

**SPECIAL ISSUE**

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REPUBLIC OF KENYA

**KENYA GAZETTE SUPPLEMENT**

**NATIONAL ASSEMBLY BILLS, 2024**

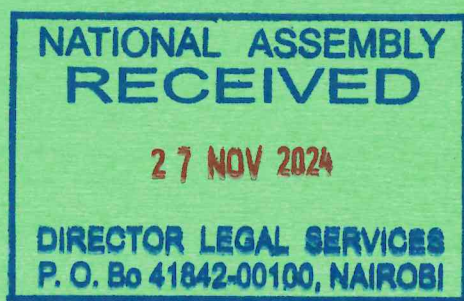
**NAIROBI, 26th November, 2024**

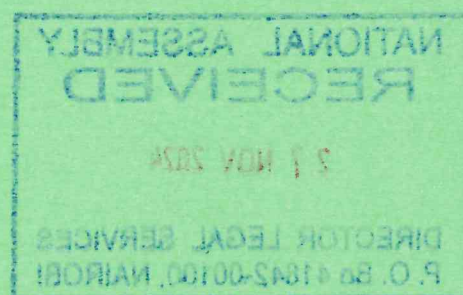
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## **THE KENYA INSTITUTE OF PRIMATE RESEARCH BILL, 2024**

### **A Bill for**

**AN ACT of Parliament to make provision for the establishment, powers and functions of the Kenya Institute of Primate Research; to provide for the conduct of research using non-human primates and other experimental animals for improvement of human health in Kenya and for connected purposes**

**ENACTED** by the Parliament of Kenya as follows—

### **PART I – PRELIMINARIES**

1. This Act may be cited as the Kenya Institute of Primate Research Act, 2024. Short title.

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

“basic research” means research for the advancement of scientific knowledge on health;

“biologicals” means a diverse group of medicines which includes vaccines, anti-venoms, phages, growth factors, immune modulators, monoclonal antibodies and products derived from human blood and plasma;

“biomedical research” means preclinical translational research and testing of medical products in animal models and non-human primates;

“Board” means the Board of Directors of the Institute appointed under section 9;

“breeding colony” means a congregation of generational non-human primates maintained in a designated primate facility;

“Cabinet Secretary” means the Cabinet Secretary responsible for matters relating to health;

“conservation and ecosystem health research” means research on the interaction of animal species and humans and their health status in relation to the environment;



“Director-General” means the Director-General of the Institute appointed under section 16;

“health products and technologies research” means research for drugs or biologicals discovery and testing and related technologies and their evaluation for efficacy, dosage and safety before use in humans;

“human health” means a state of complete physical, mental and social well-being and includes the absence of disease or infirmity;

“incubation centre” means a designated location for nurturing or mentoring research scientists to move research findings from basic research to product development;

“in-vitro fertilization” means an assisted reproductive technology procedure that involves fertilization outside the body;

“Institute” means the Kenya Institute of Primate Research established under section 5;

“Nairobi Metropolitan Area” means the metropolitan region comprising of Nairobi, Kiambu, Machakos and Kajiado counties;

“non-human primates” means all animals in the order of primates except humans;

“pre-clinical research” means research using animals for the testing of biologicals, drugs or procedures for efficacy, dosage and safety before use in humans;

“primatology” means the study of non-human primates in their natural habitat and their interactions to humans;

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

“research infrastructure” means laboratories, biosafety and biosecurity facilities, laboratory equipment, animal cages, vehicles, information, communication and technology equipment, bio-containment facilities, bio-



banks, quarantine and other research related infrastructure supporting the conduct of research;

“sponsoring entity” means a person or an organization providing funds to the Institute for the conduct of research;

“translational research” means research focused on translating or moving results from basic science discoveries into use in humans; and

“zoonotic diseases” means the diseases that may be transmitted between animals and humans.

3. The objects of this Act shall be to—

Objects of the Act.

- (a) establish the Kenya Institute of Primate Research 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;
- (b) improve human health and biodiversity through biomedical research and non-human primate conservation;
- (c) ensure the protection of animal species and their habitats from extinction; and
- (d) establish a training centre for biomedical research, preclinical and clinical research using non-human primates and other experimental animals.

4. A person involved in the implementation of this Act shall have regard to —

Guiding Principles.

- (a) scientific integrity;
- (b) ethics and professional standards;
- (c) quality animal care; and
- (d) openness and accountability.

## **PART II—THE KENYA INSTITUTE OF PRIMATE RESEARCH**

5. (1) There is established an Institute known as the Kenya Institute of Primate Research.

Establishment of the Institute.



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

- (a) suing and being sued;
- (b) taking, purchasing or otherwise acquiring, holding, charging and disposing of movable and immovable property;
- (c) borrowing money;
- (d) entering into contracts; and
- (e) doing or performing all other things or acts necessary for the proper performance of its functions under this Act, which may lawfully be done or performed by a body corporate.

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

Headquarters of  
the Institute.

(2) Despite subsection (1), the Institute may establish such centres as it considers necessary for the proper discharge of its functions.

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

Functions of the  
Institute.

- (a) conduct basic, pre-clinical and translational research, as may be appropriate using non-human primates and, in collaboration with relevant government agencies, other experimental animals including on reproductive health, One Health, infectious and non-communicable diseases;
- (b) undertake studies on primatology, biodiversity conservation and ecosystem health;
- (c) establish and operate a national breeding colony of non-human primates and other experimental laboratory animals for purposes of research;
- (d) promote and undertake scientific and technological invention and innovation for biodiversity and human health using non-human primates and other experimental laboratory animals;
- (e) establish incubation centres for innovation and product development for human health for



- purposes of linking research and industry in the health products value chain;
- (f) in collaboration with the relevant government agencies, undertake research for the improvement of national in-vitro fertilization services for human health;
  - (g) develop and characterize non-human primates and other experimental animal models for priority human diseases in the country;
  - (h) establish and maintain infrastructure and systems for research on non-human primates including a national non-human primate database on population estimates, trends, conservation status, ecology, habitats, spatial distribution, genome sequence and zoonotic diseases;
  - (i) serve as a national research centre for venom and anti-venom including snake bite disease;
  - (j) contribute and respond to early warning systems for emerging and re-emerging diseases;
  - (k) undertake research on neglected tropical diseases including the human African trypanosomiasis disease;
  - (l) build capacity including through providing training on matters related to the conduct of research by the Institute;
  - (m) provide policy advice and make recommendations to the Cabinet Secretary on matters related to research for human health using non-primate humans and other experimental animals;
  - (n) establish a training centre for biomedical research, preclinical research; science entrepreneurship and primatology;
  - (o) serve as the reference laboratory for the conduct of pre-clinical testing of biologicals and health products and technologies using non-human primates and other experimental animals;
  - (p) certify animal care and use programs and facilities for experimental animals; and



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

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

Powers of the  
Institute.

- (2) The Institute shall have the power to—

- (a) manage, control and administer the assets of the Institute in accordance with the Public Procurement and Asset Disposal Act;
- (b) open such bank accounts for the funds of the Institute as may be necessary;
- (c) determine the provisions to be made for capital and recurrent expenditure and for the reserves of the Institute;
- (d) with the approval of the Cabinet Secretary for the time being responsible for matters relating to the National Treasury, invest any surplus funds of the Institute not immediately required for the purposes of this Act, as the Board may determine;
- (e) receive gifts, grants, donations or endowments made to the Institute or any other monies in respect of the Institute and make legitimate disbursements therefrom in accordance with the provisions of this Act;
- (f) levy or charge fees for the services rendered by the Institute as may be determined from time to time by the Board;
- (g) enter into association, collaboration or partnerships with such other bodies or organizations, within or outside Kenya, as it may consider desirable or appropriate and in furtherance of the purposes for which the Institute is established;
- (h) create, develop, apply for and hold rights in intellectual property, and enter into agreements or arrangements for the commercial exploitation of such rights or otherwise as may be appropriate;

Cap. 412C.



- (i) obtain, breed and maintain colonies of non-human primates and other experimental laboratory animals for research purposes;
- (j) establish research centres and departments as may be necessary for the performance of its functions under this Act; and
- (k) undertake any activity necessary for the performance of any of its functions.

9. (1) The management of the Institute shall vest in a Board of Directors comprising of—

The Board of Directors of the Institute.

- (a) a non-executive chairperson appointed by the President;
- (b) the Principal Secretary in the Ministry responsible for matters relating to health or a representative designated in writing;
- (c) the Principal Secretary for the National Treasury or a representative designated in writing;
- (d) six members appointed by the Cabinet Secretary two of whom shall have knowledge and expertise in biomedical research and not more than three of whom shall be public officers; and
- (e) the Director-General who shall be an *ex-officio* member of the Board.

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

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

Qualification for appointment as Chairperson or Member of the Board.

- (a) holds a Doctor of Philosophy degree in biomedical sciences or its equivalent from a university recognized in Kenya;
- (b) has professional knowledge and experience of at least fifteen years in biomedical science or other science-related field;
- (c) has served in a senior management level for a period of at least fifteen years;



- (d) has had a distinguished career as a scientist in research; and
- (e) meets the requirements of Chapter Six of the Constitution.

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

- (a) holds at least a post-graduate degree in biomedical sciences or other science-related field from a university recognized in Kenya;
- (b) has professional knowledge and experience of at least ten years; and
- (c) meets the requirements of Chapter Six of the Constitution.

**11.** (1) The chairperson shall hold office for a term of four years and shall be eligible for re-appointment for one further term of four years. Term of office.

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

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

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

- (a) is unable to perform the functions of the office by reason of prolonged physical or mental illness;
- (b) is otherwise unable or unfit to discharge his or her duties;
- (c) is adjudged bankrupt;
- (d) is convicted of an offence and sentenced to imprisonment for a term exceeding six months, without the option of a fine;
- (e) is absent from three consecutive meetings of the Board without lawful cause;



- (f) resigns by notice in writing to the appointing authority;
- (g) dies; or
- (h) is removed from office in accordance with the provisions of the Constitution or any other written law.

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

Committees of the Board.

(2) The Board may co-opt into the membership of a committee any person whose knowledge and expertise may be necessary for the effective performance of the functions of the Institute in accordance with the Government directives.

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

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

Conduct of business and affairs of the Board.

(2) The Board may regulate its own procedure.

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

Delegation by the Board.

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

Director-General of the Institute.

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

- (a) holds a Doctor of Philosophy degree in biomedical sciences or other science-related field from a university recognized in Kenya;
- (b) has had at least ten years professional experience in matters of biomedical science or other science-related field;



- (c) has served in a senior management level for a period of at least ten years; and
- (d) meets the requirements of Chapter Six of the Constitution.

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

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

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

(6) The Director-General shall—

- (a) be the Chief Executive Officer of the Institute;
- (b) be the accounting officer of the Institute;
- (c) be responsible for—
  - (i) implementing the decisions of the Board;
  - (ii) the day-to-day administration and management of the affairs of the Institute; and
  - (iii) the co-ordination and supervision of the staff of the Institute; and
- (d) perform any other duties as may be assigned by the Board and any other written law.

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

- (a) inability to perform the functions of the office arising out of physical or mental infirmity;
- (b) gross misconduct or misbehaviour;
- (c) incompetence or neglect of duty;
- (d) conviction for an offence relating to the functions of the Institute with a sentence to imprisonment for a term exceeding six months, without the option of a fine;

Removal from  
office of the  
Director-General.



- (e) being adjudged bankrupt;
- (f) being declared as being of unsound mind;
- (g) violation of the Constitution or any other written law; or
- (h) breaching any other grounds specified in the terms and conditions of service of the Director-General.

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

Cap. 7L.

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

Corporation  
Secretary.

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

- (a) holds a post graduate degree in law or any other relevant field from a university recognized in Kenya;
- (b) holds a bachelor's degree in law from a university recognized in Kenya;
- (c) is an Advocate of the High Court of Kenya;
- (d) is a Certified Public Secretary;
- (e) is a member in good standing of the Institute of Certified Public Secretaries of Kenya;
- (f) has at least five years' experience in governance matters; and
- (g) meets the requirements of Chapter Six of the Constitution.

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

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



- (b) take minutes of the meetings of the Board;
- (c) keep, in custody, the records of the deliberations, decisions and resolutions of the Board;
- (d) transmit decisions and resolutions of the Board to the Director-General for execution, implementation and other relevant action;
- (e) provide legal advice to the Board;
- (f) provide guidance to the Board on its duties and responsibilities on matters relating to governance; and
- (g) perform such other duties as the Board may direct.

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

Staff of the  
Institute.

(2) The staff of the Institute appointed by the Board as research scientists shall retire from service at the Institute at the age of seventy years.

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

Remuneration.

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

Protection from  
personal liability.

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



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

Common seal.

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

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

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

### **PART III—RESEARCH BY THE INSTITUTE**

23. (1) The Institute shall conduct research using non-human primates and other experimental animals including—

Management of research.

- (a) basic research;
- (b) biomedical research;
- (c) pre-clinical research;
- (d) translational research;
- (e) health products and technologies research;
- (f) conservation and ecosystem health research; and
- (g) any other type of research as may be determined by the Board from time to time.

(2) The research specified under subsection (1) may be conducted in any manner as may be deemed necessary to address priority diseases in the country.

(3) The Institute shall formulate a Code of Conduct for research for human health using non-human primates.



**24. The Institute shall—**

Conduct of pre-clinical research.

- (a) facilitate research and continuous discovery of medicines including alternative medicine and traditional medicine;
- (b) offer technical expertise in the conduct of pre-clinical research;
- (c) provide technical advice on the regulation of the conduct of pre-clinical testing and trials in the country;
- (d) uphold the integrity of data generated during pre-clinical research;
- (e) ensure the safety and well-being of non-human primates and other experimental animals involved in pre-clinical trials; and
- (f) enhance the competencies and competencies of research scientists in pre-clinical testing and validation.

**25. (1)** The Institute shall, in the event of a public health emergency undertake pre-clinical research or laboratory testing that may be necessary for purposes of—

Public health emergencies.

- (a) addressing or responding to a public health emergency;
- (b) preparing or responding to future public health emergencies; and
- (c) enhancing early warning systems in the country.

**(2)** Where the Institute undertakes pre-clinical research under subsection (1), the Institute shall—

- (a) ensure that the research does not hinder the response to the public health emergency or the provision of healthcare services; and
- (b) prioritize the health needs of affected persons in the conduct of the pre-clinical research and dissemination of the research findings.

**26. (1)** The Institute shall, on its own motion or upon reference, undertake pre-clinical validation and testing of traditional and alternative medicine for purposes of evaluating their efficacy, dosage and safety before use in humans.

Traditional and alternative medicine.



(2) Where the Institute undertakes pre-clinical validation and testing under subsection (1), the Institute shall—

- (a) utilize the country's biodiversity;
- (b) promote biodiversity conservation;
- (c) protect the ecosystem health; and
- (d) promote One Health.

**27.** The Institute shall, in conducting research, ensure—

Considerations in research.

- (a) respect for the care and welfare of animals and non-human primates in accordance with the provisions of the Prevention of Cruelty to Animals Act and the Wildlife Conservation and Management Act;
- (b) promotion and protection of biodiversity and non-human primate conservation;
- (c) compliance with the national and international regulations and treaties on the conduct of research using non-human primates including in the processing of the data collected from the research;
- (d) respect for research participants including upholding data privacy principles in accordance with the Data Protection Act and the Digital Health Act;
- (e) transparency and accountability in all research processes and procedures;
- (f) maximization of benefits and minimization of potential harms or risks in the research to all affected subjects;
- (g) scientific validity in conducting research;
- (h) integrity, reliability and validity of research outcomes;
- (i) monitoring and evaluation of the research development and implementation processes; and
- (j) quality assurance through independent scientific review to ensure the research meets ethical standards.

Cap. 360.  
Cap. 376.

Cap. 411C.  
No. 15 of 2023.



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

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

(2) The Director-General, with the approval of the Board shall appoint the members of the Scientific and Ethics Review Unit which shall comprise of—

- (a) a seasoned research scientist;
- (b) a veterinary doctor from the Department in-charge of animal science at the Institute;
- (c) the Head of Research at the Institute;
- (d) two community representatives, one of whom shall have expertise in matters of pre-clinical research;
- (e) an Advocate of the High Court of Kenya;
- (f) a representative of the Kenya Wildlife Service; and
- (g) a veterinarian, not serving at the Institute from the Division of Veterinary Services at the Ministry responsible for matters relating to livestock.

(3) The Scientific and Ethical Review Unit, in consultation with the Board shall—

- (a) ensure adherence to and compliance with the prescribed international and national standards for scientific conduct and research ethics;
- (b) ensure that all research proposals adhere to scientific and ethical principles that are fundamental to the conduct of research involving non-human primates and other experimental animals;
- (c) review and approve research proposals submitted to the Scientific and Ethics Review Unit;
- (d) monitor approved on-going research protocols to ensure adherence to scientific and ethical principles;
- (e) provide and facilitate training in research methodology and ethics towards building capacity for the research scientists and the committee members;



- (f) review and approve material transfer agreements for use and transfer of research material; and
- (g) ensure adherence to animal use policies, ethics and regulations in the use of non-human primates and other experimental animals for research.

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

Research infrastructure of the Institute.

(2) The Board shall, in establishing a research infrastructure —

- (a) provide for the processes and procedures for the operation of the research infrastructure;
- (b) ensure adherence to the prevailing ethical, regulatory and quality standards for the responsible management and use of research materials and the research data collected out of the research infrastructure;
- (c) develop and implement guidelines or procedures for the management of the research materials including its collection, processing, storage and dissemination;
- (d) provide for the security and safety of the research infrastructure; and
- (e) restrict access to the research infrastructure and the research materials related to the research infrastructure by unauthorized users.

**30.**(1) The Institute shall establish biobanks for the collection, storage and management of biologicals used in pre-clinical research.

Biobanks.

(2) The biobanks shall—

- (a) receive biologicals for storage purposes;
- (b) store aliquots of biologicals for such period as may be prescribed; and
- (c) dispose biologicals in accordance with the prescribed Regulations.



(3) The Institute shall, in establishing the biobanks under subsection (1) —

- (a) determine the protocols for the operation of the biobanks including collection, storage, processing, sharing and access of the biologicals and the associated data;
- (b) ensure adherence to ethical, regulatory and quality standards for the use and management of biologicals and associated data for the conduct of research and human health;
- (c) adopt data management systems for the management of the biobanks; and
- (d) restrict access of the biobanks by unauthorized persons.

31. (1) The Institute shall establish centralized research data bank.

Research data banks.

(2) The Institute shall store research data in the central research data bank established under subsection (1) in a secure form with restricted access in accordance with the relevant laws.

(3) The Board may access research data banks or any information collected by research scientists within the Institute for purposes of human health.

#### **PART IV—CERTIFICATION OF ANIMAL CARE AND USE PROGRAMS AND FACILITIES FOR EXPERIMENTAL ANIMALS**

32. (1) No person shall use or manage an animal care and use program or facility for experimental animals in Kenya unless the person has been certified by the Institute.

Certification.

(2) No experimental animal facility in Kenya shall operate unless certified by the Institute.

33. (1) A person required to be certified under section 32 shall apply for certification to the Board.

Application for certification.

(2) An application under subsection (1) shall be accompanied by —

- (a) a description of the experimental animals to be kept and used at the program or facility;



- (b) a description of the type and purpose of research to be undertaken at the program or facility;
- (c) the type and scope of the program or facility to be set up;
- (d) training to be undertaken for the research scientists using or managing the program or facility;
- (e) contact details of the person managing the program or facility; and
- (f) any other details as may be prescribed by the Board.

(3) A person who knowingly supplies false or misleading information under this section commits an offence and shall be liable, on conviction, to a fine not exceeding three hundred thousand shillings or to imprisonment for a term not exceeding one year, or to both.

(4) The Board shall issue a certificate where the applicant meets the requirements for certification.

(5) A person shall notify the Board of a change in any of the particulars set out under subsection (2).

(6) On receipt of a notification under subsection (5), the Director-General, with the approval of the Board, shall amend the respective entry in the Register.

**34.** A certificate issued under this Act shall be valid for the period determined at the time of the application after taking into account the need for the certificate, and the holder of the certificate may apply for a renewal of the certificate thirty days before the expiry of the certificate.

Validity of the certificate.

**35. (1)** The Director-General shall keep and maintain a register of the certified animal care and use programs and facilities for experimental animals.

Register of animal care and use programs and facilities.

(2) The register under subsection (1) shall contain—

(a) a copy of—

- (i) every application received;
- (ii) the program or facility evaluation report;



- (iii) the certificate issued; and
- (iv) the approval by the Board.

(b) any other information that the Board may consider necessary.

(3) The Director-General may, at the request of the holder of the certificate issued under this Act, remove any entry in the register which has ceased to be applicable.

(4) The register shall be a public document and shall be available for inspection by any person.

**36.** The Board may, on issuance of a notice to show cause, vary terms and conditions of the certificate or cancel the certification where—

Cancellation or variation of the certificate.

- (a) any information given by the applicant is found to be false or misleading; or
- (b) the holder of the certificate, without lawful excuse, fails to comply with any of the requirements of this Act.

**37. (1)** The Board may 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 this Act.

Compliance and audit.

(2) Where the Institute conducts an audit under subsection (1), the Board shall assess matters relating to —

- (a) animal care and use program oversight;
- (b) environment, housing and management;
- (c) veterinary care;
- (d) the physical plants and animal facilities;
- (e) adherence to the prescribed guidelines and standards on animal care and use;
- (f) adherence to the highest scientific, humane, and ethical principles; and
- (g) any other matter as may be determined by the Board.



## **PART V—CAPACITY BUILDING BY THE INSTITUTE**

**38.** The Institute shall build capacity through—

Capacity building.

- (a) the conduct of biomedical and pre-clinical research;
- (b) providing training in the areas set out in the Second Schedule; and
- (c) providing scientific and technical advice on the care and use of experimental animals.

**39.** (1) The training centre of the Institute shall provide specialized short course training programmes in accordance with the functions of the Institute and the training or capacity needs of the country or the region.

Training centre.

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

(3) The Board shall determine the—

- (a) curriculum of the training programmes; and
- (b) training manuals to be used for purposes of the training programmes.

## **PART VI—INTELLECTUAL PROPERTY**

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

Rights to vest in the Institute.

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

**41.** Any information on intellectual property that may not be required to be included in any statement of corporate intent, annual report or financial statements by the Institute may be properly withheld and may be released upon request in accordance with the provisions of the Access to Information Act.

Withholding intellectual property information.

Cap. 7M.



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

Registration of intellectual property.

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

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

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

Ownership of intellectual property.

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

(3) All rights and obligations relating to any invention produced by an employee or associate of the Institute or sponsoring entity, not subject to any agreement approved by the relevant government agency expressly stating otherwise, shall belong exclusively to the Institute.

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

- (a) forfeiture is necessary in the interests of the security of the country; or
- (b) scientific innovation, invention or patent is of strategic importance to the country in accordance with the relevant laws.



**44.**(1) The Institute or sponsoring entity shall determine the commercialization of intellectual property owned by it and shall ensure that reasonable efforts are made to keep the inventors or innovators informed, and where appropriate involved in the commercialization of the intellectual property to which they contributed.

Commercialization  
of intellectual  
property.

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

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

- (a) licensing;
- (b) assignment or sale;
- (c) formation of a commercialization entity or joint venture; or
- (d) donation or royalty free access on humanitarian or other grounds.

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

Benefits.

(2) Where financial benefits are derived from the transfer or licensing of intellectual property rights, any direct costs incurred including expenses relating to the generation of the invention, fees and any other charges resulting from the application for, granting or maintenance of the intellectual property rights and in marketing the invention or innovation shall first be recovered by the owner of the intellectual property.

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

- (a) an innovator or inventor where the inventor has left the employment of the Institute or sponsoring entity;
- (b) the estate of the innovator or inventor where the inventor dies intestate; and
- (c) a beneficiary where the inventor dies testate.



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

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

## **PART VII—FINANCIAL PROVISIONS**

**46.** (1) The funds of the Institute shall comprise of — Funds of the Institute.

- (a) monies appropriated by the National Assembly;
- (b) monies as may accrue to or vest in the Institute in the course of the exercise of its powers or the performance of its functions under this Act;
- (c) monies from fees paid to the Institute in respect of the services offered by it;
- (d) monies as may be payable to the Institute pursuant to this Act or any other written law;
- (e) gifts, grants, donations or endowments as may be given to the Institute; and
- (f) monies from any other lawful source provided for the Institute.

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

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

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



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

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

**48.** The Financial Year of the Institute shall be the period of twelve months ending on the thirtieth day of June in each year.

Financial Year.

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

Annual estimates.

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

- (a) payment of salaries, allowances and other charges in respect of the staff of the Institute;
- (b) payment of allowances and any other emoluments to the members of the Board;
- (c) payment of pensions, gratuities and other charges in respect of retirement benefits which are payable out of the funds of the Institute;
- (d) proper maintenance of buildings and grounds of the Institute;
- (e) acquisition, maintenance, repair and replacement of the equipment and other movable property of the Institute; or
- (f) creation of such reserve funds to meet future or contingent liabilities in respect of retirement benefits, insurance or replacement of buildings or equipment, or in respect of such other matters as the Institute may consider appropriate.

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



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

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

Accounts and  
audit.

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

- (a) a statement of income and expenditure of the Institute during the year; and
- (b) a statement of the assets and liabilities of the Institute on the last day of that year.

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

Cap. 412A.  
Cap. 412B.

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

Annual report.

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

#### **PART VIII—PROVISIONS ON DELEGATED LEGISLATION**

**52.** (1) The Cabinet Secretary may, in consultation with the Board, make regulations for the better carrying into effect of the provisions of this Act.

Regulations.

(2) The regulations made under this section may provide for—

- (a) the fees to be charged under this Act;
- (b) the forms to be used in connection with this Act;
- (c) the management and access of the national breeding colony;
- (d) the establishment and management of incubation centres;



- (e) the management of biologicals;
- (f) the scientific and ethics review mechanism on the conduct of research using non-human primates and other experimental animals;
- (g) the standards and procedures for scientific conduct and research;
- (h) the standards of animal care and use programs and facilities for experimental animals;
- (i) the collection, storage, use and transfer of research materials; and
- (j) any other matter that may be related to the conduct of research using non-human primates and other experimental animals for purposes of human health.

## **PART IX—GENERAL PROVISIONS**

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

Experts.

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

Duty to protect personal data held by the Institute.

Cap. 411C.

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

Disclosure of information held by the Institute.

(2) The Institute shall not disclose any information that would in the opinion of the Board compromise the integrity of the research output, patent and other related rights.

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

Confidentiality.



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

Exemptions.  
Cap. 412A.

**58.** (1) A person who—

Offences.

- (a) refuses or fails, without reasonable cause to comply with a request to furnish the Institute with any information or to produce any documents or records; or
- (b) in furnishing such information under paragraph (a), makes a statement which the person knows or ought to know to be false, commits an offence and shall be liable, on conviction, to a fine not exceeding three hundred thousand shillings or to imprisonment for a term not exceeding one year, or to both.

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

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

**59.** A person who contravenes the provisions of this Act where no penalty is provided, commits an offence and shall be liable, on conviction, to a fine not exceeding five million shillings or to imprisonment for a term not exceeding five years, or to both.

General penalty.

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

Relationship with  
the National  
Commission for  
Science  
Technology and  
Innovation.



- (a) be responsible for research related to non-human primates and other experimental animals; and
- (b) review and approve research proposals related to non-human primates and other experimental animals in accordance with this Act.

## **PART X—REPEAL AND TRANSITIONAL PROVISIONS**

**61.** In this Part, “former institute” means the Kenya Institute of Primate Research established under the Kenya Institute of Primate Research Order, 2017.

Interpretation of part.  
L.N. 273/2017.

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

Reference to the former Institute.

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

Agreements, contracts and other binding instruments.

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

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

Assets and liabilities.

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



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

**65.** A direction, notice, order, permit, authorization, licence or any other document that was granted, issued or made under the Kenya Institute of Primate Research Order, 2017 (now revoked) and that was valid immediately before the coming into force of this Act, shall be given effect as if granted, issued or made under this Act.

Directions, orders, etc. of the former Institute.

**66.** The annual estimates of the former Institute for the Financial Year in which this Act comes into operation shall be deemed to be the annual estimates of the Institute for the remainder of that Financial Year:

Annual estimates of the former Institute.

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

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

Legal proceedings.

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

Board of the former Institute.

**69.** The Director-General of the former Institute shall continue to serve for the remainder of his or her term on the commencement date of this Act.

Chief Executive Officer of the former Institute.

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

Staff of the former Institute.



71. (1) Where on the commencement of this Act any disciplinary proceedings against any officer or member of staff of the former Institute are in the course of being heard, or have been heard or investigated by the former Institute but no order or decision has been made thereon, the Institute shall carry on and complete the hearing or investigation and make an order or render a decision, as if it were done under this Act.

Disciplinary  
proceedings.

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

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

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

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

Pension.

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



governing those schemes or funds, service with the Institute shall be deemed to be service in the former Institute.

(3) The Board may, by order, make provisions with respect to pension or provident fund benefits of the members of staff of the Institute and with respect to the pension scheme and provident fund of the former Institute.

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

**73.** The Kenya Institute of Primate Research Order, 2017 is hereby revoked.

Revocation of  
L.N. 273/2017.



( s. 14(1))

## **FIRST SCHEDULE**

### **CONDUCT OF BUSINESS AND AFFAIRS OF THE BOARD**

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

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

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

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

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

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

(a) venue and time of the meeting; and

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

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

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



(9) The Board may, with approval of the Cabinet Secretary, co-opt or invite any number of persons to act as advisors or consultants at any of its meetings or form such committees to perform such functions or duties of the Board as the Board shall determine.

(10) Subject to the provisions on quorum, no proceedings shall be invalid by reason only of a vacancy among the members of the Board.

(11) Subject to the provisions of this Schedule, the Board may determine its own procedure and the procedure for any committee of the Board.

(12) The quorum for the meetings of the Board shall be five members. Co-opted or invited persons shall not be counted in the quorum of the meetings of the Board and shall not be eligible to vote.

2. Any contract or instrument which, if entered into or executed by a person not being a body corporate, would not require to be under seal, may be entered into or executed on behalf of the Institute by any person generally or specially authorized by the Institute for that purpose.

Contracts and  
instruments.

3. (1) If a member of the Board is present at a meeting of the Board or any committee at which any matter is the subject of consideration and in which matter that person is directly or indirectly interested in a private capacity, that person shall as soon as is practicable before the commencement of the meeting, declare such interest.

Disclosure of  
Interest.

(2) The person making the disclosure of interest under paragraph (1) shall not, unless the Board or committee otherwise directs, take part in any consideration or, discussion of, or vote on any question touching on the matter.

(3) A person who contravenes subparagraph (1) commits an offence and shall be liable, on conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding six months, or to both.

(4) No member of the Board or officer, employee or agent of the Board shall enter into a service contract or trade with the Board.



(5) A disclosure of interest made under this paragraph shall be recorded in the minutes of the meeting at which it is made.

4. The Board shall cause minutes of all resolutions and proceedings of meetings of the Board to be entered in books kept for that purpose.

Minutes.



( s. 38)

## **SECOND SCHEDULE**

### **AREAS OF TRAINING**

- (a) Biomedical research and pre-clinical research for human health using non-human primates and other experimental animals.
- (b) Reproductive Health
- (c) Primatology.
- (d) Ecology and conservation of endangered species.
- (e) Biodiversity.
- (f) Vector borne diseases.
- (g) Snakebite disease.
- (h) Molecular biology.
- (i) Immunology.
- (j) Disease ecology.
- (k) Zoonosis.
- (l) One Health.
- (m) Phage biology.
- (n) Linking research to industry and scientific entrepreneurship and innovation.
- (o) Laboratory animal science.
- (p) Animal welfare, care and use.
- (q) Ethical use and care of non-human primates and other experimental animals in laboratory settings.



## **MEMORANDUM OF OBJECTS AND REASONS**

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.

The Kenya Institute of Primate Research (as currently established vide a Legal Order pursuant to section 16 and 17 of the Science, Technology and Innovation Act, (Cap. 511) needs to be properly anchored in Act of Parliament so as to ensure efficiency and effectiveness in the performance of its functions.

**Part I (clause 1 to 4)** provides for preliminary matters including the short title, the objects of the Act and guiding principles on the implementation of the law when it becomes operational. It further provides various definitions such as biomedical research and primatology among others.

**Part II (clause 5 to 22)** provides for the establishment of the Kenya Institute of Primate Research, 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.

**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 as well as the type of research to be undertaken using non-human primates and other experimental animals among others.

**PART IV (clause 32-37)** makes provision for the certification of animal care and use programs or facilities for experimental animals and experimental animal facilities, 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.

**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.



**Part VI (clause 40-45)** provides for the management of intellectual property over innovations and inventions on health products made by the Institute.

**Part VII (clause 46-51)** provides the sources of funds of the Institute, the modalities on annual reporting by the Institute and handling of the accounts of the Institute including the audit of its finances.

**Part VIII (clause 52)** provides for the delegation of power to the Cabinet Secretary in the Ministry responsible 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.

**Part IX (clause 53-60)** provides for the general provisions such as confidentiality, disclosure and protection of personal data in the conduct of research, offences and penalties.

**Part X (clause 61-73)** provides for the revocation of the Kenya Institute of Primate Research Order, 2017 as well as transitional provisions in relation to the existing contracts and staff among other things in light of the revocation of the 2017 Order.

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

The **Second Schedule of the Bill** provides the training areas to be provided by the Institute.

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

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

#### **Statement on whether the Bill concerns County Governments**

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

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

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

Dated the 12th September, 2024.

ROBERT PUKOSE,  
*Chairperson of the Departmental Committee on Health.*