focus on ethical standards ● Ethics In Research: ○ Mandatory ethics training for all researchers and technicians working with non-human primates and other experimental animals, emphasizing welfare and ethical research practices. SECOND SCHEDULE: ADDITIONAL AREAS OF TRAINING ● Genetic Sciences and Genomics: Training in genomic technologies, genetic therapies, and their implications for both human and wildlife health ● Data Science and Bioinformatics: Comprehensive courses on data management, statistical analysis, and bioinformatics applications in biological research ● Artificial Intelligence and Machine Learning: Application of AI and ML in biomedical research,
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				including algorithm development and disease modeling. ● Advanced Molecular Biology Techniques: Integration of modern genetic editing tools and their applications in research. ● Integrative Omics Technologies: Combining genomics, proteomics, and metabolomics data to enhance understanding of biological and ecological systems. ● Digital Health and Epidemiology: Utilizing digital tools and AI models to improve public health initiatives and epidemiological research. ● Ethical Implications of Emerging Technologies: Addressing the ethical challenges posed by genetics, AI, and large-scale data analytics in research.
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KENYA INSTITUTE OF PRIMATE RESEARCH (KIPRE) AND ITS CONTRIBUTION TO BETA AND UHC AGENDA:- JUSTIFICATION FOR STAND-ALONE SEMI AUTONOMOUS GOVERNMENT AGENCY

1.0 BACKGROUND

Kenya Institute of Primate Research (KIPRE) is a State Corporation established under the Legal Notice No. 273 of 2017 anchored in Science, Technology & Innovation Act no 28 of 2013 Cap 511 of laws Kenya and executive order no. 2 of 2023 to be the National Centre undertaking Biomedical and Preclinical research using non-human primates and other experimental animals for development of human health products (testing safety/toxicity, efficacy and dosage) and other services that meet local and international standards operating under the Ministry of Health, State Department for Public Health & Professional Standards. KIPRE's agenda is in line with the Government's commitment to provide Universal Health Coverage (UHC) within BETA.

The Kenya Institute of Primate Research (formerly Institute of Primate Research) has been in **existence since 1958** operating as a Directorate under the National Museums of Kenya (NMK) until its establishment as a semi-Autonomous Government Agency-SAGA (detailed KIPRE history is enclosed)

1.1 KIPRE'S FUTURE SUSTAINABILITY

KIPRE's research agenda is geared towards production and commercialization of medical products including drugs, vaccines and snakebite antivenom for human and become self-sustaining in the next 5-10 years. KIPRE research agenda is guided by a Professional Board of Directors and a team of 14 international advisory board members composed of eminent scientists representing the globe and the diverse areas of the institutional research.

1.2 ASSETS FOR RESEARCH AT KIPRE

While acknowledging immense support given by the Kenya Government in funding research and operations at KIPRE throughout its existence. KIPRE's research assets include: well developed laboratories, vehicles, buildings, staff houses, land (in Nairobi, Kajiado, Samburu and recently Tana River) and the Ololua Nature Trail. Additionally, KIPRE has very highly trained research staff for delivery of the health research mandate.

1.3 JUSTIFICATION FOR KIPRE TO OPERATE AS A STAND-ALONE SAGA

In view of the recent Cabinet communication on merging of SAGA's, we request to allow KIPRE to continue operating as a stand-alone SAGA to enable seamless research and development agenda with a focus to produce drugs/vaccines (including snakebite anti-venom) and become self-sustaining in the next 5-10 years as mentioned in the KIPRE strategic focus above.

1.4 KIPRE STRATEGIC FOCUS AND ACHIEVEMENTS

In line with its core mandate (detailed below), KIPRE's research:

1. Is the largest snakebite anti-venom research and development facility in Africa seeking to develop and produce the 1st African based snakebite anti-venom (in partnership with Biovax and Indian Premium Serum company)
2. Is the largest primate research centre in the region and serves to provide a platform for pre-clinical testing of health products before use in humans
3. Is the largest one-health center for dealing with emerging epidemic and pandemic preparedness by mapping and providing early warning signs, developing and pre-clinically

testing preventive and promotive health products e.g vaccines, drugs and medical technologies.

4. Has well developed pipeline for vaccine/drug development with proven record.
5. Expanded with sub-station/field station in Ngare-Narok (Samburu) on donated community land of 75 acres for emerging diseases, snakebite research and conservation activities
6. Expanded with sub-station/field station in Tana River on donated land provided by Ozi Community on 15 acres for vector-borne diseases, water-borne diseases, snakebite research and conservation activities

1.5 FUNCTIONS FOR KIPRE

The core functions of the Kenya Institute of Primate Research as provided under Clause 5 of the Legal Notice No. 273 of 2017 anchored in Science, Technology & Innovation Act no 28 of 2013 are as follows:

- (a) To conduct basic, pre-clinical and translational research using non-human primates and other experimental animals in liaison with the relevant government agencies;
- (b) Establish an incubation Centre linking research and industry in the health products value chain;
- (c) Contribute to early warning systems for emerging and re-emerging diseases;
- (d) Establish and operate a national breeding colony of non-human primates and other experimental laboratory animals for research purposes;
- (e) Provide national in-vitro fertilization services for endangered wildlife of Kenya in liaison with relevant Government agencies;
- (f) Undertake studies in non-human primate conservation biology and primatology
- (g) Create and maintain a national non-human primate database on consensus research affiliations, and geo-spatial distribution of non-human and related zoonotic diseases;
- (h) Serve as a national research Centre for venom and anti-venom including snake bite disease;
- (i) Undertake basic and pre-clinical research on reproductive health, infectious and non-communicable diseases using non-human primates;
- (j) Develop and characterize both non-human primate and other experimental animal models for priority diseases in Kenya;
- (k) Undertake research in Human African Trypanosomiasis disease
- (l) Undertake capacity building in animal welfare, ethical use and care of non-human primates and other experimental animals in laboratory settings;
- (m) Perform any other function which is incidental to the performance of any of the foregoing functions.

1.6 DETAILED KIPRE HISTORY

The Kenya Institute of Primate Research (KIPRE) (formerly Institute of Primate Research-IPR) was founded in 1958 by Dr. LSB Leakey and Cynthia Booth, as the Tigoni primate research center in Limuru. In the first eight years, Tigoni rapidly developed as a research center focusing on studies on the estrous cycle, birth, sexual behavior, and growth of non-human primates. Dr. Leakey fostered field research of primates in their natural habitat, which he understood as key to understanding human evolution. At the end of 1966, the Tigoni National Primate Research center moved with all its equipment and outdoor cages from where it was privately owned by Cynthia Booth to a new 20-acre property about half a mile away that LSB Leakey had solicited and helped to raise funds to purchase it, the funds were granted by the Mani Lalp foundation. By the time the research center was relocating, there were some 120 monkeys in the collection, representing 12 species. Now that the center had become independent of Cynthia Booth, Sir Ferdinand Cavendish-Bentick, the then



chairman of the Museums' trustees of Kenya, offered to facilitate the provision of the funds to the center.

Upon the death of Dr. LSB Leakey on October 1st 1972, his son Dr. Richard Leakey took office as the Director of the National Museums in 1973 and assumed responsibility of running the Tigon National Primate research Center which was now referred to as the Institute of Primate research. Dr. Richard Leakey appointed Dr. Sandy Richards as the Director. Funding originated first from the Louise Leakey Foundation and then from the Kenya Government, and they supported studies in primate morphology, behavior, anatomy, physiology and nutrition. In 1973, Dr. Jim Else took over as the Director and in the remaining years of the 1970's, the Institute of Primate Research began to flourish. It was during Jim's tenure that interest was generated in the development of a primate research center for biomedical research in a country in which animals were indigenous. From 1972-1983 development money from the National Institute of Health through the regional primate research centers in the USA and the World Health Organization (WHO) special programs in human reproduction enabled the expansion of the animal colony and staff. The staff in particular gained from training programs and from a number of consultants based in IPR.

At the beginning of the 1980's, Dr. Richard Leakey obtained 450 acres of land at Oloolua Forest in the name of the National Museums of Kenya (NMK), and by 1983 the construction of new offices, laboratories and animal facilities was completed through funding from the Government of the Netherlands. IPR then moved to its present location at Oloolua, just outside Karen, a suburb of Nairobi. Over the subsequent years, growth of the Institution has been tremendous. Animal numbers have greatly increased, the facilities were enlarged to encompass more laboratories and an administration complex as well as staff housing.

In recent years, KIPRE has successfully competed to secure research funding and as a consequence, research areas have expanded from conservation, ecology, and primatology of the 1960s to include reproductive biology in the 1970's and tropical and infectious parasitology, virology in the 1980's. Through the Kenya Government and International donor community efforts, including individual researcher-driven collaborative research ventures between KIPRE scientists and global partners, KIPRE has grown in its research scope to include new areas of research work that include Reproductive Health, Tropical infectious diseases, Non-communicable diseases, Conservation Biology, Kenya Snakebite Research and Intervention Centre to One Health research ventures.

KIPRE is a WHO collaborating research institute with an International Advisory Board comprising of eminent scientists from across the global with diverse expertise to guide its research agenda. The Institution is compliant with both local and international rules and regulations.

