

## AN ACT TO ESTABLISH THE ZANZIBAR HEALTH RESEARCH INSTITUTE AND OTHER MATTERS CONNECTED THEREWITH

#### ARRANGEMENT OF SECTIONS

#### **SECTIONS**

#### TITLE

### PART ONE PRELIMINARY PROVISIONS

- 1. Short title and Commencement.
- 2. Interpretation.

# PART TWO THE HEALTH RESEARCH INSTITUTE

- 3. Establishment of the Institute.
- 4. Seal and logo of the Institute.
- 5. Objectives of the Institute.
- 6. Functions of the Institute.
- 7. Powers of the Institute.

# PART THREE ADMINISTRATION AND MANAGEMENT OF THE INSTITUTE

- 8. Establishment and Composition of the Board.
- 9. Secretary of the Board.
- 10. Functions of the Board.
- 11. Powers of the Board.
- 12. Meetings of the Board.
- 13. Vice Chairperson.
- 14. Quorum of a meeting.
- 15. Decisions of the Board.



- 16. Tenure of the Chairperson and members of the Board.
- 17. Procedures of the meetings.
- 18. Vacancy of a Member.
- 19. Remuneration for Members.
- 20. Co-option.
- 21. Conflict of interest.
- 22. Delegation of the functions of the Board.
- 23. Termination or suspension of the member of the Board.
- 24. Committees of the Board.

# PART FOUR THE DIRECTOR GENERAL AND OTHER STAFF OF THE INSTITUTE

- 25. Appointment of the Director General.
- 26. Functions of the Director General.
- 27. Staff of the Institute.

### PART FIVE BIOLOGICAL MATERIALS FOR HEALTH RESEARCH, AND RESEARCH IN TRADITIONAL AND ALTERNATIVE MEDICINE

- 28. Purposes of collection of biological materials.
- 29. Storage of biological materials
- 30. Exportation and importation of biological materials.
- 31. Control of Biological materials.
- 32. Research in traditional and alternative medicine.

### PART SIX INTELLECTUAL PROPERTY RIGHTS

33. Intellectual property rights.



### PART SEVEN FINANCIAL PROVISIONS

- 34. Funds of the Institute.
- 35. Estimates of income and expenditure.
- 36. Accounts and audit.
- 37. Annual performance report.
- 38. Opening of bank account.

### PART EIGHT OFFENCES AND PENALTIES

- 39. Offences and Penalties.
- 40. General penalty.

# PART NINE MISCELLANEOUS PROVISIONS

- 41. Clinical Trial.
- 42. Regulations.
- 43. Repeal and Savings.



**ACT NO. 5 OF 2020** 

**I ASSENT** 

{ DR. ALI MOHAMED SHEIN}
PRESIDENT OF ZANZIBAR AND CHAIRMAN OF
THE REVOLUTIONARY COUNCIL

Alhein

.., 2020

# AN ACT TO ESTABLISH THE ZANZIBAR HEALTH RESEARCH INSTITUTE AND OTHER MATTERS CONNECTED THEREWITH

**ENACTED** by the House of Representatives of Zanzibar.

#### PART ONE PRELIMINARY PROVISIONS

Short title and Commencement.

1. This Act may be cited as the Zanzibar Health Research Institute Act, 2020 and shall come into operation after being assented to by the President.

Interpretation.

- 2. In this Act, unless the context otherwise requires:
  - "alternative health practitioner" means a person formally trained and has acquired knowledge, skills and competence in alternative medicine practices and disciplines as recognized nationally and internationally;
  - "alternative medicine" means the total sum of knowledge and practice used in diagnostic, prevention, treatment and elimination of physical, mental and social imbalance relying exclusively on various established alternative medicine system of respective disciplines;

"animal" means any vertebrate, invertebrate or other fauna except man;



- "animal subject" means an animal which is used for health research or clinical trial;
- "bio-bank" means a collection of biological materials and the associated data and information which is stored in an organized system;
- "biological materials" means organs and parts of organs, cells and tissue, sub cellular structures and cell products, blood, saliva, virus, sputum, gametes, embryos, foetal tissue and waste including urine, feces, sweat, hair, epithelial scales, nail clippings, placenta and cell lines from human or animal tissue;
- "blood product" means any product derived or produced from blood, including circulating progenitor cells, bone marrow progenitor cells and umbilical cord progenitor cells;
- "Board" means the Board of Directors of the Institute established under the provisions of section 8(1) of this Act;
- "clinical trial" means a systematic study, involving human participants or animal subjects, that serves to answer specific questions about the safety or efficacy of a medicine, vaccine or method of prevention or treatment;
- "Chairperson" means the Chairperson of the Board appointed under the provisions of section 8(1)(a) of this Act;
- "Director General" means the Director General of the Institute appointed under the provisions of section 25 (1) of this Act;
- "Genetic material" means a part of a cell that carries biological information which can be passed over the next generation;
- "Government" means the Revolutionary Government of Zanzibar;
- "health center" means public or private buildings or other places, operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health services;



"health research" means any activity conducted which:

- (a) contributes to knowledge of the biological, clinical, psychological or social processes in human beings or animals;
- (b) uses scientific methods to generate information to deal with health and disease;
- (c) improves scientific methods for provision of health services and human pathology;
- (d) investigates causes of disease and the effects of the environment on the human body; or
- (e) develops new applications of pharmaceuticals, medicines and health technology;
- "human participant" means any living person who consents to participate in a health research activity or a body of a deceased person or part of a body of a deceased person;
- "Institute" means the Zanzibar Health Research Institute as established under section 3 of this Act;
- "Intellectual property rights" means an exclusive right granted to an inventor and owner of works that are the result of human intellectual creativity;
- "material transfer agreement" means a written contract between the provider and recipient of research material;
- "medicine" means human medicine, veterinary medicine, medicinal product, herbal medicine or any substance or mixture of substances for human or veterinary use, or intended to be used or manufactured for use for its therapeutic efficacy or for its pharmacological purpose in the diagnosis, treatment, alleviation, modification or prevention of disease or abnormal physical or mental state or the symptoms of disease in a person or animal;
- "Minister" means the Minister responsible for matters relating to health;
- "President" means the President of Zanzibar and Chairman of the Revolutionary Council;



"research proposal" means a research proposal for health research approved by the Board;

"Researcher" means a person who carries out academic or scientific research;

"Secretary" means the Secretary to the Board appointed under section 9 (1) of this Act;

"traditional medicines" means the total combination of knowledge and practices, whether explicable or not, used in diagnosing, preventing or eliminating physical, mental or social diseases and which may rely exclusively on past experience and observation handed down from generation to generation, verbally or in writing;

"traditional health practitioner" means a person recognized by a community or Traditional Medicine Council in which that person lives as competent to provide health care using vegetables, animal or mineral substances and other methods based on social, cultural and religious background and knowledge, attitudes and beliefs that are prevalent in the community regarding the physical, mental and social well-being of a person, including the causes of disease and disability.

### PART TWO THE HEALTH RESEARCH INSTITUTE

Establishment of the Institute.

- **3.-**(1) There shall be an Institute to be known as the Zanzibar Health Research Institute.
  - (2) The Board may decide an acronym for better use of the Institute.
- (3) The Institute shall be a semi-autonomous body and shall, subject to the approval of the Minister, be capable of:
  - (a) acquiring, holding, purchasing or disposing any movable and immovable property;
  - (b) entering into any contract or transaction in its own name in accordance with the existing laws;
  - (c) borrowing any such sum of money from any financial institution in accordance with the provisions of the Public Finance Management Act; and



(d) performing or doing any act or thing which an institute of its nature may by law, be entitled to perform or do.

Seal and logo of the Institute.

- **4.-**(1) There shall be a common seal and logo of the Institute in shape and size as may be determined by the Board.
- (2) The application of the seal and logo of the Institute on any document shall be authenticated by the signature of the Director General or any other officer of the Institute authorized by the Director General.
- (3) A document purported to be an instrument issued by the Institute shall be sealed with the seal of the Institute and authenticated in accordance with subsection (2) of this section.

Objectives of the Institute.

- **5.** The objectives of the Institute shall be the following:
  - (a) promoting, assisting and undertaking research that meets the highest national and international scientific standards of excellence and ethics that pertains to all aspects of health;
  - (b) promoting the use of research findings for evidence based intervention;
  - (c) providing a mechanism of ensuring that health research conducted in Zanzibar:
    - (i) is in line with national health research priorities and policies;
    - (ii) is addressing health research problems identified nationally and internationally;
  - (d) identifying, promoting and developing special talents among health researchers with a view to developing a critical mass of Research Scientists in Zanzibar; and
  - (e) encouraging collaborative research between researchers within Zanzibar Health Research Institute and researchers in other research and development institutions within and outside Zanzibar;

Functions of the Institute.

- **6.** The functions of the Institute shall be the following:
  - (a) carrying out and promoting research in all aspects of health and traditional medical practices for the purpose of facilitating the development and application of preventive, curative and rehabilitative health practices and herbal medicine;



- (b) inspecting any institution or site approved by the Zanzibar Health Research Institute for the conduct of health research, including databases and bio-banks;
- (c) providing facilities and training programmes for local personnel to carrying out scientific and applied research in health and allied sciences;
- (d) going through all health research proposals and ensuring that are not harmful or dangerous and are for benefit of the people of Zanzibar;
- (e) monitoring, controlling and coordinating health research carried out on behalf of, or for the benefit of the people of Zanzibar;
- (f) establishing a system of registration of findings, operate systems of documentation and dissemination of information to public, Government, international research communities, voluntary organizations and private sectors on all aspects of health research carried out in Zanzibar;
- (g) assuming responsibility for the control of any other center which may be established by the Institute or vested in the Institute;
- (h) ensuring transparency and accountability to Zanzibaris for the investment in health research;
- (i) establishing good governance structures and systems for effective performance of the Institute;
- (j) consulting, collaborating and forming partnerships with persons or organizations in or outside Zanzibar that have an interest in issues pertaining to health or health research;
- (k) facilitating dialogues between the policy makers, researchers in different disciplines, health providers and communities in order to ensure that research is relevant to the needs of the people and that research findings are utilized by the relevant stakeholders for the improvement of livelihood of the people;
- (l) registering health researchers from carrying out health researches;
- (m) establishing research quality assurance system;
- (n) addressing emerging health opportunities, threats and challenges and accelerating the discovery of cures and treatments and improvements to health care, prevention and wellness strategies;



- (o) fostering the discussion of ethical issues and the application of ethical principles to health research;
- (p) pursuing opportunities and providing support for the participation of Zanzibar scientists in international collaboration and partnerships in health research;
- (q) cooperating with the Government or any person, or body of persons in promoting health research;
- (r) monitoring clinical trial which is undertaken in Zanzibar; and
- (s) performing any other functions as may be directed by the Minister.

Powers of the Institute.

### 7.-(1) The Institute may:

- (a) require or oblige any health researcher or research institution to submit such information or records as may be necessary to enable the Institute to monitor the performance or activities of the health researcher or research institution;
- (b) in case of misconduct, stop health researchers and research institutions from carrying out research in Zanzibar;
- (c) confiscate, impound and destroy, where necessary, biological materials obtained by any person in contravention of any provision of this Act; and
- (d) require any health researcher who, or research institution which is in control of a health research activity to inform the Institute of the intention to move from a site prior to re-locating.
- (2) The Institute may authorize any officer to conduct an inspection at any reasonable time, at any site, port of entry and port of exit

# PART THREE ADMINISTRATION AND MANAGEMENT OF THE INSTITUTE

Establishment and Composition of the Board.

- **8.-**(1) There shall be a Board of Directors of the Institute which shall be composed of:
  - (a) a Chairperson who shall be appointed by the President;



- (b) Director General;
- (c) Director General of the National Institute for Medical Research;
- (d) Director of Prevention and Health Education;
- (e) A representative from a School of Medicine of the State University of Zanzibar (SUZA);
- (f) A representative from Pathology Laboratory; and
- (g) two other members, one among them shall be from private sector.
- (2) A person shall qualify to be appointed as a Chairperson of the Board if he:
  - (a) is a Zanzibari;
  - (b) has at least first degree in the field of health administration, health science or any other related field from the recognized institution;
  - (c) has a working experience of not less than ten years in the public service; and
  - (d) has high level of integrity.
- (3) Save for the Chairperson and ex officio members, other members shall be appointed by the Minister in consultation with the relevant institutions based on experience, professionalism and gender equality.

Secretary of the Board.

- **9.-**(1) The Board shall appoint a legal officer who is an employee of the Institute with at least first degree in law and experience of not less than three years to be a Secretary of the Board.
  - (2) The Secretary shall be accountable to the Board, and shall:
    - (a) take the accurate minutes of meetings of the Board;
    - (b) maintain the correct and sufficient records of the Board;
    - (c) give proper notifications of the meetings of the Board to the members;
    - (d) provide correct advice to the Board when so needed; and
    - (e) perform any other functions as directed by the Board.



Functions of the Board.

- **10.** The functions of the Board shall be the following:
  - (a) overseeing and monitoring the operation and performance of the Institute;
  - (b) advising the Minister in respect of any matter relating to health research or health policy and strategic issues relating to health research;
  - (c) reviewing and approving policies, business and operating plans, budgets, reports and audited financial statements of the Institute;
  - (d) recommending to the relevant authority any matter concerning the remunerations or other terms and conditions of employees' services of the Institute in accordance with the Public Service Act;
  - (e) ensuring the efficient use of resources;
  - (f) establishing and supervising staff regulations and financial regulations for the Institute:
  - (g) reviewing and approving goals, targets and performance measures of the Institute in alignment with the approved:
    - (i) strategic plan of the Institute;
    - (ii) annual plan of the Institute; and
    - (iii) performance agreement;
  - (h) providing incentive terms and conditions of service for researchers so as to motivate research and reward productivity in accordance with the Public Service Act; and
  - (i) performing any other functions conferred by this Act or which may be necessary for achieving the purposes for which the Institute is established.

Powers of the Board.

- 11. The Board shall have a general power to supervise in respect to the performance of the functions of the Institute, and in particular shall have powers to:
  - (a) recommend the organizational structure of the Institute to the Public Service Commission;
  - (b) recommend to the Public Service Commission on the terms and conditions of services of the employees of the Institute;



- (c) recruit or appoint staff of the Institute in accordance with the provisions of the Public Service Act:
- (d) take disciplinary actions against any staff in case of the violation of codes of conduct according to the Public Service Act or its Regulations; and
- (e) approve fees and other charges of the services rendered by the Institute.

Meetings of the Board.

- 12.-(1) The Board shall meet ordinarily once in every three months and may meet at any time when the need arises for the performance of its functions under this Act.
  - (2) All meetings of the Board shall be convened and presided by the Chairperson.
- (3) Where the Chairperson is absence, the Vice-Chairperson shall convene and preside the meeting of the Board.
- (4) Where the Chairperson and Vice Chairperson are absent, the members present shall elect one among them to preside the meeting, and the member so elected shall exercise all the powers and discharge all the duties of the Chairperson.

Vice Chairperson. 13. The members of the Board shall elect one among them to be a Vice Chairperson of the Board.

Quorum of a meeting.

**14.** More than half of the total number of members shall constitute a quorum at any meeting of the Board.

Decisions of the Board.

15. The Board shall make its decisions by consensus, and in the event of disagreement, the decision shall be reached by voting, and in case of an equality in the votes, the Chairperson shall have a casting vote.

Tenure of the Chairperson and members of the Board.

- 16.-(1) The Chairperson of the Board shall hold office for a term of four years from the date of appointment and may be eligible for re-appointment for another term.
- (2) Save for an ex-officio member, other members of the Board shall hold office for a period of three years from the date of appointment and may be eligible for re-appointment for another term.

Procedures of the meetings.

17. Subject to the provisions of this Act, the Board shall have power to regulate its own procedures in respect of the meetings and the proper conduct of its business including committees of the Board.



Vacancy of a Member.

- **18.** The office of a member of the Board shall become vacant if he:
  - (a) dies;
  - (b) fails to attend three consecutive meetings of the Board without sufficient cause:
  - (c) resigns or becomes in any manner disqualified from membership of the Board; or
  - (d) fails to perform his duties by reasons of physical or mental health.

Remuneration for Members.

19. The Chairperson and other members of the Board shall be entitled to be paid such remuneration in accordance with the Public Service Act and Public Finance Management Act.

Co-option.

**20.** The Board may co-opt any person who is not a member of the Board to attend any deliberations of the meeting of the Board as an expert, but such person so co-opted shall not have the right to vote.

Conflict of interest.

21. A member who has direct or indirect interest in a contract or proposed contract or any matter being deliberated by the Board, shall declare the nature of his interest to the Board and the Board shall refrain him from participating in the deliberation of the matter.

Delegation of the functions of the Board. 22. The Board may, if it deems fit for the proper performance of its functions, delegate some of its functions to the Director General, a committee or any other staff of the Institute.

Termination or suspension of the member of the Board.

- **23.** The Minister may terminate or suspend any member of the Board other than Chairperson and ex-officio member, if that member:
  - (a) is unable to perform the functions of his office;
  - (b) is convicted of a criminal offence involving fraud, dishonesty or moral turpitude; or
  - (c) fails to attend three consecutive meetings of the Board without the leave of the Chairperson.

Committees of the Board.

**24.-**(1) The Board may, for the purpose of facilitating the performance of its functions, establish committees to perform specific functions as it may consider necessary.



(2) The composition, proceedings, terms and other matters relating to such Committees so established, shall be as prescribed by the Board.

# PART FOUR THE DIRECTOR GENERAL AND OTHER STAFF OF THE INSTITUTE

Appointment of the Director General.

- **25.-**(1) There shall be a Director General of the Institute who shall be appointed by the President.
  - (2) A person shall qualify to be appointed as a Director General if he:
    - (a) is a Zanzibari;
    - (b) has at least first degree in the field of health science or any other related field from a recognized institution;
    - (c) has a working experience of not less than seven years in the field of health science or any other related field; and
    - (d) has high level of integrity;

Functions of the Director General.

- **26.-**(1) The Director General shall be the Chief Executive Officer and be responsible for day to day activities of the Institute.
- (2) Without prejudice to the generality of the provisions under subsection (1) of this section, the Director General shall:
  - (a) provide leadership to the Institute in planning and implementation of the policies and programmes of the Institute;
  - (b) manage the affairs of the Institute in an efficient and effective quality services delivery;
  - (c) manage the funds, resources and properties of the Institute;
  - (d) prepare, propose and implement the strategic plan, business plan and operational plan of the Institute;
  - (e) ensure that the policies and regulations of the Institute are implemented and that the agreed objectives, targets and service standards are met;
  - (f) oversee and promote smooth performance of the Institute;



- (g) perform any other duties necessary for the implementation of this Act as may be assigned to him by the Board;
- (h) ensure all staff are adequately trained to perform their responsibilities and operations in an ethical and responsible manner;
- (i) be accountable all revenue and expenditure of the Institute in accordance with the relevant laws;
- (j) supervise the disciplinary matters of the employees of the Institute in accordance with the provisions of the Public Service Act;
- (k) report on activities of the Institute to the Board; and
- (l) perform any other duty necessary for the implementation of the provisions of this Act.

Staff of the Institute.

- 27.-(1) The Board may, upon such terms and conditions, employ other staff or hire a consultant or expert as may be necessary for proper performance of the functions of the Institute.
- (2) The recruitment of the staff made under subsection (1) of this section, shall be made in accordance with the provisions of the Public Service Act or its Regulations.

### PART FIVE BIOLOGICAL MATERIALS FOR HEALTH RESEARCH, AND RESEARCH IN TRADITIONAL AND ALTERNATIVE MEDICINE

Purposes of collection of biological materials.

28. Notwithstanding any other law, biological materials for health research shall only be collected for the purposes of which it is indicated in the research proposal.

Storage of biological materials.

- **29.-**(1) The Minister may, by notice in the Official Gazette, designate specific research institution or health center as a bio-bank, and grant or revoke a license, in the manner prescribed in the Regulations.
- (2) A research institution or health center designated as a bio-bank under subsection (1) of this section, may:
  - (a) receive biological materials for storage purposes;



- (b) store biological material remnants for a period not exceeding ten years, unless the Institute approves a longer period of time for special reasons; and
- (c) dispose of biological materials that are due, whose disposal shall consider prescribed bio-hazard waste guidelines under supervision of the Institute.
- (3) A bio-bank shall comply with the provisions of the Public and Environmental Health Act, Occupational Safety and Health Act and Zanzibar Environmental Management Act.
- (4) A person who keeps biological materials without having license commits an offence and shall, upon conviction, be liable to a fine of not less than Thirty Million Tanzanian Shillings or to imprisonment for a term of not less than ten years, or both.

Exportation and importation of biological materials.

- **30.-**(1) A person shall not export or import biological materials without the prior written approval of the Institute as provided under subsection (2) of this section.
- (2) The Institute may, on the recommendation of the Board, permit the export or import of biological materials if all the prescribed elements of a material transfer agreement are met.
- (3) A person who contravenes this section commits an offence and shall, upon conviction, be liable to a fine of not less than Thirty Million Tanzanian Shillings or to imprisonment for a period of not less than ten years, or to both.

Control of Biological materials.

- **31.-**(1) A person shall not transfer any biological material unless he has approval of the Institute.
- (2) A person who transfers biological material without approval of the Institute commits an offence and shall, upon conviction, be liable to a fine of not less than Thirty Million Tanzanian Shillings or to imprisonment for a period of not less than ten years, or to both, and his biological material transferred shall be confiscated.

Research in traditional and alternative medicine.

#### **32.** The Institute shall:

- (a) facilitate conduct of health research in traditional, or alternative medicine in Zanzibar;
- (b) ensure that information on traditional and alternative medicine are widely disseminated;



- (c) foster collaborative research between and among traditional and conventional health researchers; and
- (d) ensure that nothing in the execution of this Act prevents traditional health practitioners from individually or collectively protecting their intellectual property rights and indigenous knowledge relating to the processing of their medicinal preparations or final products.

## PART SIX INTELLECTUAL PROPERTY RIGHTS

Intellectual property rights.

- **33.-**(1) Any intellectual property rights arising from, or connected with, health research undertaken under this Act shall be protected in accordance with the Zanzibar Industrial Property Act.
- (2) The Institute shall develop, promulgate and enforce intellectual property rights policy for the objectives of:
  - (a) clarifying the ownership of or right to use the intellectual property resulting from the institution's own or collaborative research and development activities;
  - (b) setting out the rules of the Institute on how to accurately identify, evaluate, protect and manage intellectual property for its further development, usually through some form of commercialization;
  - (c) providing a transparent framework for cooperation with researchers and third parties; and
  - (d) providing guidelines on the sharing of economic benefits arising from the commercialization of intellectual property.
- (3) Upon the adoption and promulgation of the Intellectual Property Policy by the Institute, the Minister shall make regulations for the purpose of enforcement and protection of rights under that Policy.



### PART SEVEN FINANCIAL PROVISIONS

Funds of the Institute.

- **34.-**(1) The funds and resources of the Institute shall consist of:
  - (a) such sums as may be approved by the House of Representatives in the form of subvention;
  - (b) moneys received by the Institute for goods or services rendered by the Institute;
  - (c) such lawful grants, gifts, donations, contributions, loans, bequests, or investment as the Institute may receive from any person or organization; and
  - (d) any such other moneys that may vest or legally acquired by the Institute in the course of its operations or otherwise.
- (2) The Institute shall perform its functions in accordance with the common financial principles and shall ensure that, as far as possible, its revenue is sufficient to meet its expenditure properly in accordance with its strategic framework.
- (3) The Minister may, after consultation with the Minister responsible for finance, determine, in respect of the Institute, the amount of revenue which shall remain the property of the Institute, and a balance of that revenue shall be treated as public funds and credited to the Government account.
- (4) All financial transactions of the Institute shall be made and governed in accordance with the Public Finance Management Act and any other financial law.

Estimates of income and expenditure.

- **35.-**(1) The Director General shall, in respect of every financial year, submit to the Board of Directors for deliberations and recommendations, a detailed estimates of the income and expenditure of the Institute for the next year.
- (2) Upon deliberations and recommendations by the Board, the budget of the Institute shall be dealt in the same manner as part of the budget of the Ministry.
- (3) For the purpose of this section, estimates of income and expenditure shall include supplementary estimates.
- (4) The estimates of income and expenditure of the Institute shall be prepared subject with the requirements and provisions of the Public Finance Management Act and any other directives as may be issued by the Government from time to time.



(5) The Director General shall ensure that all payments out of the Institute's funds are correctly made and properly authorized, and adequate control is maintained over its property and over the incurring of liabilities by the Institute.

Accounts and audit.

- **36.-**(1) The Institute shall cause to be made and kept the proper and complete books of accounts reflecting all incomes and expenditure of the Institute.
- (2) The Director General shall, subject to such directives from the Institute, prepare in relation to the operations of the Institute, in respect of each financial year, statement of accounts which shall include:
  - (a) financial statement and statement of income and expenditure; and
  - (b) such other information in respect of financial affairs of the Institute as required under the Public Finance Management Act.
- (3) Within three months of closing of every financial year, the accounts including the financial statement of the Institute in respect of that financial year shall be submitted to the Controller and Auditor General.

Annual performance report.

- **37.-**(1) The Director General shall, within two months after the end of each financial year, prepare and submit to the Minister, an annual report in respect of that financial year containing:
  - (a) a copy of the audited accounts of the Institute, together with the auditor's report on those accounts;
  - (b) report of the Institute during the financial year; and
  - (c) such other information as the Minister may require.
- (2) The Minister shall cause a copy of the annual report of the Institute to be laid before the House of Representatives, within two months or at the next meeting of the House of Representatives, after he has received the report under subsection (1) of this section.

Opening of Bank Account.

**38.** The Institute shall, subject to the provisions of the Public Finance Management Act, open bank account and deposit its moneys for proper performance of its functions under this Act.



### PART EIGHT OFFENCES AND PENALTIES

### Offences and Penalties.

### **39.** A person who:

- (a) forges, counterfeits, alters or intends to forge, counterfeit or alter any license issued by the Institute;
- (b) uses the license in other activity other than the activity authorized by the Institute;
- (c) hinders or obstructs an officer or staff of the Institute in discharging of his lawful duties conferred under this Act:
- (d) refuses or fails, without reasonable excuse, to give any information to an officer or staff of the Institute which he is lawfully required to give under this Act;
- (e) makes or provides a false or incorrect declaration or statement during the process of applying the license or any written approval; or
- (f) contravenes any provisions of this Act or Regulations made under this Act,

commits an offence and shall, upon conviction, be liable to a fine of not less than Thirty Million Tanzanian Shillings or to imprisonment for a term of not less than ten years, or both.

### General penalty.

**40.** A person who contravenes the provisions of this Act or Regulations made under this Act for which no specific penalty is provided shall be liable, and upon conviction, to a fine of not less than Five Million Tanzanian Shillings or to imprisonment for a term of not less than five years, or both.

### PART NINE MISCELLANEOUS PROVISIONS

### Clinical Trial.

- **41.-**(1) A person shall not conduct a clinical trial on human beings in Zanzibar without written approval from the Minister.
- (2) The manner, procedures and other proceedings of getting the written approval from the Minister shall be prescribed in the Regulations made under this Act.



(3) A person who contravenes the provisions of this section commits an offence.

Regulations.

**42.** The Minister may make Regulations for proper implementation of the provisions of this Act.

Repeal and Savings.

**43.-**(1) The Legal Notice No. 125 of 2018 is hereby repealed.

(2) Notwithstanding the repeal under subsection (1) of this section, anything done under the repealed Legal Notice shall be deemed to be done under the provisions of this Act.

PASSED by the House of Representatives of Zanzibar on 1st April, 2020

(RAYA ISSA MSELLEM)

Clerk of the House of Representatives of Zanzibar.