

NO. 28 OF 2013

THE SCIENCE, TECHNOLOGY AND INNOVATION ACT

SUBSIDIARY LEGISLATION

List of Subsidiary Legislation

	<i>Page</i>
1. The Science, Technology and Innovation (Registration and Accreditation of Research Institutions) Regulations.....	3
2. The Science, Technology and Innovation (Relevance and Quality Assurance in Research) Regulations.....	15
3. The Science, Technology and Innovation (Research Licensing) Regulations.....	21
4. The Kenya Institute of Primate Research Order.....	29

**THE SCIENCE, TECHNOLOGY AND INNOVATION (REGISTRATION
AND ACCREDITATION OF RESEARCH INSTITUTIONS) REGULATIONS**

ARRANGEMENT OF REGULATIONS

Regulation

1. Citation
2. Interpretation
3. Objectives

PART II – REGISTRATION

4. Vetting committee
5. Application for registration
6. Notification of decision
7. Revocation of registration

PART III – ACCREDITATION

8. Application for accreditation
9. Criteria for accreditation
10. Process of accreditation
11. Standards for accredited institutions
12. Monitoring and evaluation
13. Duration of accreditation

PART IV – MISCELLANEOUS

14. Information and records
15. Recognition of researchers

SCHEDULES

FORM FOR APPLICATION FOR REGISTRATION

CERTIFICATE OF REGISTRATION

STANDARDS FOR REGISTERED INSTITUTIONS

APPLICATION FOR ACCREDITATION

CRITERIA FOR ACCREDITATION

PROCESS OF ACCREDITATION

STANDARDS FOR ACCREDITED INSTITUTIONS

THE SCIENCE, TECHNOLOGY AND INNOVATION (REGISTRATION AND ACCREDITATION OF RESEARCH INSTITUTIONS) REGULATIONS

[Legal Notice 106 of 2014]

1. Citation

These Regulations may be cited as the Science, Technology and Innovation (Registration and Accreditation of Research Institutions) Regulations, 2014.

2. Interpretation

In these Regulations, unless the context otherwise requires—

"accreditation" refers to the establishment of the status, legitimacy or appropriateness of an institution, programme of research;

"Act" means the Science, Technology and Innovation Act (Cap. 511);

"Commission" means the National Commission for Science, Technology and Innovation established under section 3 of the Act;

"committee" means the Registration and Accreditation committee established under Regulations 4;

"eligible" means meeting the stipulated requirements;

"institution" means a research institution registered under the Act;

"secretary" means the Secretary of the Commission appointed under section 8 of the Act;

"scientific research" refers to any investigation or research or inquiry or interview that aims to collect data or information, academic or non-academic, in areas of humanities or pure sciences or engineering or technology or for purpose of marketing survey or opinion polls that will lead to new knowledge or information;

"scheduled science" means any of the groups of sciences listed in the Second Schedule to the Act;

"eligibility" has the meaning assigned it under the law relating to Universities Act (Cap. 210).

3. Objectives

The main objective of these Regulations is to uphold the standard of research in the country and secure public confidence in the national research systems.

PART II – REGISTRATION

4. Vetting committee

(1) There shall be a Registration and Accreditation committee which shall be appointed by the Commission.

(2) The committee shall be a standing committee of the Commission and shall consist of—

- (a) five persons appointed from the Commission; and
- (b) two other persons co-opted by the Secretary from time-to-time from outside the Commission on the basis of their specialization in any particular case.

(3) The committee may determine the procedure for its meetings.

5. Application for registration

(1) An application for registration under section 17 of the Act shall be in the form set out in the First Schedule.

[Subsidiary]

(2) The applicant shall forward the application form to the Secretary together with an application fee of two hundred and fifty thousand shillings.

(3) The Secretary shall upon receipt of the application under paragraph (2), refer it to the committee.

(4) A research institution shall be eligible for registration is—

- (a) it is competent to undertake scientific research in the area of discipline;
- (b) it has the capacity in terms of human and financial resources to carry out research;
- (c) it has a physical location for its offices and research facilities; and
- (d) at least half of its directors are Kenyans with relevant expertise.

(5) The committee of the Commission shall present its preliminary reports regarding the application to the Secretary within a period of thirty days from the date of receipt.

(6) The committee shall thereafter consider the application and present a detailed report to the Commission within a period of sixty days together with its recommendation as to whether the research institution in respect of which the application is made should be registered.

(7) Where the committee recommends registration, the Secretary shall forward the same to the Cabinet Secretary who may then proceed to grant, within one hundred and twenty days from the date of receipt of the application, a Certificate of Registration in the form set out in the Second Schedule subject to such conditions as the Cabinet Secretary may specify.

(8) All research institutions registered under these regulations shall adhere to the standards set out in the Third Schedule and code of ethics and guidelines for research.

6. Notification of decision

The Secretary shall notify every applicant of the decision of the committee within fourteen days of receipt of the application, and, where the committee rejects any application, it shall furnish the concerned applicant with reasons thereof.

7. Revocation of registration

The registration of a research institution may be revoked by the Cabinet Secretary where the institution fails to comply with any of the conditions or the standards and guidelines for research after recommendation by the Commission.

PART III – ACCREDITATION

8. Application for accreditation

(1) A research institution which is registered under these Regulations may after the expiration of the period of one year after such registration, apply to the Commission for accreditation.

(2) An application for accreditation shall be in the form set out in the Fourth Schedule and shall be forwarded to the Secretary together with a fee of two hundred and fifty thousand shillings.

9. Criteria for accreditation

A research institution shall be eligible for accreditation if it satisfies the criteria set out in the Fifth Schedule.

10. Process of accreditation

The Commission shall carry out the accreditation of a research institution in accordance with the process set out in the Sixth Schedule.

11. Standards for accredited institutions

A research institution which is accredited under these regulations shall be required to adhere to the standards and guidelines set out in the Seventh Schedule.

12. Monitoring and evaluation

(1) The Commission shall at least once in every three years monitor and evaluate accredited research institutions to ensure compliance by research institutes with the standards set out in the Seventh Schedule.

(2) Notwithstanding paragraph (1), research institutions shall be required to carry out annual monitoring and evaluation internally and to submit the report to the Commission.

13. Duration of accreditation

(1) Accreditation shall be granted to eligible institutions for a period of three years after which it may be renewed on application to the Commission in accordance with these regulations.

(2) There shall be payable a fee of two hundred and fifty thousand shillings in respect of an application of renewal.

PART IV – MISCELLANEOUS

14. Information and records

(1) Research findings and information regarding research systems shall be stored in a designated section of the research institution with clear labeled subject area.

(2) Research findings carried by staff or the research institution shall be in form books or documents and must be bound and the title of the research, author, year and other the relevant information be printed clearly on the cover page.

(3) A report of research work by staff and research institution must be submitted to the commission within two months after publication or compilation of the report of the research work.

15. Recognition of researchers

(1) The Commission shall register, license and regulate researchers in the Scheduled science areas in the Second Schedule to the Act.

(2) The Commission may accredit competent organization or societies to carry out this function on its behalf.

FIRST SCHEDULE

[r. 5(1)]

FORM FOR APPLICATION FOR REGISTRATION

APPLICATION FOR REGISTRATION/RENEWAL**PART I (To be completed by the applicant)****1. Personal Information**

- (a) Full name of Applicant
- (b) Name of Institution applying for registration
- (c) Position of applicant in the Institution
- (d) National Identification Number (ID No.)/Passport
- (e) Permanent Residence Address
- (f) Postal Address
- (g) Contacts: Telephone Fax

E-mail

(Please attach the CV of Applicant and the employees in the top management board)

2. Personal References

[Subsidiary]

(Give names and full addresses of two senior academic/professional referees who are not employees of the research institution to be registered. These should be professionally qualified in the field of research institution intends undertake).

(i) Name

Address

Occupation

Contacts: Telephone Fax

E-mail

Date

(Referee's Signature)

(ii) Name

Address

Occupation

Contacts: Telephone Fax

E-mail

Date

(Referee's Signature)

(a) Is your research institution registered in another country? Yes/No

(b) If yes, please give the details such as country of registration and number registration certificate and date below

.....

4. What is the proposed governance structure of the research institution (please attach the structure to application).....

5. Give initial financial capital and fixed assets for research activities of the proposed research institution

.....

6. Provide in details the area of discipline the proposed research institution shall undertake

.....

I certify that I have read and understood the regulations on the registration and accreditation of research institutions in Kenya, 2013.

Signature Date

PART II*(For official use by NACOSTI only)*

Date Application was received Signature

Approved/not approved

Date Signature

Secretary, National Commission for Science, Technology and Innovation

SECOND SCHEDULE

[r. 5(7)]

CERTIFICATE OF REGISTRATION

FRONT PAGE

Certificate No.

Name of Research Institution

Physical Address

Telephone E-mail

Signature Date

BACK PAGE

Conditions:

1. The certificate of registration is not transferable to another entity.
2. The area of research for which certificate of registration was applied for cannot be changed.
3. The research institution cannot change its physical location without approval of the Secretary of the Commission.
4. The research institutions must notify the Secretary of the Commission in case there are changes in information provided during application of registration.
5. The research activities to the Secretary of the Commission by 31st January every year.
6. The Cabinet Secretary on the advise of the Secretary of the Commission may revoke the Certificate of Registration if the research does not comply with these conditions.

THIRD SCHEDULE

[r. 5(8)]

STANDARDS FOR REGISTERED INSTITUTIONS

An institution must apply to be accredited to Secretary of the Commission

The applying Institution must submit eligible application in a prescribed form as indication of interest to the National Commission of Science, Technology and Innovation. (Application form for accreditation to be drawn from Part IV (17)(3))

Compliance is required for each of the following standards and each standard should be interpreted and applied in the context of the institution's mission and purposes.

Standard 1: Mission, Goals and Objectives

1. The institution's mission must clearly define its purposes within the context of science, technology and innovation and explain whom the institution serves and what it intends to accomplish.
2. The institution's stated goals and objectives, consistent with the aspirations and expectations of research, science and technology must clearly specify how the institution will fulfill its mission.
3. The mission, goals and objectives have been developed and recognized by the institution with its members and its governing body and should be utilized to develop and shape the institution's programs and practices and to evaluate its effectiveness.

Standard 2: Planning, Resource Allocation and Institutional sustainability

[Subsidiary]

1. The institution must be able to conduct ongoing planning and resources allocation based on its mission and should be able to use the results of its assessment activities for institutional sustainability.
2. The implementation and subsequent evaluation of the success of the strategic plan a resource allocation support the development and change necessary to improve and maintain institutional quality.

Standard 3: Institutional Resources and sustainability

The institution should demonstrate is ability to mobilize human, financial, technical, physical facilities, and other resources necessary for the achievement of its mission, including environmental sustainability and institutional policy on Issues of physical challenged. Documentary evidence needed for human resources (sources of funding and sustainability.)

Standard 4: Leadership, Governance and integrity

The institution's policy should clearly define the roles of institutional constituencies in policy development and decision-making. The governance should include active governing body with sufficient autonomy to assure adherence to ethical standard institutional to fulfill its responsibilities of policy and resources development, consistent with the mission of the institution. In the conduct of its programs and activities involving the institution to demonstrate adherence to ethical standards.

Standard 5: Institutional Assessment

The institution has developed and implemented an assessment plan and process that evaluates its overall effectiveness in: achieving its mission and goals; implementing planning, resource allocation, and institutional renewal processes; using institutional resources efficiently; providing leadership and governance; providing administrative structure and services; demonstrating institutional integrity; and assuring that institutional processes and resources support appropriate learning and other outcomes for its students and graduates,

Standard 6: Institutional Database

The institution should maintain research database that can be accessed by Commission.

FOURTH SCHEDULE

[r. 8(2)]

APPLICATION FOR ACCREDITATION

PART I (To be completed by the applicant)

1. Personal Information

- (a) Full name of Applicant
- (b) Name of Institution to be accredited
- (c) Position of Applicant in the Institution
- (d) National Identification Number (ID No.)/Passport
- (e) Permanent Residence Address
- (f) Postal Address
- (g) Contacts:
Telephone E-mail

(Please attach the CV of Applicant and the employees'in the top management/board)

2. Have you applied for accreditation before? Yes/No

If you have applied for accreditation before, please give the details of date of application and accreditation certificate number below

.....

3. What is the governance structure of the research institution (please attach the structure to application).

.....

4. Provide in details the area of discipline the research institution undertakes.

.....

I certify that I have read and understood the regulations on the registration of research institutions and accreditation of research institutions in Kenya, 2014

Signature

Date

PART II

(For official use by NACOSTI only)

Date Application was Received

Signature

Approved/not approved

Date Signature

Secretary, National Commission for Science, Technology and Innovation

FIFTH SCHEDULE

[r. 9]

CRITERIA FOR ACCREDITATION

1. Copy of registration
2. Audited financial statement
3. Mou of collaborating institutions.
4. Copy of institutional organogram.
5. List of available equipment.
6. List of research activities.
7. Vicinity map.
8. Payment or non-refundable fee for accreditation process.

SIXTH SCHEDULE

[r. 10]

PROCESS OF ACCREDITATION

The accreditation procedures

The institutions applying for accreditation will be assessed in accordance with clearly defined procedures. The process will be outlined as follows;

1. Application procedure

[Subsidiary]

- Request for accreditation
 - Application for accreditation reviewing of the application and submitted documents.
 - Acknowledge receipt of confirmation
 - Payment of prescribe fees.
2. Assessment procedure
- Assessment will be carried out by committee
 - Vetting committee to inspect facilities of the institution.
 - Vetting committee prepare assessment report.
3. Accreditation procedure
- Evaluation of the technical assessment reports by the Commission.
 - Decision on accreditation by the Commission.
 - Issuance of Accreditation certificate.
 - The Gazettement of the accredited institution.
- 4- surveillance procedure
- Annual internal monitoring.
 - Evaluation after three years the commission.
 - Apply for renewal of accreditation after every three years.

GUIDELINES FOR APPLICATION OF ACCREDITATION

1. Compliancy with Government regulation- Institution must be registered with the commission (certificate of registration and documents showing legal status)
2. Credibility- must have been inexistence for last one year (The institution must have been operational for at least one year)
3. Vision, mission and mandate and values-
4. Financial status- latest audited financial statement and sources of funding.
5. Organization profile and Human Resource- organogram and research programme, qualifications of staff (CVs)
6. Facilities-permanent offices, equipment and calibration log, IT equipment's, libraries
7. Validity of accreditation:
 - Accreditation granted shall be for three (3) years unless withdrawn by commission.
 - Institution shall be authorized to conduct within their mandate as specified in certificate of accreditation.

SEVENTH SCHEDULE

[rr. 11, 12]

STANDARDS FOR ACCREDITED INSTITUTIONS

Compliance is required for each of the following standards and ach standard should be interpreted and applied in the context of the institution's mission and purposes.

Standard I: Mission, Goals and Objectives

1. The institution's mission must clearly define its purposes within the context of science, technology and innovation and explain whom the institution serves and what it intends to accomplish.
2. The institution's stated goals and objectives, consistent with the aspirations and expectations of research, science and technology must clearly specify how the institution will fulfill its mission.
3. The mission. Goals and objectives have been developed and recognized by the institution with its members and its governing body and should be utilized to develop and shape the institution's programs and practices and to evaluate its effectiveness.

Standard 2: Planning, Resource Allocation and Institutional sustainability

4. The institution must be able to conduct ongoing planning and resources allocation based on its mission and should be able to use the results of its assessment activities for institutional sustainability.
5. The implementation and subsequent evaluation of the success of the strategic plan and resource allocation support the development and change necessary to improve and to maintain institutional quality.

Standard 3: Institutional Resources and sustainability

The institution should demonstrate its ability to mobilize human, financial, technical, physical facilities, and other resources necessary for the achievement of its mission, including environmental sustainability and institutional policy on Issues of physical challenged. Documentary evidence needed for human resources (sources of funding and sustainability.)

Standard 4: Leadership and Governance

The institution's system of governance should clearly define the role of institution constituencies in policy development and decision making. The governance structure should include active governing body with sufficient autonomy to assure institution integrity and ethical standard to fulfill its responsibilities.

Standard 5: Integrity

In the conduct of its programs and activities, the institution should demonstrate adherence to ethical standards.

Standard 6: Institutional Assessment

The institution should have an inbuilt mechanism for monitoring and evaluating effectiveness.

Standard 7: Institutional Database

The institution should maintain research database that can be accessed by the commission.

THE SCIENCE, TECHNOLOGY AND INNOVATION (RELEVANCE AND QUALITY ASSURANCE IN RESEARCH) REGULATIONS

ARRANGEMENT OF REGULATIONS

PART I – PRELIMINARY

Regulation

1. Citation
2. Interpretation
3. Application
4. Objectives

PART II – RELEVANCE AND QUALITY ASSURANCE

5. Relevance
6. Research Capacity
7. Code of ethics
8. Requirements for quality assurance
9. Intellectual

PART III – INSPECTION, MONITORING AND EVALUATION

10. Inspection
11. Monitoring
12. Evaluation

SCHEDULES

GUIDELINES FOR INTELLECTUAL PROPERTY MANAGEMENT POLICY

ITEMS TO BE CONSIDERED FOR MONITORING AND EVALUATION

THE SCIENCE, TECHNOLOGY AND INNOVATION (RELEVANCE AND QUALITY ASSURANCE IN RESEARCH) REGULATIONS

[Legal Notice 107 of 2014]

PART I – PRELIMINARY

1. Citation

These Regulations may be cited as the Science, Technology and Innovation (Relevance and Quality Assurance in Research) Regulations.

2. Interpretation

In these Regulations, unless the context otherwise requires—

"evaluation" means the process of collecting and analyzing information about a research project or programme to ascertain whether it is on track to reach the stated objectives, and whether or not the project or programme achieved or contributed to the desired impact;

"innovation" means the application of new solutions that meet new requirements, inarticulate needs, or existing market needs;

"intellectual property" means creation of the mind, inventions literary and artistic works and symbols, names, images and designs used in commerce and for which exclusive rights are recognized;

"monitoring" means supervising research activities in progress at a research institution to ensure they are proceeding according to plan in order to meet the set objectives;

"quality" means a measure of excellence as a distinctive attribute of the study design, methodology, conduct and other attributes of research project or programmes at a research institution meeting the set objectives;

"relevance" means scientifically or socially beneficial research to socio-economic development;

"research" means any investigation or inquiry which aims to collect and collate data or information, academic or non-academic, in areas of humanities or pure sciences or technology that will lead to new knowledge or information.

3. Application

These Regulations shall apply to all persons and research institutions undertaking research in Kenya.

4. Objectives

The objective of these Regulations is to promote the highest standards, and quality of research for the realization of institutional mandates and national priorities.

PART II – RELEVANCE AND QUALITY ASSURANCE

5. Relevance

Research programmes and activities in research institutions shall be considered relevant if they address national priorities and aspirations and reflect institutional mandates and ethics.

6. Research Capacity

Every research institution shall put in place clear organizational structures with definite responsibilities, systems, procedures, financial resources and facilities for implementing its projects or programmes.

[Subsidiary]**7. Code of ethics**

(1) A research institution shall adhere to the code of ethics for the time being prescribed for the respective areas of research.

(2) A research institution shall be required to establish an institutional scientific and ethical review committee which shall be accredited by the Commission.

(3) An institutional scientific and ethical review committee shall develop guidelines or manuals and deposit them with the Commission.

8. Requirements for quality assurance

(1) A research institution shall develop standard operating procedures and manuals to provide an optimum degree of order in research activities in their specific contexts and in line with international benchmarks recognized by the Commission.

(2) For the purposes of attaining relevance and quality in research, institutions shall develop—

- (a) a strategic plan;
- (b) a service charter;
- (c) manuals on human resources, finance and procurement;
- (d) performance reporting procedures;
- (e) good corporate governance;
- (f) relevant policy codes of ethics;
- (g) information, innovation and knowledge management manual;
- (h) productivity and quality management manual; and
- (i) customer care and orientation manual.

9. Intellectual

(1) Each research institution shall put in place a policy on intellectual property rights in line with the relevant law for the time being in force.

(2) In the development of the policy under subparagraph (1), a research institution shall follow the guidelines set out in the First Schedule.

PART III – INSPECTION, MONITORING AND EVALUATION**10. Inspection**

(1) The Commission shall inspect, monitor and evaluate every research institution in order to verify relevance and assure quality and compliance with these Regulations.

(2) The inspections referred to in subparagraph (1) shall comprise a pre-registration inspection, a compliance inspection and a special inspection as may be directed by the Commission from time to time.

(3) The Commission shall appoint experts in relevant disciplines, who may include persons from outside the commission, to carry out the inspections.

11. Monitoring

(1) The Commission shall undertake regular systematic collection and analysis of information on the progress of research in an institution with the purpose of improving efficiency and effectiveness in the operations of the institution.

(2) The Commission shall in carrying out monitoring under subparagraph (1) follow the guidelines set out in the Second Schedule.

12. Evaluation

(1) The Commission shall undertake an assessment of the impact of a project or programme against the objectives and expected outputs thereof as stated at the design stage of the project, and shall require the institution to provide a full explanation where the set objectives and outputs are found not to have been achieved.

(2) The Commission may, where the researcher is found to have been negligent in the implementation of the research under subparagraph (1), take appropriate action, which may include recommendation of suspension of funds, recovery of any misappropriated funds or legal action.

FIRST SCHEDULE

[r. 9]

GUIDELINES FOR INTELLECTUAL PROPERTY MANAGEMENT POLICY

1. *Objectives of an Intellectual Property Policy for Institutions*

Intellectual property, management policy should bring harmony to the conflicting interests of all the stakeholders in the generation and commercialization of a patent. Universities and Research and Development institutions should be dedicated to teaching and research, and to the dissemination of all new knowledge generated. The basic goal of an intellectual property management policy should therefore be—

- (a) to provide for the intellectual property generated at the institution;
- (b) to promote the progress of science and technology;
- (c) to ensure that discoveries, inventions and creations generated by staff and students are utilized in ways most likely to benefit the public; and
- (d) to ensure fair and equitable distribution of all benefits accruing from inventions and creations at the institutions.

2. *Issues to be addressed by an Intellectual Property Management Policy*

In order to harmonize the various conflicting interests of stakeholders and achieve broad-based objectives, an intellectual property management policy for universities and R & D institutions should address some of the following issues:

- (a) Coverage of intellectual property policy;
- (b) Ownership of intellectual property;
- (c) Disclosure of intellectual property;
- (d) Marketing, commercialization and licensing of patents;
- (e) Distribution of benefits;
- (f) Rights and obligations of an inventor and the institution;
- (g) Conflict resolution mechanism;
- (h) Material Transfer Agreements;
- (i) Access and benefits sharing management; and
- (j) Other pertinent issues.

SECOND SCHEDULE

[r. 11(2)]

ITEMS TO BE CONSIDERED FOR MONITORING AND EVALUATION

Monitoring shall address issues as follows—

- (a) Purpose of the institution (adherence to the character, mandate and objectives);
- (b) Research policy;
- (c) Human resource capacity and capabilities;
- (d) Research infrastructure and environment;

[Subsidiary]

- (e) Facilities like laboratories, communication; transport and any other;
 - (f) Internal quality assurance system;
 - (g) Management of intellectual property rights;
 - (h) Standard operating procedures and manuals;
 - (i) Logical framework;
 - (j) Collaboration and partnerships with industry, national and institutions and universities;
 - (k) Integrated information management system for storage and retrieval;
 - (l) Scientific and ethical review committees; and
 - (m) Dissemination strategies.
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**THE SCIENCE, TECHNOLOGY AND INNOVATION
(RESEARCH LICENSING) REGULATIONS**

ARRANGEMENT OF REGULATIONS

PART I – PRELIMINARY

Regulation

1. Citation
2. Interpretation
3. Co-ordination of research
4. Exemption

PART II – LICENSING

5. Application for licence
6. Consideration of an application
7. Grant and renewal of licence
8. Determination of a revised application
9. Appeal against refusal
10. Register
11. Monitoring to ensure compliance
12. Notice to rectify and sanctions
13. Revocation
14. Final report submission

SCHEDULES

APPLICATION FORM FOR LICENCE

LICENCE

THE SCIENCE, TECHNOLOGY AND INNOVATION (RESEARCH LICENSING) REGULATIONS

[Legal Notice 108 of 2014]

PART I – PRELIMINARY

1. Citation

These Regulations may be cited as the Science, Technology and Innovation (Research Licensing) Regulations.

2. Interpretation

In these Regulations, unless the context otherwise requires-

"Act" means the Science, Technology and Innovation Act (Cap. 511);

"Commission" means the National Commission for Science, Technology and Innovation established under section 3 of the Act;

"licence" means a licence issued under regulation 5 and includes a permit;

"licensee" means the holder of a licence or permit;

"research" means the systematic investigation into and study of materials and sources in order to establish facts and reach new conclusion;

"researcher" means a person licenced under these regulations to conduct research.

3. Co-ordination of research

All scientific research activities shall be co-ordinated by the Commission to ensure that no harm occurs to the natural, social and cultural environments of Kenya and human life.

4. Exemption

These Regulations shall not apply to a person conducting research under a University or a research institute program.

PART II – LICENSING

5. Application for licence

(1) An application for a licence under section 12 of the Act shall be in the form set out in the First Schedule and shall be accompanied by-

- (a) a cover letter and full proposal; and
- (b) such fees as may be specified by the Commission from time to time and published in the *Gazette*.

(2) A foreign researcher applying for a licence shall be affiliated to a local relevant institution.

(3) Where a research requires ethical review or issuance of a permit by another national institution, the applicant shall obtain such review or permit prior to making an application for a licence to the Commission.

(4) Where a research involves the transfer or exportation of specimens or materials, the applicant shall seek and obtain clearance from the relevant Government agency before making an application for a license to the Commission.

6. Consideration of an application

The Commission shall, within thirty days from the date of receipt of the application under paragraph 5 consider the application and notify the applicant on the decision of the Commission.

[Subsidiary]**7. Grant and renewal of licence**

(1) Where the Commission is satisfied that the applicant satisfies the requirements set out in the Act, the Commission shall grant a research licence.

(2) A licence granted under paragraph (1) shall be valid for a period of one year from the date of issue and shall be renewable on receipt of an application for renewal at least two months prior to the date of expiry.

(3) A research licence issued under the Act shall be in the form set out in the Second Schedule.

(4) Where the Commission is of the opinion that the application does not meet the conditions required under the Act, the Commission may-

- (a) reject the application; or
- (b) make its comments or recommendations thereon and forward them to the applicant.

(5) An application whose application has been commented upon may resubmit a revised application within a period of sixty days on receipt of the Commission's comments.

8. Determination of a revised application

On receipt of a revised application under paragraph 7(5) the Commission shall, within thirty days from the date of receipt determine the application in accordance with these regulations, and if satisfied, grant a licence in accordance with the Act.

9. Appeal against refusal

Any person aggrieved by the decision of the Commission under these Regulations, may appeal to the Cabinet Secretary within thirty days of being notified of the decision.

10. Register

The Commission shall maintain a register of all persons granted licences under the Act which shall indicate—

- (a) the name of the licensee;
- (b) the nature of the research undertaken by the licensee;
- (c) the physical address of the premises of the licensee;
- (d) the number and date of issue of the licence; and
- (e) source of funding.

11. Monitoring to ensure compliance

The Commission may at least once in a year conduct or cause to be conducted an evaluation of research carried out under the Act for the purpose of assessing and evaluating compliance with the conditions of the licence.

12. Notice to rectify and sanctions

The Commission may by notice in writing, require a researcher who is the subject of an evaluation under paragraph 11 to comply with any such standard or instruction as the Commission may specify within a prescribed time and in a prescribed manner.

13. Revocation

The Commission may revoke a research licence if the licensee contravenes any of the conditions of the licence.

14. Final report submission

An applicant who has been licensed under these Regulations to conduct research in Kenya shall deposit a copy of the final research report to the Commission within one year of completion.

FIRST SCHEDULE

[r. 5]

APPLICATION FORM FOR LICENCE**PART I (to be completed by the applicant)****1. Personal Information**

- (a) Full name of Applicant
- (b) Name of Institution (if applying for institutional permit and attach CV of researchers)
- (c) Approving Authority (e.g. CEO, Director)
- (d) National Identification Number (ID No.)/Passport No.
- (e) Physical Address.....
- (g) Contacts:
 - Telephone Fax.....
 - Mobile No.
 - E-mail
- (h) Gender
- (i) Highest Qualification

(Please attach the above details and Curriculum Vitae for other researchers in your team)

2. Personal References

(Give names and full addresses of two senior academic/professional referees, These should be professionally qualified in the field of research which the applicant wishes to undertake)

- (i) Name.....
 - Address.....
 - Profession/Occupation.....
 - Contacts:
 - Tel:..... Mobile.....
 - Fax.....
 - E-mail.....
- (ii) Name.....
 - Address.....
 - Profession/Occupation.....
 - Contacts:
 - Tel:.....
 - Fax.....
 - E-mail.....

[Subsidiary]

- (a) Have you applied for a licence to conduct research in Kenya before? Yes/No
- (b) If (a) above is yes, provide the title of the recent research previously applied for

.....

.....

.....

.....

.....

- (c) If the application was approved vide the Licence, No.

.....

.....

Dated.....

- (d) If the application was rejected vide the application. No.

.....

.....

Dated

4. Title of the research project

.....

.....

.....

.....

- (a) Source(s) of finance

.....

.....

- (b) Amount of currency

.....

.....

6. Purpose of the research

.....

.....

7. Location of research:

Location/Division

County

8. Estimated period of the project: from.....to.....

9. Do you need access to the Public Records? (if yes list)

.....

.....

10. Do you need to interview any Government Officials? (if yes list them)

.....

.....

 11. What research tools (e.g. questionnaire) do you intend to use? (*attach copies*)

.....

 I certify that I have read and understood the Science, Technology and Innovation (Research Licensing) Regulations, 2014. I do agree to abide by them as required and that the information given by me in Part I is correct to the best of my knowledge.

Signature Date.....

PPART II

(For official use only)

Date Application Received.....

Signature.....

Receipt Number.....

Approved/not approved.....

Date.....Signature.....

Secretary, National Commission for Science, Technology and Innovation

SECOND SCHEDULE

[r. 7(3)]

LICENCE

Application Reference No.

Licence No.

This is to certify that the application to conduct research in Kenya received from of P.O Box

to the Commission in accordance with Research Licence Regulations to conduct research titled

located at (Locality and county) has been evaluated and a licence is hereby issued, subject to the attached conditions.

This License is valid from to

Dated thisday 20

Signature

(Official Seal)

Commission Secretary National Commission for Science, Technology and Innovation

Conditions of Licence

1. The licence shall only be used for the intended research and the specified period and research site.

2. Neither the licence nor any right thereunder shall be transferred, assigned, or disposed of in any manner, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the licence to any person.

[Subsidiary]

3. The Commission reserves the right to cancel at any time during the research period if in the opinion of the Commission the research is not implemented in conformity with the provisions of the Act or any other written Law.
 4. Upon request of the Commission, the licensee shall, at any time before expiration of the licence, submit written statements, signed under oath or affirmation if appropriate, to enable the Commission to determine whether or not the licence should be modified, suspended, or revoked.
 5. The Licensee shall inform the County Governor in the area of research before commencement of the research, failure to which will lead to cancellation of the licence.
 6. Excavation, filming and collection of specimens are subject to further permissions from relevant government agencies.
 7. The Commission reserves the right to modify the conditions of this Licence including its cancellation without prior notice.
 8. This Licence does not give authority to transfer research materials.
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THE KENYA INSTITUTE OF PRIMATE RESEARCH ORDER

ARRANGEMENT OF PARAGRAPHS

PART I – PRELIMINARY

Paragraph

1. Citation
2. Interpretation

PART II – ESTABLISHMENT AND FUNCTIONS OF THE INSTITUTE

3. Establishment
4. Objective
5. Functions of the Institute
6. Powers of the Institute

PART III – THE BOARD OF THE INSTITUTE

7. The establishment of the Board
8. Powers of the Board
9. Director General
10. Committees
11. Delegation by Board
12. Vacancy in office
13. Meetings
14. Disclosure of interest
15. Common seal
16. Remuneration
17. Appointment of staff
18. Protection from personal liability

PART IV – FINANCIAL PROVISIONS

19. Funds of the Institute
20. Financial year
21. Annual estimates
22. Books of accounts
23. Audit
24. Investments of funds
25. *[Spent]*

SCHEDULES

TRANSITIONAL PROVISIONS

THE KENYA INSTITUTE OF PRIMATE RESEARCH ORDER

[Legal Notice 273 of 2017]

PART I – PRELIMINARY**1. Citation**

This Order may be cited as the Kenya Institute of Primate Research Order.

2. Interpretation

In this Order, except where the context otherwise requires—

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

"Board" means the Board of the Institute established under paragraph 7;

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

"Cabinet Secretary" means the Cabinet Secretary for the time being responsible for matters relating to science and technology;

"conservation Biology" means the study of animal species with the aim protecting them their habitats from extinction;

"Director-General" means the Director General of the Institute appointed under paragraph 9;

"incubation centre" means a designated location for nurturing or mentoring scientists to move basic research to product development;

"Institute" means the Kenya Institute of Primate Research established under paragraph 3;

"member" means a member of the Board;

"non-human primate" means all animals in the order of primates except humans;

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

"staff" means the staff of the Institute;

"zoonotic diseases" means those diseases that can be transmitted between animals and humans.

PART II – ESTABLISHMENT AND FUNCTIONS OF THE INSTITUTE**3. Establishment**

(1) There is hereby established a Institute to be known as the Kenya Institute of Primate Research which shall be a body corporate with perpetual succession and a common seal, and which shall in its corporate name, be capable of—

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

[Subsidiary]

(2) The Institute shall be a successor to the Institute of Primate Research, a Directorate under the National Museums of Kenya and existing immediately before the commencement of this Order.

4. Objective

The Institute shall be the national centre undertaking biomedical and preclinical research in primates for development of health products and other services that meet local and international standards.

5. Functions of the Institute

The functions of the Institute shall be to—

- (a) 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 census, 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; and
- (m) perform any other function which is incidental to the performance of any of the foregoing functions.

6. Powers of the Institute

The Institute shall in the performance of its functions under this Act have power to—

- (a) create, develop, apply for and hold intellectual property rights and enter into agreements or arrangements for their commercial exploitation or otherwise as the Board may consider appropriate;
- (b) enter into partnerships and collaborations with other similar institutions or professional organizations, whether within or outside Kenya;
- (c) charge fees for services rendered by it;
- (d) breed and maintain colonies of non-human primates and other experimental laboratory animals for research purposes; and
- (e) do any other thing which is necessary or convenient to be done in connection with or incidental to its functions.

PART III – THE BOARD OF THE INSTITUTE

7. The establishment of the Board

(1) There shall be a Board of Directors of the Institute, which shall have the responsibility of managing the Institute in accordance with this Order.

(2) The Board shall consist of—

- (a) a chairperson appointed by the Cabinet Secretary;
- (b) the Principal Secretary in the Ministry for the time being responsible for matters relating to science and technology;
- (c) the Principal Secretary in the National Treasury;
- (d) the Director-General of the National Museums of Kenya;
- (e) five persons with knowledge and experience in research, two of whom should be having experience in biomedical research; and
- (f) the Director-General of the Institute, who shall be an *ex-officio* member.

(3) A person shall be qualified for appointment as a chairperson of the Board if the person—

- (a) in the case of the chairperson—
 - (i) holds a doctorate degree from a university recognized in Kenya;
 - (ii) is an eminent scientist in research; and has at least fifteen years' experience in leadership and management of public or private institutions; and
- (b) in the case of any other member of the Board, holds at least a Masters degree from a university recognised in Kenya.

(4) The chairperson and members of the Board of the institute shall be required to be persons of integrity in accordance with Chapter Six of the Constitution and capable of contributing to science, technology and innovation.

(5) All appointments under this section shall be by notice in the *Kenya Gazette*.

(6) The members of the Board shall hold office, in the case of the chairman, for a period of four years, and in the case of any other member other than an *ex-officio* member, for a period of three years, and shall be eligible for reappointment for one further term.

8. Powers of the Board

The Board shall have all the powers necessary for the proper performance of its functions under this Order, and in particular, but without prejudice to the generality of the foregoing, the Board shall have power to—

- (a) manage, supervise and administer the assets of the Institute in such a manner as best promotes the purpose for which the Institute is established;
- (b) determine the provisions to be made for capital, and recurrent expenditure and for reserves of the Institute;
- (c) receive any grants, gifts, donations or endowments on behalf of the Institute and make legitimate disbursements therefrom;
- (d) enter into association with such other bodies or organizations within or outside Kenya as the Board may consider desirable or appropriate and in furtherance of the purpose for which the Institute is established;
- (e) open a banking account or bank accounts for the funds of the Institute; and
- (f) perform any other function that enhances or adds value to the proper performance of the functions of the Institute.

[Subsidiary]**9. Director General**

(1) There shall be a Director-General of the Institute who shall be appointed by the Board following competitive recruitment and on such terms and conditions as may be specified in the instrument of appointment.

(2) The Director-General shall be the chief executive officer of the Institute and responsible to the Board for the day-to-day management of the affairs of the Institute.

(3) A person shall be qualified to be appointed as Director-General where such person—

- (a) has a Doctorate degree in biomedical sciences or other related scientific fields; and
- (b) has at least ten years' experience in the management of a public institution.

(4) The Director General shall hold office for a period of five years renewable for one further term.

10. Committees

(1) The Board may establish such committees as it may consider appropriate for the performance of its functions under this Order.

(2) The Board may from time to time co-opt into its membership any person whose knowledge and experience may assist it in the consideration of any particular matter for the time being before the Board.

11. Delegation by Board

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

12. Vacancy in office

(1) The office of the Chairperson or a member of the Board, other than an *ex-officio* member, shall become vacant—

- (a) when the member resigns by notice in writing to the Cabinet Secretary, which notice shall take effect on the date specified therein, and, where no date is specified, on the date of receipt of the notice by the Cabinet Secretary; or
- (b) where the vacancy occurs pursuant to subsection (2).

(2) The office of the chairperson or a member of the Board shall become vacant if the chairperson or member—

- (i) becomes insolvent or enters into a composition or scheme of arrangement for the benefit his creditors;
- (ii) is convicted of any offence and sentenced to imprisonment for a period of more than six months by a court of competent jurisdiction;
- (iii) is incapacitated by reason of infirmity of body or mind;
- (iv) is absent from three consecutive meetings of the Board without the leave of the Cabinet Secretary in case of the chairperson, or in case of a member, the Chairperson; or
- (v) is otherwise unable or unfit to discharge the functions of his office.

(3) Where the office of the chairperson or a member of the Board becomes vacant under this paragraph, the Cabinet Secretary may appoint another person as a replacement of the person vacating office.

13. Meetings

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.

14. Disclosure of interest

(1) If a member is directly or indirectly interested in any contract, proposed contract or other matter before the Board and is present at a meeting of the Board at which the contract, proposed contract or other matter is the subject of consideration, the member shall, at the meeting and as soon as reasonably practicable after the commencement thereof, disclose the fact, and shall not take part in the consideration or discussion of, or vote on, any questions with respect to the contract or other matter, or be counted in the quorum of the meeting during consideration of the matter.

(2) A disclosure of interest made under this section shall be recorded in the minutes of the meeting at which it is made and also in the Conflict of Interest Register maintained by the Institute.

15. Common seal

(1) The common seal of the Institute shall be kept in such custody as the Board may direct and shall not be used except in the manner authorized by the Board.

(2) All deeds, instruments, contracts and other documents shall be deemed to be duly executed by or on behalf of the Board—

- (a) where they are required to be under seal, when the seal is authenticated by the signature of the chairperson, or any other member of the Board nominated in that behalf by a decision of the Board, and the Director-General:

Provided that 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 Board on behalf of either the Chairperson or the Director-General;

- (b) where they are not required to be under seal, if executed in that behalf by a member authorized by the Board for that purpose.

16. Remuneration

The members of the Board shall be paid such remuneration or allowances as the Board may, with the approval of the Salaries and Remuneration Commission, determine.

17. Appointment of staff

The Board may appoint such officers and staff as may be necessary for the proper discharge of the functions of the Institute under this Order upon such terms and conditions of service all the Board may determine.

18. Protection from personal liability

Nothing done by a member of the Board or any officer, employee or agent of the Board shall, if it is done *bona fide* for executing the functions, powers or duties of the Board, render the member, officer, employee or agent or any person acting on the directions of the Board, personally liable for any action, claim or demand whatsoever.

PART IV – FINANCIAL PROVISIONS**19. Funds of the Institute**

The funds of the Institute shall comprise of—

- (a) such sums as may be appropriated by Parliament for the purposes of the Institute;
- (b) such 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 Order or under any other written law; and
- (c) all monies from any other source provided for or donated or lent to the Institute.

[Subsidiary]

20. Financial year

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

21. Annual estimates

(1) At least four months before the commencement of each financial year, the Board shall cause to be prepared estimates of the revenue and expenditure of the Institute for that year.

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

- (a) the payment of salaries, allowances, pensions, gratuities and other charges in respect of the Board and staff of the Institute;
- (b) provision of funds for the functions of the Institute; and
- (c) the proper maintenance of the Assets and grounds of the Institute.

(3) The annual estimates shall be approved by the Board at least two months before the commencement of the financial year to which they relate and shall be submitted to the Cabinet Secretary for approval.

22. Books of accounts

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

23. Audit

(1) The Board shall ensure that all money received is properly brought to account, all payments out of its funds are correctly made and properly authorized and that adequate control is maintained over its assets and liabilities.

(2) The accounts of the Institute shall be audited in accordance with the Public Audit Act (Cap. 412B).

24. Investments of funds

(1) The Board may from time to time invest any of the funds of the Institute in any securities in which trust funds are authorized by law subject to approval by the Cabinet Secretary in charge of the National Treasury.

(2) The Board may, subject to the approval of the National Treasury, place on deposit with such bank or banks as the Board may determine, any monies not immediately required for the purposes of the Institute.

25.

[Spent]

SCHEDULE

[p. 25]

TRANSITIONAL PROVISIONS

Spent
