

GOVERNMENT OF ZAMBIA

ACT

No. 2 of 2013

Date of Assent: 21/03/13

An Act to establish the National Health Research Authority and provide for its functions and powers; establish the National Health Research Ethics Board and provide for its functions and powers; provide a regulatory framework for the development, regulation, financing and coordination of health research and ensure the development of consistent health research standards and guidelines for ethically sound health research; provide for the establishment of health research ethics committees and the regulation and management of research institutions, health researchers and health establishments involved in or undertaking research; provide for the regulation of biological material for health research; provide for ethical approval for the conduct of clinical trials; provide for the use of traditional, complementary and alternative medicines in health research; provide for data management and intellectual property rights in health research; provide for the designation of bio banks; and provide for matters connected with, or incidental to, the foregoing.

[22nd March, 2013

ENACTED by the Parliament of Zambia.

Enactment

PART I.

PRELIMINARY

1. This Act may be cited as the National Health Research Act, 2013.

Short title

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

Interpretation

Cap. 1

- “ accreditation ” means a process of certification of competence in health research;
- “ animal subject ” means an animal which is used for health research or clinical trial;
- “ Authority ” means the National Health Research Authority established under section *four*;
- “ Board ” means the National Health Research Ethics Board constituted under section *thirteen*;
- “ bio-bank ” means a collection of biological materials and the associated data and information which is stored in an organised system;
- “ biological materials ” means organs and parts of organs, cells and tissue, sub cellular structures and cell products, blood, saliva, sputum, gametes (sperm and ova), embryos and foetal tissue, waste, including urine, faeces, 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 Chairperson ” means the person appointed as Chairperson of the Board in accordance with section *thirteen*;
- “ Cabinet ” has the meaning assigned to it in the Constitution;
- “ central health research repository ” means the central health research repository as prescribed by the Minister under section *thirty-three*;
- “ Chairperson ” means the person appointed Chairperson of the Council under section *seven*;
- “ clinical trial regulations ” means regulations made under section *fifty-four*;
- “ 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;
- “ committee ” means a committee of the Council established under section *nine*;

THE NATIONAL HEALTH RESEARCH ACT, 2013

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- “consent” means a voluntary agreement to participate in health research by a person, who is not a minor, with full understanding of the potential risks and benefits of the health research;
- “Council” means the Council of the Authority constituted under subsection *seven*;
- “Director” means the person appointed Director of the Authority under section *eleven*;
- “embryo” means a human offspring in the first eight weeks from conception or animal offspring in the first trimester, the gestation or incubation period for the relevant species as the case may be;
- “ethical approval” means approved by the Board for the conduct, in Zambia, of research on human participants or animal subjects in accordance with sections *fourteen* and *forty-five*;
- “genetic material” means a part of a cell that carries information which can be inherited;
- “health establishment” means a public or private establishment, including its facilities, 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 an 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;
- “health research ethics committee” means a committee registered and accredited by the Board under section *eighteen*;

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“ health researcher ” means an individual who undertakes health research;

“ 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 as provided in the Human Tissue Act;

“ human research guidelines ” means guidelines for the conduct of health research involving human participants issued under section *thirty-six*;

“ inspector ” means a person appointed by the Authority as an inspector for the purposes of this Act;

“ national health research strategic plan ” means a national plan that prioritises health research as provided under section *thirty-one*;

“ intellectual property rights ” means an exclusive right granted to inventors and owners of works that are the result of human intellectual creativity;

“ interim regulatory requirements ” means a regulatory framework issued under section *thirty-eight*;

“ legal guardian ” means a person lawfully vested with the power, and charged with the obligation, of taking care of and managing the property and rights of a person who, because of age, understanding or self control, is incapable of administering that person’s own affairs;

“ material transfer agreement ” means a written contract between the provider and recipient of research material as prescribed under section *fifty-three*;

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“ medicine ” has the meaning assigned to it in the Medicines and Allied Substances Act, 2013;

“ member ” means a member of the Council;

“ minor ” means a person below the age of eighteen years;

“ private health establishment ” means a health establishment that is not owned or controlled by the Government;

“ public health establishment ” means a health establishment that is owned or controlled by the Government;

“ public policy ” means the objectives relating to the health, morals and well being of the citizens approved by Cabinet as part of the national health programme;

- “regulatory framework” means any statute dealing with, or impacting on, health research, or regulations, rules, regulatory requirements, guidelines or practice directives relating to, or impacting on, health research, made in accordance with this Act;
- “reproductive cloning” means the genetic duplication of an existing organism especially by transferring the nucleus of a somatic cell of the organism into an enucleated oocyte;
- “research institution” means an organisation, whether public or private, including a university, which undertakes health research;
- “research protocol” means a research proposal for health research approved by the Board in accordance with section *seventeen*;
- “Secretary” means the Secretary to the Council appointed under section *twelve*;
- “site” means a place approved by the Board for the conduct of health research;
- “social norm” means a pattern of behaviour in a particular group or community or culture accepted as normal in that group or community;
- “therapeutic cloning” means a procedure for producing tissues or organs from genetically identical cells that originate from undifferentiated stem cells for purposes of repairing or replacing damaged tissues;
- “traditional, complementary and alternative 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 recognised by a community in which that person lives as competent to provide health care, using vegetable, 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;

“Trust Account” means the Health Research Trust Account established under section *forty-one*;

“vertebrate animal” means a bird, fish, reptile, amphibian or mammal, other than a human being, which is a member of the phylum vertebrates, or a bee, butterfly and any other insect used in the production of animal products, and includes the carcass of an animal; and

“Vice-Chairperson” means the person elected Vice-Chairperson of the Council under section *seven*.

Application and scope

3. (1) Notwithstanding any other law, this Act applies to all health research conducted in Zambia, biological material and the use of personal health data.

(2) Notwithstanding subsection (1), this Act applies to health research undertaken outside Zambia under the direction of a person or body established in Zambia.

PART II

THE NATIONAL HEALTH RESEARCH AUTHORITY

Establishment of National Health Research Authority

4. (1) There is hereby established the National Health Research Authority which shall be a body corporate with perpetual succession and a common seal, capable of suing and of being sued in its corporate name, and with powers, subject to the provisions of this Act, to do all such acts and things as a body corporate may, by law, do or perform.

(2) The Schedule applies to the Authority.

Functions of Authority

5. (1) The functions of the Authority are to—

(a) regulate the conduct of research and monitor and evaluate all health research in Zambia;

(b) facilitate research and development in health research and provide oversight and coordination of health research;

(c) develop mechanisms for setting national health research priorities and strategies in accordance with the needs of Zambia;

(d) promote the translation of health research outcomes into policy;

(e) advise the Minister on all matters related to health research;

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- (f) identify and recommend to the Minister national health research priorities for incorporation in national health research strategic plans;
 - (g) advise the Minister on the application and implementation of national health research strategic plans;
 - (h) foster partnerships in product development and commercialisation of innovations in health research;
 - (i) harmonise, network and promote public-private partnerships in health research;
 - (j) register and accredit research institutions and health researchers;
 - (k) investigate reports of professional misconduct relating to health research and report the misconduct to the relevant professional association or statutory body;
 - (l) facilitate the development of health research capacity of individuals, institutions and systems by building quality human resources which are capable of responding to the essential research and health demands of Zambia;
 - (m) mobilise and disburse resources for health research;
 - (n) advocate for health research within society, and in the public and the private sectors;
 - (o) recommend to law enforcement authorities the prosecution of health researchers and research institutions that contravene this Act;
 - (p) collaborate with health researchers and research institutions outside Zambia;
 - (q) promote multi-disciplinary and inter-sectoral research collaboration in a bid to establish essential health research which is consistent with the national health research strategic plan; and
 - (r) do all such things as are connected with, or incidental to, the functions of the Authority under this Act.
- (2) The Authority shall, in performing its functions under this Act—
- (a) develop and review accreditation guidelines for health researchers and research institutions;
 - (b) maintain a database of research undertaken and facilitate the dissemination of research results;

- (c) establish and maintain a central health research repository; and
- (d) maintain a profile of non-complying health researchers and research institutions.
- Powers of Authority**
6. The Authority may—
- (a) withdraw the accreditation of a health researcher or research institution;
- (b) ban health researchers and research institutions from carrying out research in Zambia;
- (c) stop an ongoing health research activity;
- (d) inspect any institution or site approved by the Board for the conduct of health research, including databases and bio banks;
- (e) confiscate, impound and destroy, where necessary, biological materials obtained by any person in contravention of any provision of this Act;
- (f) require any health researcher or research institution to submit such information and records as may be necessary to enable the Authority to monitor the performance or activities of the health researcher or research institution;
- (g) consider any matter relating to health research and make representations on those matters to the Minister; and
- (h) require any health researcher who, or research institution which, is in control of a health research activity to inform the Authority of the intention to move from a site prior to re-locating.
- Council of Authority**
7. (1) The Authority shall be governed by a Council.
- (2) The Council shall consist of the following part-time members who shall be appointed by the Minister:
- (a) one representative each recommended by the Ministries responsible for—
- (i) science, technology and vocational training;
- (ii) finance;
- (iii) justice;
- (iv) defence;

- (v) health;
 - (vi) community development;
 - (vii) education; and
 - (viii) livestock and fisheries development;
- (b) one representative each recommended by—
- (i) a research and development institution;
 - (ii) a higher education institution; and
 - (iii) a civil society organisation concerned with matters of health;
- (c) a traditional health practitioner;
- (d) a renowned health researcher; and
- (e) two other persons.
- (3) A person shall not be appointed as a member of the Council if the person —
- (a) is an undischarged bankrupt;
 - (b) has been convicted of an offence related to health research under this Act or any other written law;
 - (c) has been convicted of an offence involving fraud or dishonesty;
 - (d) is an employee of the Authority;
 - (e) has a mental disability that makes the person incapable of performing the functions of a member; or
 - (f) is not resident in Zambia.

(4) The Minister shall, when appointing the members of the Council, ensure equitable gender representation and that at least a third of the members have health research experience.

(5) The Minister shall appoint the Chairperson of the Council from among the members of the Council.

(6) The Vice-Chairperson of the Council shall be elected by the members from amongst themselves.

8. (1) Except as otherwise provided under this Act, the Council shall exercise the following functions and powers of the Authority:

- (a) set, review and enforce ethical standards and human and animal research ethical guidelines, including ethical standards and guidelines for clinical trials;

Exercise of
functions and
powers of
Authority

- (b) determine policy matters in health research;
- (c) review the policy and strategic plan of the Authority and oversee the implementation and efficient operation of the policy and functions of the Authority;
- (d) approve the annual budget and plans of the Authority;
- (e) monitor and evaluate the performance of the Authority against budgets and plans;
- (f) establish and approve conditions of service of the staff of the Authority;
- (g) make recommendations to the Minister for amendments to this Act or issuance of regulations under this Act; and
- (h) perform any other function conferred or imposed on the Council by or under this Act.

(2) The Minister may give to the Council general or specific directions, consistent with this Act, relating to the discharge of the functions of the Authority and the Council shall give effect to those directions.

Committees
of
Council

9. (1) The Council may, for purposes of performing the functions of the Authority, establish such committees as it considers necessary for the effective exercise of the functions of the Authority.

(2) The Council may appoint, as members of a committee, persons who are or are not members of the Council; except that at least one member of the Council shall be a member of a committee.

(3) A person serving as a member of a committee shall hold office for such period as the Council may determine.

(4) Subject to any specific or general direction of the Council, a committee may regulate its own procedure.

Delegation of
functions

10. The Council may, by direction, in writing, and subject to such terms and conditions as it considers necessary, delegate to the Director, any member or any committee any of the functions of the Authority.

Director

11. (1) The Council shall appoint, on such terms and conditions as it may determine, a Director who shall be the chief executive officer of the Authority.

(2) The Director shall be responsible, under the general direction of the Council, for—

(a) the management and administration of the affairs of the Authority;

(b) the implementation of the decisions of the Council; and

(c) any other function assigned or delegated to the Director by the Council or by or under this Act.

(3) The Director shall attend meetings of the Council and may address those meetings but shall not vote on any matter.

(4) The person presiding at any meeting of the Council may request the Director to withdraw from the meeting.

12. (1) The Council may appoint, on such terms and conditions as it may determine, the Secretary, inspectors and such other staff as may be necessary for the performance of the functions of the Authority.

Secretary,
inspectors
and other
staff of
Authority

(2) The Council shall provide an inspector with a certificate of appointment, in the prescribed form, which shall be *prima facie* evidence of the inspector's appointment.

PART III.

THE NATIONAL HEALTH RESEARCH ETHICS SYSTEM

13. (1) There is established the National Health Research Ethics Board which shall consist of one representative from each of the following disciplines and sectors:

National
Health
Research
Ethics
Board

(a) law;

(b) pharmacology;

(c) pharmacy;

(d) theology;

(e) biostatistics;

(f) epidemiology;

(g) public health;

(h) biomedical science;

(i) veterinary medicine;

(j) traditional medicine;

(k) nursing;

(l) social science; and

(m) clinical medicine.

(2) The members of the Board shall be appointed by the Council and shall serve on a part-time basis.

(3) An organisation or association that represents members in the disciplines or sectors stipulated in subsection (1) shall recommend a representative for appointment as a member of the Board.

(4) The Chairperson of the Board shall be appointed by the Council from among the members of the Board.

(5) The Vice-Chairperson of the Board shall be elected by the members from amongst themselves.

Functions of
Board

14. (1) The Board shall regulate ethics on human and animal research as provided by or under this Act, and oversee and ensure adherence to health research ethics as provided in the regulatory framework and ethics guidelines.

(2) Notwithstanding the generality of subsection (1), the Board shall—

- (a) regulate the conduct of research and monitor and evaluate all health research;
- (b) register and accredit health researchers and health research ethics committees;
- (c) regulate and monitor the conduct of health research and health research ethics committees;
- (d) institute such disciplinary action, as may be prescribed, against any health researcher or research institution found to be in violation of any ethical standards or guidelines set for conducting of health research;
- (e) act as an appeals body from decisions of the health research ethics committees;
- (f) adjudicate complaints about the functioning of health research ethics committees and hear any complaint by a health researcher regarding a health research ethics committee;
- (g) notify any violation of professional conduct to the appropriate professional association or statutory body;
- (h) create awareness among health research reviewers, decision and policy makers and the community on the basic principles of health research ethics;
- (i) promote training in health research ethics and support the formation of health research ethics committees;
- (j) audit health research ethics committees; and
- (k) review research proposals and research protocols in order to ensure that health research conducted by a research institution or health researcher promotes health, contributes to the prevention of communicable or non-

communicable diseases or disability or results in cures for communicable or non-communicable diseases and is in accordance with health research ethics.

(3) The Board shall give ethical approval for—

- (a) all clinical trials involving medicines, vaccines or other biological products, new therapeutic regimes, as well as invasive diagnostic procedures;
- (b) multi-center and multi-national collaborative health research;
- (c) health research which is fully or partially initiated, financed and wholly or partly carried out by external donors or international agencies;
- (d) health research which is carried out by an international agency or agencies with bilateral or multi-lateral collaboration or agreements with the Government; and
- (e) health research proposals that meet the health research ethics guidelines.

(4) The Board may delegate any of its functions to an accredited health research ethics committee.

15. (1) A member of the Board shall hold office for a period of three years from the date of appointment and is eligible for re-appointment for one further term of three years.

Tenure of
office and
vacancy of
Board

(2) A member may resign upon giving one month's notice, in writing, to the Council.

(3) The office of member becomes vacant —

- (a) upon the member's death;
- (b) if the member is absent, without reasonable excuse, from three consecutive meetings of the Board of which the member had notice without the prior approval of the Board;
- (c) on ceasing to be a representative of the organisation or association which recommended the member;
- (d) if the member is found guilty of professional misconduct by the relevant professional association or statutory body;
- (e) if the member is convicted of an offence involving fraud or dishonesty;
- (f) if the member becomes mentally or physically incapable of performing the duties of a member; or
- (g) if the member is declared bankrupt.

(4) The Council may fill a vacancy on the Board by appointing another person to replace the member who vacates office for the remainder of the term.

Proceedings
of Board

16. (1) The Board shall regulate its own procedures at meetings.

(2) The quorum at any meeting of the Board shall be eight members.

(3) The disciplinary proceedings of the Board shall be as prescribed.

Research
protocol

17. All proposals for health research under this Act shall be reviewed by the Board or any other accredited health research ethics committee, as may be prescribed, and shall be approved by the Board.

Health
research
ethics
committees

18. (1) A research institution and health establishment, at which health research is conducted, shall constitute health research ethics committees, which shall be registered with, and accredited by, the Board or any other accredited health research ethics committee.

(2) The members of a health research ethics committee shall be appointed by the respective research institution and the representation shall be consistent in discipline as provided under subsection (1) of section *thirteen*.

(3) The Minister, in consultation with the Authority, shall, by statutory instrument, make regulations for accrediting health researchers and research institutions.

Functions and
procedures of
health research
ethics
committee

19. (1) A health research ethics committee shall have such functions and powers as may be prescribed.

(2) A health research ethics committee shall comply with the provisions of this Act.

(3) A health research ethics committee shall regulate its own procedure at meetings.

(4) The disciplinary procedures for a health research ethics committee shall be as prescribed.

Misconduct
by
health
researchers

20. (1) A health researcher commits misconduct if the health researcher—

(a) does not comply with a prescribed professional code of conduct;

(b) conducts health research which involves human participants or potentially affects humans without first obtaining ethical approval under this Act or other approvals required under any other written law;

- (c) collects samples or information from human participants without first obtaining consent from the participants in accordance with this Act;
- (d) shares samples collected from human participants with other health researchers or research institutions without first obtaining the relevant approvals under this Act;
- (e) shares samples collected from human participants without an approved material transfer agreement, as provided under this Act;
- (f) shares samples collected prospectively from human participants with other health researchers or research institutions without the informed consent of the donors of the samples to do so;
- (g) fails to submit prescribed mandatory reports to a health research ethics committee and the Board;
- (h) fails to uphold privacy and confidentiality of participants' information;
- (i) deviates from an approved research protocol;
- (j) fails to report deviations from an approved research protocol to the relevant health research ethics committee or the Board;
- (k) fabricates, falsifies or knowingly plagiarises data; or
- (l) forges approvals or other relevant documents under this Act.

(2) A health researcher who contravenes subsection (1) and who is found guilty by a health research ethics committee or the Board is liable to a fine not exceeding four hundred thousand penalty units or shall be banned from conducting health research for a minimum of five years.

(3) Notwithstanding subsection (2), a health researcher who commits a criminal offence is liable to prosecution.

(4) The Minister shall, in consultation with the Authority, by statutory instrument, issue regulations for dealing with misconduct by health researchers and procedures for their discipline.

21. (1) A health researcher or research institution whose interests are affected by an action or decision of a health research

Complaints

ethics committee may lodge a complaint with the Board and request an investigation concerning the action or decision of the health research ethics committee, on one or more of the grounds set out in subsection (2).

(2) A health researcher or research institution, referred to in subsection (1), may lodge a complaint on any of the following grounds:

- (a) that the action or decision breached the rules of natural justice;
- (b) that the action or decision was induced or affected by fraud;
- (c) that there was no evidence or other material to justify the action or decision;
- (d) that an irrelevant consideration was taken into account in relation to the action;
- (e) that a relevant consideration was not taken into account in relation to the action or decision;
- (f) that in the course of the decision making process, a discretionary power was exercised for a purpose other than the purpose for which the power was conferred;
- (g) that the action or decision involved the exercise of a discretionary power in bad faith;
- (h) that, in the course of the decision making process, a personal discretionary power was exercised at the direction of another person;
- (i) that the decision involved the exercise of a discretionary power in accordance with a rule or policy without regard to the merits of the particular case; or
- (j) that the exercise of the power was done in a way that constituted an abuse of the power.

(3) A complaint shall—

- (a) be in writing;
- (b) be signed by the complainant;
- (c) describe the action complained about;
- (d) specify the nature of, and grounds for, the complaint; and
- (e) be lodged with the Board.

(4) The Board shall investigate a complaint concerning an action or decision of a health research ethics committee if a complaint is lodged with it or on its own initiative.

(5) The Board may decide not to investigate a complaint lodged under this section or decide to discontinue an investigation if it—

(a) is satisfied that the complainant became aware of the matter constituting a ground for the complaint more than twelve months before making the complaint to the Board; or

(b) has reasonable grounds for believing that —

(i) the complaint is frivolous or vexatious or is not made in good faith; or

(ii) the investigation or any further investigation of the action is not justified in all the circumstances.

(6) The Board shall, if it decides not to investigate a complaint or to discontinue an investigation, give the complainant written notice of the decision, which shall include the reasons for the decision.

(7) The Minister shall prescribe the manner, form and process for investigating, hearing and deciding on complaints by the Board.

22. A person who is requested by the Board or a health research ethics committee to—

(a) provide information, documents or other records; or

(b) answer a question;

to assist the Board or a health research ethics committee in its investigation on a matter shall not be subject to any liability or penalty under this Act or any other written law.

23. (1) The Board shall make a report to the Council where, upon investigating a complaint concerning an action or decision of a health research ethics committee, it determines that the action was based on one of the grounds set out in section *twenty*.

(2) A copy of the report of the Board shall be submitted to the Minister and the person responsible for, or board of, the relevant research institution, health researcher or health establishment and to the complainant.

(3) The Council shall ensure, having regard to the recommendations made in the report of the Board, that the relevant research institution, health researcher or health establishment—

Immunity
from
liability or
penalty

Reports by
Board

- (a) takes whatever action that the Board considers appropriate; and
- (b) informs the complainant of the action that the research institution, health researcher or health establishment has taken and of its reasons for taking the action.

Staff of
Board

24. The Authority shall—

- (a) second staff to service the Board; and
- (b) provide to the Board facilities necessary for it to perform its functions and exercise its powers under this Act.

Disclosure of
interest by
members of
Board

25. (1) Where the Board is investigating, or is to investigate, a complaint concerning an action or decision of a health research ethics committee and a member of the Board has, or acquires, an interest that could conflict with the proper performance of the member's functions in relation to the investigation, the member shall disclose the interest to the Board and the member shall only take part in the investigation if the complainant and the Board agree that the member may so take part.

(2) If, in relation to an investigation of a complaint by the Board—

- (a) a member discloses an interest under subsection (1); and
- (b) the complainant and the Board do not agree to the member taking part in the investigation;

the member shall not take part in the investigation of the complaint.

Protection of
personal
information

26. (1) The Board shall not, except in the performance or exercise of its functions or powers under this Act, make a record of or disclose to any person any information about another person that the Board has access to in the performance or exercise of its functions or powers under this Act.

(2) Except for the purposes of this Act, if the Board has possession of a document or other record or notice of a matter or thing as a result of its functions or powers under this Act, a court shall not require the Board to—

- (a) produce the document or other record in its possession;
or
- (b) disclose the matter or thing of which it had notice.

Immunity of
member of
Board or
committee

27. An action or other proceeding shall not lie or be instituted against a member of the Board or a committee, or in respect of, any act or thing done or omitted to be done in good faith in the

exercise of or performance, or purported exercise or performance of any of the powers, functions or duties conferred under this Act.

28. The Board shall, as soon as practicable after the end of each financial year, give the Authority a written report of the Board's activities during that year.

Annual
report of
Board

29. (1) A person who is aggrieved with the decision of the Board may, within fourteen days of service of the decision, appeal to the Council and thereafter may appeal to a court of competent jurisdiction.

Appeals

(2) A decision of the Board made under this section shall not take effect until the expiration of the time for lodging an appeal, the appeal is withdrawn or disposed of.

30. Where a health researcher has committed an offence for which the health researcher has been punished in another country and what the health researcher did constitutes a misconduct under this Act, that health researcher shall be banned, by the Council on the recommendation of the Board, from conducting health research in Zambia.

Jurisdiction
over offences
committed
outside
Zambia

PART IV

REGULATORY FRAMEWORK FOR HEALTH RESEARCH

31. (1) The Authority shall identify and prioritise areas for health research and advise the Minister, who shall recommend the priority areas to Cabinet for approval as national health research priority areas which shall be incorporated in a national health research strategic plan.

Priority area
for health
research

(2) The Authority shall, in identifying priorities for health research, take into consideration—

- (a) the burden of disease in the country;
- (b) the cost effectiveness of interventions aimed at reducing the burden of disease;
- (c) the availability of resources for the implementation of an intervention at the level closest to the affected communities;
- (d) the health needs of special groups;
- (e) the health needs of communities; and
- (f) emerging public health problems.

(3) A health researcher and research institution shall align health research activities to the subsisting national health research strategic plan.

(4) The Authority may allow research outside a national research strategic plan if it is in the public interest or public policy so requires.

Dissemination
of health
research
information

32. (1) The Minister, in consultation with the Authority, shall prescribe mechanisms for dissemination of health research information as follows:

(a) any health research conducted in Zambia shall first be disseminated locally before being disseminated outside Zambia; and

(b) any person intending to publish health research information for health research undertaken in Zambia shall first notify the Authority, in writing, citing the research title and the ethical approval obtained from the Board.

(2) The Authority may, for the purposes of disseminating health research information, facilitate fora or media through which health research information may be disseminated, timely, to a broad audience in Zambia.

(3) A person shall not disseminate information that is identifiable without—

(a) the written consent of the source of the information; and

(b) approval from the responsible authority.

(4) The Authority may, under such circumstances as it considers necessary, make exemptions in relation to the dissemination of information as provided under this section.

Access to, and
deposition of,
health research
databases

33. (1) The Authority has the right to access all health research databases in Zambia.

(2) The Minister, in consultation with the Authority, shall put in place a national system for —

(a) creating and securing health research databases;

(b) storing and retrieving health research data; and

(c) disseminating health research data from the national system.

(3) The Minister may, in consultation with the Authority, by statutory instrument, make regulations for ensuring that databases for internally and externally funded health research are kept in a central health research repository as prescribed by the Minister.

(4) The Authority has the right to access databases, bio banks or any information collected by health researchers and research institutions.

34. The Authority shall —

Monitoring
and
evaluation

- (a) develop monitoring and evaluation mechanisms for all health research programmes and activities;
- (b) promote training of health workers in health research methodologies and ethics, documentation, monitoring and evaluation; and
- (c) monitor and evaluate ongoing health research programmes and activities being undertaken in Zambia.

35. The Minister may, in consultation with the Authority—

Partnerships
in health
research

- (a) establish mechanisms for involving communities in health research;
- (b) facilitate the establishment of a consultative forum for wide dissemination of national health research priority areas and outputs; and
- (c) make regulations for the protection of interests of stakeholders and the sharing of risks, benefits and outputs in health research programmes and activities.

36. (1) Without limiting any of the matters on which the Council may issue guidelines under this Act, the Council shall issue guidelines on the conduct of human research.

Human
research
guidelines

(2) The Council shall issue guidelines on the conduct of human research in collaboration with the Board.

37. (1) The Minister, in consultation with the Authority, shall, before issuing any proposed regulatory framework, consult with relevant stakeholders in accordance with this section, except that this section shall not apply—

Consultation
about
regulatory
framework

- (a) to a statutory instrument; or
- (b) if the proposed regulatory framework is urgent or is of minor significance, as the Minister may determine.

(2) If the Minister, in consultation with the Authority, intends to issue any regulatory framework, the Minister shall publish a notice, in the *Gazette* or in a daily newspaper of general circulation in Zambia—

(a) stating the intention to issue the regulatory framework;
and

(b) inviting persons or bodies to make submissions relating to the proposed regulatory framework in accordance with the procedures, and within the period, specified in the notice.

(3) As soon as practicable after the end of the period specified under paragraph (b) of subsection (2), the Minister, in consultation with the Authority, shall, having regard to any submissions received pursuant to the invitation referred to in that paragraph—

(a) prepare a draft of the regulatory framework and publish a notice, in the *Gazette* and in a daily newspaper of general circulation in Zambia—

(i) containing a summary of the provisions of the draft regulatory framework;

(ii) stating where copies of the draft regulatory framework may be obtained; and

(iii) inviting persons or bodies to make submissions relating to the draft regulatory framework in accordance with the procedures, and within the period, specified in the notice; or

(b) publish a notice, in the *Gazette* and in a daily newspaper of general circulation in Zambia, stating that it no longer proposes to issue the regulatory framework.

(4) The Minister, in consultation with the Authority, shall take into account any submissions received pursuant to the invitation referred to in subparagraph (iii) of paragraph (a) of subsection (3) before issuing the proposed regulatory framework.

Interim
regulatory
requirements

38. (1) The Minister, in consultation with the Authority, may make interim regulatory requirements and issue the requirements without following the procedure provided in section *thirty-seven* if a matter —

(a) would ordinarily be the subject of a regulatory framework;

(b) needs, for any reason or circumstance, to be dealt with urgently; and

(c) raises issues that are of minor significance;

and shall publish a notice, in the *Gazette* or a daily newspaper of general circulation in Zambia, stating the reasons for not following the procedures provided under section *thirty-seven*.

(2) Notwithstanding subsection (1), the Minister, in consultation with the Authority, shall, within thirty days of the issue of an interim regulatory requirement, publish a notice in the manner and form prescribed—

(a) setting out the reasons for issuing the interim regulatory requirement and a summary of the interim regulatory requirement; and

(b) inviting persons or bodies to make submissions to the Minister on the interim regulatory requirement, within the period specified in the notice.

(3) If the Minister fails, within forty-five days after the end of the period specified in subsection (2), to comply with the procedures provided for in subsection (2), any interim regulatory requirement shall be revoked on the forty-fifth day.

39. The Minister, in consultation with the Authority, may, without undertaking consultation, revoke any regulatory framework or interim regulatory requirements.

Revocation of
regulatory
frameworks

40. The Authority shall develop and publish procedures to assist persons or bodies to make submissions under this Part.

Procedures
for making
submissions

41. (1) There shall be established a Health Research Trust Account.

Health
Research
Trust
Account

(2) The Trust Account shall be opened as a special account, in a commercial bank, for the purposes of the Public Finance Act, 2004.

Act No. 15
of 2004

(3) If interest is received by the Authority from the investment of an amount standing to the credit of the Trust Account, an amount equal to the interest shall be credited to the Trust Account.

42. There shall be credited to the Trust Account amounts equal to amounts that are given or bequeathed for the purposes of the Trust Account and as provided in the Schedule.

Credit of
amounts to
Trust
Account

43. (1) The purposes of the Trust Account are—

Purposes of
Trust
Account

(a) to provide assistance—

(i) to the Departments of the Ministries responsible for human and animal health that are engaged in health research;

- (ii) to universities for the purpose of health research;
- (iii) to research institutions and health researchers engaged in health research; and
- (iv) for the training of persons in health research; and

(b) provide for any other purpose that is prescribed for the purpose of this section.

(2) Any assistance provided under subsection (1) shall be provided in such cases and subject to such conditions as the Minister, acting on the advice of the Authority, shall determine.

(3) Without limiting the generality of the conditions to which a grant of assistance may be made under subparagraphs (i) (ii) or (iii) of paragraph (a) of subsection (1), such assistance shall be provided if the recipient agrees to comply with the regulatory framework in force relating to the conduct of health research and signs a research grant.

Accounting
for gifts and
bequests
Act No. 15
of 2004

44. (1) Notwithstanding the other provisions of this Act, but subject to subsection (2) and the Public Finance Act, 2004, any money that is—

- (a) held by the Authority on trust for the purposes of the Trust Account; or
- (b) accepted by the Authority for the purposes of the Trust Account which is subject to a condition;

shall not be dealt with except in accordance with this Act, the condition and the obligations of the trustees as set out in a Trust to be established by the Minister for the purposes of this Act.

(2) There shall be kept separate accounts of each sum of money standing to the credit of the Trust Account that represents an amount given as a gift or bequest for specific health research.

PART V

HEALTH RESEARCH ON, OR EXPERIMENTATION WITH HUMAN PARTICIPANTS AND ANIMAL SUBJECTS

Health
research on,
or
experimentation
with, human
participants
or animal
subjects

45. (1) Health research or experiments on a human participant shall be conducted—

- (a) in the prescribed manner consistent with this Act;
- (b) with the written consent of the person, after the person has been informed of the objectives of the research or

experimentation and any possible potential risks or benefits on that person's health; .

- (c) in the case of a deceased person, with written consent as provided in the Human Tissue Act;
- (d) if it does not threaten national security;
- (e) if it does not violate social and cultural norms; and
- (f) in Zambia, with ethical approval by the Board or accredited health research ethics committee in accordance with this Act.

Cap. 306

(2) Research involving human participants shall embrace all the following basic pillars of health research ethics:

- (a) respect of persons (autonomy);
- (b) benefit to the research participants (beneficence); and
- (c) equal distribution of risks and benefits (justice).

(3) The following elements shall be adhered to in conducting health research on human participants:

- (a) social or scientific value;
- (b) scientific validity;
- (c) fair selection of participants;
- (d) favourable risk benefit ratio;
- (e) informed consent;
- (f) respect of participants;
- (g) confidentiality;
- (h) protection of interests of stakeholders;
- (i) good clinical and laboratory practice; and
- (j) independent review.

(4) Health research on a minor for therapeutic purposes shall be conducted—

- (a) if it is in the best interest of the minor;
- (b) in such manner and on such conditions as may be prescribed in a regulatory framework;
- (c) with the consent of the parent or legal guardian of the minor; and
- (d) if the minor is capable of understanding the nature and

the potential risks and benefits of the health research, with the consent of the minor.

(5) Health research on a minor for non therapeutic purposes shall be conducted —

- (a) in such manner and on such conditions as may be prescribed;
- (b) with the consent of the Authority;
- (c) with the consent of the parent or legal guardian of the minor; and
- (d) if the minor is capable of understanding the nature and potential risks and benefits of the health research, the consent of the minor.

(6) The Authority shall not consent to a health research under paragraph (b) of subsection (5), in circumstances where—

- (a) the objectives of the health research or experimentation may also be achieved if it is conducted on an adult;
- (b) the health research or experimentation is not likely to significantly improve scientific understanding of the minor's condition, disease or disorder to such an extent that shall result in significant benefit to the minor;
- (c) the reasons for the consent to the health research or experimentation by the parent or guardian of the minor and, if applicable, the minor, are contrary to social norms and public policy;
- (d) the health research or experimentation poses a significant risk to the health of the minor; or
- (e) there is some risk to the health or well being of the minor and the potential benefit of the health research or experimentation does not significantly outweigh that risk.

(7) Health research involving special groups such as prisoners, pregnant women, persons with mental disabilities, or workers in a hierarchical system shall be conducted—

- (a) in such manner and on such terms and conditions as may be prescribed;
- (b) with the consent of the Authority, on recommendations from a committee of relevant experts established by the Minister; and

(c) if the person is capable of understanding, with the written consent of the person, after the person has been informed of the objectives of the health research or experimentation and any possible potential risks and benefits on the person's health.

(8) The Authority shall not consent to health research under paragraph (b) of subsection (7) in circumstances where—

(a) the objectives of the health research or experimentation may also be achieved if conducted on the general population;

(b) the health research or experimentation is not likely to significantly improve scientific understanding of the special group's condition, disease or disorder to such an extent as shall result in significant benefit to their health or well being;

(c) the reasons for the consent to the health research or experimentation are contrary to social norms and public policy;

(d) the health research or experimentation poses a significant risk to the health of the special group under consideration; or

(e) there is some risk to the health or well being of the special group and the potential benefit of the health research or experimentation shall not significantly outweigh that risk.

(9) Health research shall not be conducted without the inclusion of a Zambian, who resides in Zambia, on the research team as a principal or co-principal researcher.

(10) A research institution that hosts foreign students or other individuals for the purposes of conducting health research shall ensure that the students and those other individuals comply with the Immigration and Deportation Act, 2010.

(11) The Minister may, by statutory instrument, make regulations for the conduct of health research on, or experimentation with, animal subjects.

(12) Notwithstanding the generality of subsection (11), regulations made by the Minister under that subsection may provide for—

(a) the methods, circumstances, conditions and procedures under which health research may be conducted on animal subjects;

- (b) the principles and standards applicable to the conduct of health research on animal subjects; and
- (c) any other matters necessary for the proper conduct of health research on animal subjects in accordance with the provisions of this Act.

Prohibition of reproductive cloning of human beings

46. (1) A person shall not —

- (a) manipulate any genetic material, including the genetic material of humans for the purpose of cloning a human being; or
- (b) engage in any activity, including nuclear transfer or embryo splitting, gametes, zygotes or embryos for the purpose of reproductive cloning of a human being.

(2) A person shall not export or import human zygotes or embryos without the prior written approval of the Minister.

(3) A person who contravenes a provision of this section or who fails to comply with this section commits an offence and is liable, upon conviction, to a fine not exceeding four hundred thousand penalty units or to imprisonment for a period not exceeding five years, or to both.

(4) The Minister may, in consultation with the Authority, if it is consistent with this Act and any other written law, and upon such terms and conditions as the Minister may consider necessary, by notice in the *Gazette*, exempt any person or category of persons from any or all of the provisions of this section.

Prohibition of removal of tissue, organs, blood, blood products or gametes from living persons for research purposes

47. (1) A person shall not remove any tissue, organ, blood, blood product or gametes from a living person for health research purposes unless it is done with the written consent of the person from whom the tissue, organ, blood, blood product or gametes are removed in accordance with this Act, the regulatory framework or as is otherwise prescribed.

(2) A person shall not withdraw blood, blood products, tissue or gametes from a living person for any unspecified future health research activity or unspecified storage.

(3) A person shall not remove any tissue or organ which is not replaceable by natural processes from a minor.

(4) A person shall not sell or cause another person to sell that person's tissue, organ, blood, blood product or gametes from a living body for any purposes including health research.

(5) A person who contravenes this section commits an offence and is liable, upon conviction, to a fine not exceeding four million penalty units or to imprisonment for a period not exceeding seven years or to both.

PART VI

BIOLOGICAL MATERIALS FOR HEALTH RESEARCH

48. Notwithstanding any other law, biological material for health research shall only be collected for the purposes for which it is indicated in the research protocol.

Purposes of collection of biological materials

49. (1) The Minister shall designate specific research institutions and sites as bio-banks in accordance with section *fifty-one*, and grant a licence, in the prescribed manner, to research institution, site or health establishment which are able to provide storage services.

Storage of biological materials

(2) A bio-bank shall comply with the provisions of the Environmental Management Act, 2011, and the Health Professions Act, 2009.

Act No. 12 of 2011
Act No. 24 of 2009

(3) A person, other than the holder of a licence granted in accordance with subsection (1), who keeps biological materials commits an offence and is liable, upon conviction, to a fine not exceeding two million penalty units or to imprisonment for a term not exceeding four years, or to both.

50. (1) A person shall not export or import biological materials without the prior written approval of the Authority as provided under subsection (2).

Exportation and importation of biological materials

(2) The Authority 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 is liable, upon conviction, to a fine not exceeding two million penalty units or to imprisonment for a period not exceeding four years, or to both.

51. (1) The Minister may, by notice in the *Gazette*, designate any research institution, site or health establishment as a bio-bank.

Designation of institution as bio-bank

(2) A research institution, site or health establishment designated as a bio-bank under subsection (1), may

(a) receive biological materials for storage purposes;

(b) store biological material remnants for a period not exceeding ten years, unless the Authority approves a longer period of time for special reasons; and

(c) dispose of biological materials that are due for disposal following prescribed bio-hazard waste guidelines.

Searches at
ports of
entry, exit
and sites
Cap. 295
Act No. 16
of 2005
Act No. 18
of 2010

52. (1) An officer authorised under the Public Health Act, Ionising Radiation Protection Act, 2005, and Immigration and Deportation Act, 2010, and any other relevant law enforcement officer may conduct a search, at any reasonable time, at any site, port of entry and port of exit.

(2) Any biological material that is found to have been transferred without the necessary approvals and supporting documentation, as required under this Act, shall be confiscated and the person transferring the biological material commits an offence and is liable to the general penalty.

Ownership of
biological
materials and
material
transfer
agreement

53. (1) The Minister shall, in consultation with the Authority, prescribe and specify the requirements and contents of a material transfer agreement and shall provide for the terms and conditions regarding—

(a) ownership of the material, including any of its derivatives and modifications; and

(b) intellectual property rights, publication rights, the various uses of the material, including reproduction and replication, confidentiality of information and transfer to third parties and liabilities.

PART VII

CLINICAL TRIALS

Clinical trials

54. (1) The Minister, in consultation with the Authority, shall make regulations for the conduct of clinical trials in Zambia.

(2) The Minister may constitute a special expert review panel on matters of public interest, public policy or national security concerning the conduct of clinical trials.

(3) A medicine to be used in a clinical trial shall be approved by the Zambia Medicines and Regulatory Authority as prescribed under the Medicines and Allied Substances Act, 2013.

Act No. of
2013

(4) A clinical trial on human beings shall only be conducted—

(a) in the prescribed manner;

(b) if the researcher is in possession of a letter of approval issued by the relevant research ethics committee;

- (c) if the researcher has a clinical trial certificate issued by the Zambia Medicines Regulatory Authority;
- (d) has ethical approval granted by the Board;
- (e) in accordance with Part V; and
- (f) with proven evidence of being in possession of a no fault insurance for all research participants.

PART VIII

RESEARCH IN TRADITIONAL, COMPLEMENTARY AND ALTERNATIVE MEDICINE

55. (1) The Minister, in consultation with the Authority shall—

- (a) make regulations for facilitating health research in traditional, complementary and alternative medicine in Zambia;
- (b) ensure wide dissemination of information on traditional, complementary and alternative medicine;
- (c) foster collaborative research between and among traditional and conventional health researchers and research institutions; 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.

Research in traditional, complementary and alternative medicine

PART VIX

INTELLECTUAL PROPERTY RIGHTS

56. (1) Any intellectual property rights arising from, or connected with, health research undertaken under this Act shall be protected under the relevant laws and a health researcher or research institutions shall be entitled to the full dissemination of information and benefits of the health research.

Intellectual property rights

(2) Notwithstanding subsection (1), a research institution or a health researcher shall patent and hold rights of all innovations and inventions that are products of dedicated and original scientific research under the relevant laws relating to registration of intellectual property rights.

PART X

GENERAL PROVISIONS

Entry by
inspectors or
other
authorised
persons

57. (1) An inspector, agent of the Authority or any person authorised by the Authority for the purpose, may at any reasonable time, enter on to any site and inspect the site, after giving reasonable notice to a health researcher or person responsible for a research institution, for the purpose of ensuring compliance with this Act.

(2) Notwithstanding subsection (1), an inspector may enter a site or premises for purposes of this Act, with warrant, if the inspector has reasonable grounds to believe that a provision of this Act or of any other regulatory framework has been or is about to be contravened or the site or premises are used or are being used for the commission of an offence.

(3) If so requested by a health researcher or person responsible for a research institution, an inspector, agent of the Authority or a person authorised by the Authority shall produce evidence of the authorisation or permission, as the case may be, to enter on to the site or premises.

(4) A person exercising any power under this section shall do so with reasonable care and in such a manner as to cause as little damage as possible.

Duty to
provide
information
to inspector

58. (1) A health researcher or research institution and any employee or agent of a health researcher or research institution shall, on demand by an inspector—

(a) avail to the inspector such information as is within their knowledge in all matters relating to any inspection or investigation done under this Act; and

(b) produce for inspection, any research protocol, licence, material transfer agreement or other document or record, as the case may be, relating to the health research being undertaken on the site or any matter that is the cause for the inspection or investigation.

(2) A person who contravenes subsection (1) commits an offence and is liable, upon conviction, to the general penalty provided under this Act.

Service of
notice

59. (1) Any notice required to be served under this Act shall be served—

(a) by delivering it personally to the person required to be served or, if the person is absent or cannot be found

(i) by leaving it at the person's usual or last known place of abode in Zambia; or

(ii) by registered post, addressed to the person's usual or last known address in Zambia; or

(b) in the case of a notice required to be served on a company or other corporate body, by delivering it to its principal officer, leaving it at the office with an employee or sending it through registered post.

60. (1) Any direction, notice, consent, approval, permission, demand, objection, application or other thing authorised or required by this Act to be given, made or issued by, or to, the Minister, the Authority, the Council, Board, Director or health research ethics committee shall be in writing.

Authentication
of
documents

(2) A direction, notice, consent, approval, demand or other document which the Authority is authorised or required by or under this Act to give, make or issue may be signed on behalf of the Authority by—

(a) the Director or Secretary; or

(b) an officer of the Authority authorised by the Director, in writing, to sign documents of the particular kind or to sign the particular document.

61. (1) A person who commits an offence under this Act shall, if no other penalty is specified or prescribed in respect of the offence, be liable, upon conviction, to a fine not exceeding three hundred thousand penalty units or to imprisonment for a term not exceeding three years, or to both.

General
penalties for
offences

(2) In addition to the penalties, specified under subsection (1), any contravention of this Act or any regulations made under this Act shall be a ground for terminating a research protocol, licence or any permission or approval given under this Act.

(3) Where a person is convicted of an offence under this Act any research material or substance relating to the research shall be forfeited to the State.

62. Where an offence under this Act is committed by a body corporate or an unincorporate body, every director or manager of the corporate or unincorporate body is liable, upon conviction, as if the director or manager had personally committed the offence, unless the director or manager proves to the satisfaction of the court that the act constituting the offence was done without the

Offences by
body
corporate or
an
unincorporate
body

knowledge, consent or connivance of the director or manager or that the director or manager took reasonable steps to prevent the commission of the offence.

Regulations **63.** The Minister may, in consultation with the Authority, by statutory instrument, make regulations for the better carrying out of the provisions of this Act.

Transitional provisions **64.** (1) The National Health Research Advisory Committee established by the Ministry responsible for health shall cease to exist three months after the constitution of the Authority.

(2) Any health research related rights, liabilities, legal proceedings or obligations of the National Health Research Advisory Committee or any committee or research body established under the Ministry responsible for health which are transferrable shall without further assurance be transferred to the Authority.

SCHEDULE

(Sections 4 (2) and 42)

THE NATIONAL HEALTH RESEARCH AUTHORITY

PART 1

ADMINISTRATION OF AUTHORITY

1. (1) The seal of the Authority shall be such device as may be determined by the Authority and shall be kept by the Secretary.

Seal of
Authority

(2) The affixing of the seal shall be authenticated by the Chairperson or the Vice-Chairperson and the Secretary or any other person authorised in that behalf by a resolution of the Council.

(3) Any contract or instrument which, if entered into or executed by a person not being a body corporate, would not be required to be under seal, may be entered into or executed without seal on behalf of the Authority by the Secretary or any other person generally or specifically authorised by the Council in that behalf.

(4) Any document purporting to be a document under the seal of the Authority or issued on behalf of the Authority shall be received in evidence and shall be deemed to be so executed or issued, as the case may be, without further proof, unless the contrary is proved.

2. (1) A member of the Council shall, subject to the other provisions of this Schedule, hold office for a term of three years and may be re-appointed for a further term of three years.

Tenure of
office
and vacancy
of
member

(2) Upon the expiration of the term for which a member is appointed, the member shall continue to hold office until another member is appointed, but in no case shall any extension of the period exceed three months.

(3) The office of a member becomes vacant—

(a) upon the member's death;

(b) if the member is adjudged bankrupt;

(c) if the member is absent, without reasonable excuse, from three consecutive meetings of the Authority of which the member had notice, without the prior approval of the Authority;

(d) upon the expiry of one month's notice of the member's intention to resign, given by the member, in writing, to the Minister;

- (e) if the member becomes mentally or physically incapable of performing duties as a member; or
- (f) if the member is convicted of an offence under this Act or any other law.

Filling of
casual
vacancy

3. The Minister may, where the office of a member becomes vacant before the expiry of the term of office, appoint another member in place of the member who vacates office, but that member shall hold office only for the unexpired part of the term.

Proceedings
of
Council

4. (1) Subject to this Act, the Council may regulate its own procedure.

(2) The Council shall meet for the transaction of business at least once in every three months at such places and times as the Chairperson may determine.

(3) The Chairperson may, upon giving notice of not less than fourteen days, call a meeting of the Council and shall call a special meeting to be held within fourteen days of receipt of a written request to the Chairperson by at least five members of the Council.

(4) If the urgency of any particular matter does not permit the giving of such notice as is required under subparagraph (3), a special meeting may be called by the Chairperson, upon giving a shorter notice.

(5) Seven members of the Council shall form a quorum at any meeting of the Council.

(6) There shall preside at any meeting of the Council—

(a) the Chairperson; and

(b) in the absence of the Chairperson, the Vice Chairperson, and in the absence of the Chairperson and the Vice Chairperson, such member as the members present may elect for the purpose of that meeting.

(7) A decision of the Council on any question shall be by a majority of the members present and voting at the meeting and in the event of an equality of votes, the person presiding at the meeting shall have a casting vote in addition to the deliberative vote.

(8) The Council may invite any person, including any representative of the Council or any health research ethics committee, whose presence is in its opinion desirable, to attend and to participate in the deliberations of the meeting of the Council but such person or representative shall not have any vote.

(9) The validity of any proceedings, act or decision of the Council shall not be affected by any vacancy in the membership of the Council or by any defect in the appointment of any member or by reason that any person not entitled to do so took part in the proceedings.

5. The members of the Council, the Board or any committee shall be paid such allowances as the Council may, with the approval of the Minister, determine.

Allowances
for
members

6. (1) If a member or any person is present at a meeting of the Council or any committee of the Council at which any matter is the subject of consideration and in which matter the member or that person or the member's or that person's relative is directly or indirectly interested, in a private capacity, is the subject of consideration, the member or person shall, as soon as is practicable, after the commencement of the meeting, declare such interest and shall not, unless the Council or the committee otherwise directs, take part in any consideration or discussion of, or vote on, any question touching that matter.

Disclosure
of
interest

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

(3) In this paragraph, "relative" in relation to a person means—

(a) a parent, son, daughter, brother, sister, niece, uncle, aunt, grandparent or cousin of that person or that person's spouse; and

(b) a spouse of that person.

7. (1) A person shall not, without the consent, in writing, given by, or on behalf of, the Authority, publish or disclose to any unauthorised person, otherwise than in the course of duties of that person, the contents of any document, communication or information whatsoever, which relates to or which has come to the knowledge of that person in the course of that person's duties under this Act.

Prohibition
of
publication
or disclosure
of
information
to
unauthorised
persons

(2) A person who contravenes subparagraph (1) commits an offence and is liable, upon conviction, to a fine not exceeding three hundred thousand penalty units or to imprisonment for a period not exceeding two years, or to both.

(3) A person who, having any information which to the knowledge of that person has been published or disclosed in contravention of subparagraph (1), unlawfully publishes or communicates the information to any other person, commits an offence and is liable,

upon conviction, to a fine not exceeding three hundred thousand penalty units or to imprisonment for a period not exceeding two years, or to both.

Immunity

8. An action or other proceeding shall not lie or be instituted against a member of the Council, the Board or a committee of the Board for, or in respect of, any act or thing done or omitted to be done in good faith in the exercise or performance of, or purported exercise or performance of, any of the powers, functions or duties conferred under this Act.

PART II

FINANCIAL PROVISIONS

Funds of
Authority

9. (1) The funds of the Authority shall consist of such moneys as may—

- (a) be appropriated to the Authority by Parliament for the purposes of the Authority;
- (b) be paid to the Authority by way of fees, charges, grants or donations; and
- (c) otherwise vest in or accrue to the Authority.

(2) The Authority may—

- (a) accept moneys by way of grants, gifts, bequests or donations from any source in Zambia and subject to the prior approval of the Minister, in writing, from any source outside Zambia;
- (b) subject to the approval of the Minister, raise by way of loans or otherwise, such moneys as it may require for the discharge of its functions; and
- (c) in accordance with the regulations made under this Act, charge fees for services provided by the Authority.

(3) There shall be paid from the funds of the Authority—

- (a) salaries, allowances, loans, gratuities and pensions of staff of the Authority, and other payments for the recruitment and retention of staff;
- (b) such reasonable travelling and subsistence allowances for members, members of the Board or any committee of the Council, when engaged on the business of the Authority at such rates as the Minister may determine; and

(c) any other expenses incurred by the Authority in the performance of its functions.

(4) Notwithstanding subsections (1), (2) and (3) any moneys paid to the Authority as bequests and donations or grants for health research shall be paid into the Trust Account.

(5) The Authority may, after the approval of the Minister, invest in such manner as it thinks fit such of its funds as it does not immediately require for the discharge of its functions.

10. The financial year of the Authority shall be the period of twelve months ending on 31st December of each year.

Accounts
and audit

11. (1) The Authority shall cause to be kept proper books of accounts and other records relating to its accounts.

Financial
years

(2) The Authority shall, within ninety days of the expiry of the financial year, submit to the Minister a report concerning its activities during the financial year.

(3) The report referred to in subparagraph (2) shall include statements of income and expenditure and a statement of affairs or balance sheet.

(4) The accounts of the Authority shall be audited annually or whenever necessary by the Auditor General.

12. (1) As soon as practicable, but not later than ninety days after the end of the financial year, the Authority shall submit to the Minister a report concerning its activities and the activities of the Board during the financial year.

Annual
report

(2) The report referred to in subparagraph (1) shall include information on the financial affairs of the Authority and there shall be appended to the report—

(a) an audited balance sheet;

(b) an audited statement of income and expenditure; and

(c) such other information as the Minister may require.

(3) The Minister shall not later than seven days after the first sitting of the National Assembly next after receipt of the report referred to in subparagraph (1), lay the report before the National Assembly.

