

# THE HUMAN DNA REGULATION ACT, 2009

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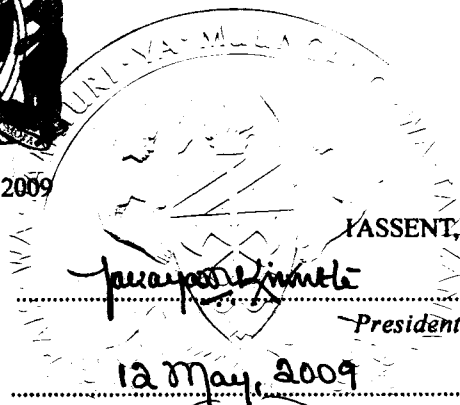
SCHEDULES

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## THE UNITED REPUBLIC OF TANZANIA



NO. 8 OF 2009



**An Act to provide for the management and regulation of collection, packing, transportation, storage, analysis and disposal of sample for Human DNA, disclosure of genetic information and research on Human DNA and to provide for related matters.**

ENACTED by Parliament of the United Republic of Tanzania.

**PART I  
PRELIMINARY PROVISIONS**

1. This Act may be cited as the Human DNA Regulation Act, 2009, and shall come into operation on such date as the Minister may, by notice published in the Gazette, appoint. Short title and commencement
2. This Act shall apply to Mainland Tanzania. Application

Interpre-  
tation

3. In this Act unless the context otherwise requires-
- “analyst” means a person who conducts or directs the analysis of sample for Human DNA, interprets data and gives results;
- “collection” the process of taking, detecting and documenting or retaining sample or objects suspected to contain sample for Human DNA ;
- “Committee” means a Human DNA Technical Committee established under section 8(1);
- “consent” in relation to a person who has attained the age of eighteen years, means voluntary acceptance of that person and , in relation to any incompetent person, means voluntary acceptance by his parent, guardian or representative;
- “court” means the District Court, the Resident Magistrate's Court or the High Court;
- “embryo” means product of human conception from the time of fertilization to the end of embryonic stage ;
- “extra corporeal embryo” means anatomic cells of an embryo developed outside the body;
- “foetus” means the product of human conception starting from completion of embryonic development until birth, miscarriage or abortion;
- “Gazetted Officer” means an officer whose appointment under this Act has been published in the Government Gazette by an order of the Minister;
- “Gene bank” means a means of preserving human genetic material for research and treatment;
- “genetic counseling” means an advice to a patient or a patient's relative on the risk of an inherited disorder, the consequences and the nature of the disorder, the probability of developing or transmitting it and the options open to them in management and family planning in order to prevent, avoid or ameliorate it;
- “genetic material” includes Human DNA and RNA;
- “human DNA” means Deoxyribonucleic acid which is the genetic material present in the nucleus of the cells and mitochondria which is inherited half from each biological parent;
- “human DNA database” means a Human DNA data bank which includes an index of Human DNA data records;
- “human DNA designated laboratory” means a laboratory designated as such pursuant to the provisions of section 72;
- “incompetent person” means a person who is under the age of eighteen years or has mental illness or is in a state of mind which impair his competency;

- “inspector” means a Human DNA service inspector appointed under section 11 of this Act;
- “institution” means any recognized organization under this Act or under any other law dealing with Human DNA;
- “intimate sample” means a sample of blood, semen or other tissue fluid, pubic hair or hair taken from an intimate part of a person's body, or a swab taken from a person's body orifice;
- “licence” includes a registration certificate and permit issued under this Act to conduct Human DNA testing;
- “Minister” means the Minister responsible for health;
- “non-intimate sample” means a sample of saliva or urine; a sample of hair other than pubic hair or hair taken from an intimate part of person's body; a sample taken from a finger nail or toe nail or from under such a nail; a swab taken from a part of a person's body other than a body orifice; or a footprint, a handprint, a fingerprint or a similar impression of a part of a person's body;
- “police officer” means in charge of a police station and includes any officer above the rank of an officer in charge of a police station and also includes when the officer in charge of a police station is absent from the station house or unable from illness or other cause to perform his duties, the police officer present at the station house who is next in rank to that officer and is above the rank of assistant inspector or when the Minister for the time being responsible for Home Affairs so directs any police officer so present;
- “population genetic” means the study of the distribution of genes in populations and how the frequencies of genes and genotype are maintained or changed;
- “receiving officer” means a person who receives sample for Human DNA ready for analysis;
- “Regulator” means the Regulator of Human DNA Services as stipulated under section 4;
- “RNA” means ribonuclei acid which is a protein maker by translating the Human DNA information;
- “requesting authority” means person or authority provided for under section 27 of this Act who initiates the process of collecting samples for Human DNA by sending the request of the same to the Human DNA laboratory established under the Government Chemist Laboratory Agency or designated laboratory for Human DNA;

- “sample for Human DNA” means any human biological specimen from which Human DNA can be extracted, or Human DNA extracted from such specimen it includes intimate sample or a non -intimate;
- “sample source's representative” means any person who has the legal authority to make decision concerning an incompetent person and includes the administrator or administratrix of the deceased person's estate or the executor or executrix;
- “sample source” means the individual from whose body sample for Human DNA has originated;
- “sampling officer” means an officer appointed and gazetted to collect sample for Human DNA under section 14;
- “transportation” means the movement of Human DNA sample from a sample source or sample source representative to the designated laboratory for Human DNA or Government Chemist Laboratory Agency.

## PART II ADMINISTRATION

The  
Regulator

4.—(1) There shall be an Office of the Regulator of Human DNA Services established within the office of the Chief Government Chemist.

(2) The Chief Government Chemist shall, by virtue of his office, be the Regulator and responsible in overseeing, regulating and the administration of Human DNA services in accordance with the provisions of this Act.

Functions  
of the  
Regulator

- 5.—(1) The Regulator shall perform the following functions to -
- (a) maintain the register of designated laboratories;
  - (b) make guidelines for the sound management and effective provision of Human DNA services;
  - (c) conduct public awareness on Human DNA technology and services;
  - (d) monitor the compliance with the provisions of this Act by the designated laboratories for Human DNA ;
  - (e) coordinate management policies, research and programmes on Human DNA services nationally and internationally;



- (f) provide technical advice to the Government and other institutions on Human DNA services management and regulation;
- (g) initiate and conduct research on Human DNA;
- (h) foster cooperation between the Government Chemist Laboratory Agency, designated laboratories for Human DNA, other institutions and organizations, on matters pertaining to the management and regulation of Human DNA services;
- (i) initiate the establishment and management of the Human DNA database;
- (j) advise the Minister the conditions that shall apply to license; and
- (k) carry out such other functions as may be assigned by the Minister.

(2) In the performance of his functions, the Regulator shall have free access to any designated laboratory for Human DNA.

(3) Any person who hinders or obstructs the Regulator or his representative in performing his functions commits an offence.

6.—(1) In the performance of his functions, the Regulator shall have and exercise the following powers to-

- (a) register and cause to be gazetted the designated laboratories pursuant to the provisions of this Act;
- (b) train and cause to be Gazetted sampling officers and inspectors as may be advised by the Technical Committee;
- (c) propose to the Minister fees chargeable under this Act;
- (d) regulate the designated laboratories for Human DNA and Human DNA research activities;
- (e) suspend or cause to be deregistered any designated laboratory for Human DNA for non compliance with this Act;
- (f) propose regulations to be made under this Act;
- (g) grant or revoke research permits or licence for Human DNA Research; and

Powers  
of the  
Regulator

(h) regulate and control researches involving Human DNA.

(2) The performance of functions and the exercise of powers by the Regulator shall be subject to the specific or general directions and approval by the Ministerial Advisory Board of the Government Chemist Laboratory Agency.

(3) The Regulator may delegate any of his powers or functions in writing to any officer or employee of the Government Chemistry Laboratory Agency who is knowledgeable in Human DNA technology.

Consulta-  
tions  
with  
other  
Institutions

7. The Regulator shall maintain as far as practicable a system of consultation and cooperation with other institutions which have in one way or another, functions related to the functions specified under this Act.

Establish-  
ment and  
functions of  
the  
Technical  
Human  
DNA  
Committee

8.—(1) There shall be a committee to be known as the Human DNA Technical Committee which shall be responsible for advising the Regulator on matters related to the management, regulation of all Human DNA services and research, and any other functions assigned to it under this Act.

(2) Without prejudice to subsection (1), the functions of the Technical Committee shall be to-

- (a) advise the Regulator on matters pertaining the provision of Human DNA services and research;
- (b) advise the Regulator on the application for registration of designated laboratories;
- (c) advise on the appointment of sampling officers and inspectors and propose their training programmes;
- (d) advise on the content and methodology of public educational awareness and campaigns on Human DNA technology and services;
- (e) advise on management policies, research and programmes on Human DNA services nationally and internationally;
- (f) advise on granting, suspension, cancellation or deregistration of designated laboratories; and

- (g) advise on any proposed regulations to be made under this Act by the Minister.

(3) The First Schedule to this Act shall have effect as to the tenure and procedures of the Human DNA Technical Committee.

(4) The Minister shall have power to amend, vary or replace all or any provision of the Schedule.

9.-(1) The Minister shall appoint members of the Technical Committee from both public and private institutions with vested interest in Human DNA technology in Tanzania.

Appoint-  
ment of  
members  
and  
composi-  
tion of  
the  
Committee

- (2) The members of the Technical Committee shall comprise of -
- (a) Chief Medical Officer who shall be the Chairman;
  - (b) a representative from the National Institute for Medical Research;
  - (c) a representative from Police Forensic Laboratory;
  - (d) a representative from Biochemistry department of any recognized university in the country;
  - (e) a representative from the department of Forensic Pathology of the National Hospital;
  - (f) a representative from Biotechnology department of any recognized university in the country;
  - (g) a representative from the Association of Private Health Facilities in Tanzania;
  - (h) a representative from Biotechnology at Commission for Science and Technology;
  - (i) a representative from the Department of Social Welfare;
  - (j) a representative from a privately owned designated laboratory for Human DNA;
  - (k) a Legal Officer from the Ministry responsible for health; and
  - (l) a representative from the Molecular Biology and Biotechnology Department of any recognized university in the country.

(3) The Regulator shall provide Secretariat services to the Committee.

Co-option  
of members

10. When dealing with a specific matter for which extra expertise is required, the Committee may co-opt persons who have the relevant expertise; such co-opted persons shall have no right to vote and shall cease to be members when the matter is determined.

Appoint-  
ment of  
inspectors

11. The Minister on the advice of the Regulator, shall appoint Inspectors from amongst officers from the Government Chemist Laboratory Agency or any other Public Office by notice published in the *Gazette*.

Powers of  
inspectors

12.—(1) The inspector, in the discharge of his duties under this Act or any regulation made thereunder, at all reasonable time without a warrant and on production of identity card, may—

- (a) enter into any premises with designated laboratory;
- (b) inquire, inspect, examine and make any copy of certificates, registers, records and other documents related to this Act and its regulations;
- (c) seize any equipment, consumable, samples for human DNA processed genetic materials, chemical or other articles believed to have been used in the contravention of the provisions of this Act and the processed genetic materials; and
- (d) cause a police officer to arrest any person believed to have committed an offence under this Act.

(2) Any person who wilfully delays, or obstructs, hinders, intimidates or assaults an inspector performing his duties, commits an offence punishable under this Act.

Duties of  
Inspectors

13.—(1) For the purpose of ensuring compliance with this Act, an inspector shall carry out periodic inspection of designated laboratories as may be directed by the Regulator.

(2) Without prejudice to the provisions of subsection (1), the inspector shall -

- (a) check and verify the number and qualifications of the staff of the designated laboratory;
- (b) check the appropriateness of the premises and the laboratory set up;
- (c) examine and verify observance of standard operating procedures; and
- (d) check compliance of quality assurance standards of designated laboratories.

(3) At the conclusion of every inspection, the inspector shall compile an inspection report and submit the same to the Regulator.

(4) Upon receipt of the report pursuant to subsection (3), the Regulator may give directions for improvement or take other action as it may deem necessary.

14.-(1) The Regulator shall, on the advice of the Technical Committee, appoint sampling officers and cause their names to be published in the *Gazette*.

Appointment and discharge of duty by sampling officers

(2) Without prejudice to sub section (1), any medical practitioner or police officer shall be a sampling officer under this Act.

(3) The sampling officer shall collect, document and transport sample for Human DNA to the laboratory for analysis.

(4) The sampling officers shall, in the course of discharging their duties, observe the sampling guidelines stipulated in the regulations made under this Act.

### PART III

#### ESTABLISHMENT OF HUMAN DNA LABORATORY

15.-(1) There shall be a Human DNA laboratory within the Government Chemist Laboratory Agency.

Establishment of Human DNA laboratory

(2) The Human DNA Laboratory shall be exempted from the provisions to application, issuance, validity, granting, suspension, cancellation and delegation of licence.

- (3) The Human DNA laboratory shall-
- (a) analyse samples for investigation purposes, or to be included in the National Human DNA data base;
  - (b) inspect designated laboratories for Human DNA;
  - (c) manage and maintain the National Human DNA database;
  - (d) give expert testimony in courts of law;
  - (e) assist domestic and international law enforcement agencies with large scale investigations and disasters;
  - (f) perform Human DNA sampling for private sector or overseas clients;
  - (g) make research, consultancy and training in matters related to Human DNA; and
  - (h) perform any other functions as may be directed by the Minister pursuant to the provisions of this Act.

(4) Notwithstanding the provisions of subsection (2), the Human DNA laboratory established under subsection (1) shall comply with all the required international standards operating procedure and quality assurance programmes.

Licensing  
Authority

16. The Regulator shall be the licensing authority responsible for the issuance, renewal, suspension and revocation of licences to run designated laboratories.

Applica-  
tion of  
licence

17.-(1) A person wishing to run a laboratory for the Human DNA shall submit an application for licence to the Regulator.

(2) Any application for a licence under this Act shall be made to the Regulator in the prescribed form and shall be accompanied by such fee as may be prescribed.

(3) Where an application is made for a licence the Regulator shall before issuing a licence consider whether -

- (a) the applicant is a resident of Tanzania or a company registered in Tanzania and is of good stand;
- (b) the applicant has appropriate premises, equipment and qualified staff to conduct Human DNA testing;
- (c) the director of the laboratory has a proven knowledge and skills in Human DNA technology;
- (d) the laboratory is registered and manuals for standard operating procedures are in place; and
- (e) the laboratory has evidence that it is implementing quality assurance programmes.

(4) A separate licence under this part shall be required in respect of each distinct set of premises in which the Human DNA testing is carried out.

(5) Where the applicant for a licence has been registered under the Private Health Laboratories Act, it shall suffice for the applicant to pay processing fee in lieu of registration fee.

18.—(1) The Regulator shall, if he is satisfied and upon the advice from the Technical Committee that the applicant qualifies to be issued with a licence, issue to the applicant a licence subject to such general or specific conditions.

Issuance  
of  
licence

(2) A licence shall be issued under the conditions to be set by the Minister as may be proposed by the Regulator from time to time.

(3) Where the Regulator considers that the applicant is not fit and appropriate person to whom the licence should be issued for running a designated laboratory, he shall refuse to issue the licence and shall give reasons for that refusal.

(4) After the issuance of a licence under this section, the Minister may, by notice published in the *Gazette*, establish a designated laboratory to carry out functions of collecting and analyzing sample for Human DNA.

19. Each licence or permit issued under this Act shall be valid for twelve months from the date of issue and may be renewed.

Validity  
and  
renewal of  
licence or  
permit

Suspension and cancellation of licence

20. The Regulator may suspend or cancel a licence for such period as he may determine if -

- (a) the licensee does not meet the standard operating procedures;
- (b) the licensee does not have qualified analysts; or
- (c) the licensee does not comply with quality assurance standards.

Issue of notice to owner of designated laboratory for Human DNA

21-(1) Where the Regulator has discovered through inspections report that the designated laboratory does not conform with the requirements under this Act, he shall issue a notice to the owner of the designated laboratory requiring him to improve the areas which do not meet the required standards.

(2) The Regulator shall in writing give the licensee a timeframe for improvement and specific areas to be improved, failure of which the licence shall be revoked.

(3) Notwithstanding the provisions of subsection (1), a licensee shall prior to suspension or revocation of his licence, be afforded an opportunity to state his case.

(4) Where the Regulator orders suspension or cancellation of a licence, he shall determine the fate of the samples for Human DNA, processed genetic materials that are in possession of the licensee, and may order transfer of the samples or part of it to the Government Chemist Laboratory Agency or other designated laboratory for Human DNA.

Non-transferability of the licence

22.-(1) A licence issued under this Act shall not be transferable.

(2) The transfer of control of a corporate entity which is a licensee shall require the prior written consent of the Regulator who may determine if such transfer requires a new licence or not.

#### PART IV

##### COLLECTION AND ANALYSIS OF SAMPLE FOR HUMAN DNA

Collection and analysis of sample for Human DNA

23. The samples for Human DNA shall be collected and analyzed for the purpose of establishing parentage, kinship, criminal investigation,



research in population genetics, medical, pharmaceutical, chemical and nutrition assessment.

24. The samples for Human DNA shall be collected by sampling officers and analyzed by the Human DNA Laboratory of the Government Chemist Laboratory Agency or other designated laboratory for Human DNA.

Authority to collect and analyze sample for Human DNA

25.-(1) The analysis of sample for Human DNA shall be initiated by a written application by the requesting authority to the Human DNA Laboratory of the Government Chemist Laboratory Agency or designated laboratories for Human DNA.

Requesting authority

(2) For the purpose of this Act the requesting authority shall be:-

- (a) the court where the subject matter is in dispute between the parties;
- (b) advocates of the court of law, Social Welfare Officers and community development officers for law matters which are not in dispute;
- (c) a Police Officer of or above the rank of inspector;
- (d) research institutions that are mandated to conduct research in Human DNA;
- (e) a District Commissioner in the case of a mass disaster; or
- (f) medical practitioner for medical cases.

26.-(1) Subject to subsection (2) of section 25 of this Act requirements for authorization from the requesting authority under this Act shall -

- (a) be in writing, signed by the sample source or the sample source's representative and dated;
- (b) identify the person collecting the sample for Human DNA or causes the sample for Human DNA to be collected;
- (c) identify the facility in which the analysis shall be performed;

Requirement of written authorization

- (d) identify the facility in which the sample for Human DNA shall be stored;
- (e) state the manner in which the sample is to be collected;
- (f) include a description of all authorized uses of the sample for Human DNA;
- (g) indicate whether or not the sample source permits the sample to be maintained or stored in an identifiable form after the analysis is completed;
- (h) include a provision that enables the sample source or the sample source's representative to prohibit the use of the sample for Human DNA for research or commercial purposes even if the sample is not an individually identifiable form;
- (i) indicate the reasons why collection of sample for Human DNA is required;
- (j) describe the specific genetic information to be disclosed; and
- (k) describe the purpose for which the analysis is being made.

(2) A written authorization under subsection (1) shall be in the form as may be prescribed in the regulations under this Act.

Scrutiny  
of the  
applica-  
tion

27. The Human DNA Laboratory of the Government Chemist Laboratory Agency or the designated laboratory for Human DNA upon receipt of the application from the requesting authority shall scrutinize the same and ensure that it conforms with the requirements of section 26 and prescribed fees have been paid.

Notice of  
rights and  
assurances

28.—(1) Subject to subsection (3), prior to collection of sample for Human DNA from a sample source, the sampling officer collecting the sample or causing the sample to be collected shall verbally inform the sample source or the sample source's representative of his rights and assurances as shall be specified in the Second Schedule to this Act and the sample source or sample source representative shall sign the form containing information indicating acceptance.

(2) The rights and assurances of the sample source shall include the following information-

- (a) sample for Human DNA shall only be used as authorized in the written authorization;

- (b) sample for Human DNA is the property of the sample source;
- (c) unless specifically prohibited by the sample source or sample source's representative, researchers may be granted access to sample for Human DNA that cannot be linked to individual identity;
- (d) sample source or the sample source's representative save for sample for Human DNA collected for criminal investigation and by court order, has the right to order the destruction of the sample for Human DNA at any time;
- (e) sample for Human DNA shall be destroyed on completion of the analysis unless the sample source or the sample source's representative has previously directed otherwise in writing;
- (f) the sample source may designate another individual as the person authorized to make decisions regarding the sample for Human DNA after the death of the sample source; and if any person is so designated, the sample source shall notify the facility in which the sample for Human DNA is stored;
- (g) save for samples collected from criminal suspects, the sample source's representative has the right to examine the records containing private genetic information and to obtain copies of such records;
- (h) sample source or sample source representative or criminal investigation authority may request for necessary corrections or amendments, if any, of the personal particulars of the sample source;
- (i) right to have copy of written authorization; and
- (j) genetic counseling services.

(3) Samples of Human DNA collected from dead bodies, criminal investigations and in compliance with court order, shall not require the consent of the sample source or sample source's representative.

29.-(1) Samples for Human DNA shall be collected from -

- (a) saliva;
- (b) hair with root;
- (c) urine;

Modes  
and types  
of  
samples  
to be  
collected  
for  
Human  
DNA

- (d) stool;
- (e) blood;
- (f) skin;
- (g) teeth;
- (h) bones;
- (i) semen;
- (j) vaginal swab;
- (k) objects believed to have stains or remains of any of the above;
- or
- (l) any other objects, human tissue or parts of a human body as the need may arise.

(2) Without prejudice to the provisions of subsection (1), upon request by the sampling officer, the requesting authority may authorize the collection of a sample other than samples stipulated under subsection (1), if it shall lead to Human DNA identification.

(3) No intimate sample shall be collected if non intimate sample may easily be obtained.

Collection  
of  
samples  
for  
Human  
DNA for  
criminal  
investiga-  
tion

30.-(1). Where the sample for Human DNA is collected for criminal investigation, the sampling officer shall inform the person from whom the sample for Human DNA is to be taken-

- (a) that the authorization by the requesting authority has been obtained;
- (b) the reasons for taking the sample for Human DNA;
- (c) the procedure to be used to collect; and
- (d) that the genetic information to be extracted from that sample for Human DNA may be used as evidence for or against that person.

(2) A criminal suspect who has not attained the age of eighteen years from whom the sample for Human DNA is to be collected, shall have the right to have the sample for Human DNA to be taken in the presence of his parent, guardian, a representative or a social welfare officer.

(3) Where an intimate sample for Human DNA is to be taken from a female person, only a female sampling officer shall take the sample for Human DNA from that person.

(4) Where a person refuses to give consent for sample for Human DNA to be taken from him under this Section, the provisison of Section 59(4) of the Criminal Procedure Act shall be invoked.

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31.-(1) The collection of sample for Human DNA shall be fair, legal and where practicable not unreasonably intrusive and shall uphold human dignity.

Collection to be humane

(2) Where collection of sample for Human DNA takes place at the scene of crime the sampling officer shall document all necessary information.

32.-(1) The sample for Human DNA shall be packed for transportation to the laboratory for analysis and shall be preserved, sealed, labelled and coded in appropriate containers.

Packing of samples

(2) The collected sample for Human DNA shall be under the custody of the sampling officer who shall keep it strictly under lock and key.

33.-(1) The sampling officer shall cause the sample for human DNA to be transported to the laboratory through appropriate and safe means.

Transportation of sample

(2) In exercising discretion pursuant to subsection (1), the sampling officer shall take into account the nature, sensitivity and urgency of the genetic information to be extracted from the sample for Human DNA.

(3) The sampling officer shall fill in a prescribed form every stage pertaining to the transportation of the sample.

34.-(1) The sample for Human DNA shall be received and recorded in a register and shall be given a laboratory number by the sample receiving officer after being satisfied that the sample for Human DNA integrity has been maintained and accompanied with the necessary documents.

Receipt and storage

(2) The receiving officer may reject any sample if such sample does not meet the requirements provided under subsection (1) and such rejection shall be communicated in writing to the requesting authority.

(3) The sample shall be handed over to the analyst in a prescribed form accompanied with the relevant documents.

(4) The analyst shall store the sample for Human DNA under lock and key.

(5) Procedures and forms for collection, packing, storage, transportation and receiving of sample for Human DNA, shall be as prescribed in the Regulations under this Act.

(6) Without prejudice to the provisions of this section, the sample for Human DNA found to be spoiled or inadequate at any stage before completion of the analysis, information on such defect or inadequacy shall be communicated in writing to the requesting authority who may collect another sample.

Analysis of  
sample for  
Human  
DNA

35.-(1) The analysis of sample for Human DNA shall be confined to private genetic information requested by any authority under section 26 such information shall be kept in secrecy.

(2) No person shall analyze a sample for Human DNA without ascertaining that written authorization for collection and analysis of the sample for Human DNA has been obtained.

Re-  
collection

36. The re-collection of sample for Human DNA may be requested by the laboratory undertaking the analysis on the reason that the previous sample—

- (a) is inadequate;
- (b) non-compliant with set principles and procedures for sample management;
- (c) contaminated; or
- (d) decomposed.

Owner-  
ship

37.-(1) A sample for Human DNA shall be the property of the sample source.

(2) Where a sample source is an incompetent person, the ownership of such sample for Human DNA shall be under the care of the sample source's parent, guardian or representative.

(3) Where a sample for a Human DNA has been collected pursuant to section 23 except for the sample for Human DNA collected for criminal investigation or by court order, the sample source or the sample source's representative shall have the right to order the destruction of the sample for Human DNA.

## PART V

### HUMAN DNA RESEARCH ACTIVITIES, MEDICAL RESEARCH AND TREATMENT

38.-(1) Any person who intends to conduct research that involves Human DNA analysis other than medical Human DNA research and genetic treatment shall apply for a permit on the prescribed form to the Regulator and shall specify the sample for Human DNA to be collected, the place, focus and purpose of the research.

Research  
involving  
genetic  
analysis

(2) Any person who intends to conduct medical and treatment research which involves Human DNA or other genetic material shall, before the commencement of such research, apply for the permit in writing in the prescribed form to the Regulator.

(3) The application and notification referred to in subsections (1) and (2) respectively shall be accompanied by a statement about -

- (a) in what way the use of samples for Human DNA is essential and necessary to the research;
- (b) how the benefit of research outcomes outweighs the potential risks to the sample sources privacy that may result from the analysis of their samples;
- (c) whether the research proposal contains adequate safeguards to protect against the disclosure of private genetic information to be generated by the research;
- (d) whether the researcher is qualified and meets the requirements provided under this Act in the collection and management of samples for Human DNA and private genetic information; and

- (e) the declaration on that the researcher shall not reveal or divulge in his report or publication findings which disclose names of the sample sources.

(4) The Regulator upon being satisfied that the application complied with subsections (1) and (3) shall grant a permit and where he is dissatisfied by the application he shall give reasons in writing for refusal.

(5) Where the Regulator has granted a permit and found that the researcher is contravening research ethics and requirements of this Act shall forthwith cancel the permit.

(6) Upon receipt of notification issued pursuant to subsection (2) and where the Regulator has objection on notification shall within thirty days communicate in writing to the applicant with reasons for such objection.

(7) Where the research results from an individual or an institute are new or unique, the researcher or the institute shall have the intellectual property right.

Non-  
medical  
research

39.-(1) A researcher who intends to conduct a non-medical Human DNA research on an incompetent person shall, before conducting such research, obtain a written consent of the parent, guardian or representative of that person.

(2) The research conducted under subsection (1) shall not abuse the incompetent person.

(3) A parent, guardian or representative of the incompetent person shall not give his consent referred to under subsection (1) for personal gain.

(4) Any person who contravenes any provision of this section commits an offence and on conviction is liable to a fine of not less than five million shillings or to imprisonment for a term of not less than three years or to both.

Analysis of  
sample for  
Human  
DNA for a  
dead person  
taken prior  
to his death

40.-(1) Notwithstanding the provisions of section 38, a sample for human DNA collected from a sample source who died prior to the completion of the research project, may be analyzed as part of the



research project, no genetic information may be disclosed without the authorization of the sample source's representative.

(2) Where consent of a sample source was procured on the basis of a contract between the researcher and a sample source, then the disclosure of genetic information or results shall require the authorization of the next of kin of the deceased; sample source.

41. The researcher before collecting a sample for Human DNA shall inform the district or regional administration where the research shall be conducted and no sample shall be collected without the consent of the sample source or the representative of the sample source and the sample or samples collected shall be those contained in the permit.

Information to district or regional administration

42. Collection of sample for Human DNA shall closely observe and preserve the dignity of the sample source and be free from inducement, coercion or undue influence.

Preservation of dignity of the sample source

43.-(1) The researcher shall be wholly responsible for the security of the sample for Human DNA collected.

Security

(2) Where loss of sample for Human DNA occurs in course of research the researcher shall be required to apply for a fresh permit for a re-collection of sample for Human DNA.

44.-(1) For the purpose of ensuring non disclosure of genetic information, the researcher shall, after completion of his research –

Safeguards against disclosure of genetic information through destruction

- (a) subject to paragraph (c), within one month notify his intention for re-use of the same sample for Human DNA on another research;
- (b) within three months, destroy the samples for Human DNA collected; or
- (c) in conformity with paragraph (a) procure consent of the sample source and re-apply to the Regulator for use of the same.

(2) Any researcher failing to comply with the provisions of subsection (1) commits an offence.

## PART VI

## PREGNANT WOMEN, FOETUSES AND EXTRA CORPOREAL EMBRYOS

Rights of  
a  
pregnant  
woman

45.-(1) The Human DNA test shall not be conducted on a pregnant woman unless the test is for medical purposes.

(2) A pregnant woman shall have rights and authority regarding samples for Human DNA taken from her for the purposes of the test referred to under subsection (1).

Collection  
and  
analysis of  
extra  
corpo-  
real  
embryo

46.-(1) Collection of samples for Human DNA from an extra corporeal embryo or foetus for Human DNA test for treatment purpose shall be conducted under the direction of a medical doctor.

(2) Any person who collects and analyses sample for human DNA from an extra corporeal embryo or foetus contrary to the provision of subsection (1) commits an offence.

Destruc-  
tion of  
samples

47. The destruction of sample for Human DNA shall be done in accordance with section 58.

## PART VII

## INCOMPETENT PERSONS

Conditions  
for  
collection  
of sample  
for Human  
DNA from  
incompe-  
tent  
person

48.-(1) For the purpose of this Act, the sample for Human DNA may be collected from incompetent persons and analysed after getting written consent from the parent, guardian or a representative on the conditions that:

- (a) there are findings indicating a disease or handicaps;
- (b) the Human DNA testing is required to clarify the existence of carrier gene of a disease or handicaps which through reasonable medical assessment can be prevented or its spread can be delayed or the fate of the incompetent person can be improved;
- (c) the Human DNA testing is required for the purpose of lawfully approved research;
- (d) the Human DNA testing is for establishing paternity of a child as ordered by the court pursuant to the provisions of the Law of Marriage Act and the Affiliation Act; or

- (e) the Human DNA testing is carried in the course of criminal investigation whereby the incompetent person is a victim or an eliminating sample.

(2) Notwithstanding the provision of subsection (1) the collection of sample for Human DNA from incompetent persons shall be done in the presence of a parent, guardian, a representative or a Social Welfare Officer.

49.-(1) The sample for Human DNA of a sample source who lacks the ability to understand the information divulged pursuant to section 28 and the information contained in an authorization under section 26 shall not be collected or analyzed unless the analysis is necessary to-

Collection  
or  
analysis  
for  
medical  
treatment

- (a) diagnose the cause of incompetence;
- (b) diagnose a genetic condition which, in reasonable medical judgment, can only be effectively ameliorated, prevented or treated while the sample source is incompetent; or
- (c) diagnose a genetic disease of a parent, sibling, child or grandchild of the sample source provided that the disease, in reasonable medical judgment, can be effectively ameliorated, prevented, or treated.

(2) The analysis of sample conducted pursuant to subsection (1) shall be limited to that which is necessary for such diagnosis.

(3) The private genetic information of incompetent persons shall be disclosed to the parent, guardian or representative of such incompetent person pursuant to the provisions of section 52 of this Act.

50. In determining application for collection and analysis of sample for Human DNA to establish paternity the court shall be guided by the principle of best interest of the child and family bond of the parties.

Best  
interest  
and  
family  
bonds to  
prevail

51. The destruction of sample for Human DNA shall be done in conformity with provisions of section 58 of this Act.

Destruc-  
tion of  
samples

## PART VIII

## DISCLOSURE OF GENETIC INFORMATION AND DESTRUCTION OF SAMPLE FOR HUMAN DNA

Disclo-  
sure of  
genetic  
informa-  
tion

52. The genetic information shall be communicated to the requesting authority who shall disclose the same information to the sample source or parent, guardian or representative of the sample source.

Revoca-  
tion or  
amend  
ment of  
the autho-  
rization  
to disclose  
genetic  
informa-  
tion

53. The sample source or sample source's representative may, through the requesting authority, revoke or amend the authorization to disclose genetic information in whole or in part at any time and reasons for such revocation or amendment shall be given.

Access to  
genetic  
records

54. The Regulator or the designated laboratories may, upon written request by the requesting authority, permit the sample source or sample source's representative to access records containing private genetic information and may be provided with a copy of such records at a fee.

Compul-  
sory  
disclosure  
of genetic  
informa-  
tion

55. The genetic information of any person shall not be divulged in compliance with an order for compulsory disclosure in civil proceedings, unless the sample source or the sample source's representative is a party to such proceedings and the genetic information is at issue.

Court to  
hear and  
determine  
Disclosure  
of genetic  
informa-  
tion

56.—(1) An order made pursuant to section 55 for the disclosure of genetic information shall only be made by the court's determination that a good cause exist.

(2) Before making an order under subsection (1) the court shall satisfy itself that—

- (a) no other ways of obtaining the private genetic information are available or may not be effective; and
- (b) there is a compelling need for the private genetic information which outweighs the potential harm to the privacy of the sample source.

57. An order made pursuant to the provisions of sections 55 and 56 for the disclosure of private genetic information shall-

Limitation of court order

- (a) limit disclosure only to persons whose need for such information is the basis of the order;
- (b) limit disclosure to those parts of records containing such information which are essential to fulfill the objective of the order;
- (c) require non disclosure of names of people in the collection and analysis of the sample of Human DNA from any documents made available to the public; and
- (d) provide protective measures to the sample source by sealing from public scrutiny the record or any part of the record of any proceedings for which disclosure of the information has been ordered.

58.-(1) After disclosure of genetic information to the requesting authority, the samples for Human DNA, processed genetic material and genetic information shall be destroyed in the following manner-

Destruction of sample for Human DNA, processed genetic material and genetic information

- (a) for paternity and civil matters, it shall be six months after the date of disclosure unless there is pending appeal where the sample for Human DNA is at issue;
- (b) for criminal matters, the sample for Human DNA and any processed genetic materials shall be destroyed after the extraction of the genetic information;
- (c) the sample for Human DNA and any processed genetic materials, within one month after the date of disclosure;
- (d) for medical cases, within three months from the date of disclosure; and
- (e) in case no one has requested the destruction of the sample for Human DNA and processed genetic materials after twelve months from the date of disclosure, the designated laboratory in custody of such sample shall destroy sample for Human DNA and any processed materials.

(2) The custodian of the sample for Human DNA and processed Human DNA materials which have been destroyed under this section shall bear no liability whatsoever.

(3) Where the genetic information is contested by way of appeal or revision, the designated laboratory shall be ordered to retain the sample for Human DNA until the final determination of the case.

(4) In exercising its appellate or reversionary powers, the court shall soon after admitting an appeal or application for revision and where the genetic information is one of the grounds of appeal or application for revision, it shall immediately send such retention order within six days of the receipt of the appeal or application.

(5) The destruction of sample for Human DNA and any processed genetic material shall be done under the supervision of the in charge of the Human DNA laboratory.

Human  
DNA  
Database  
and gene  
Bank

59.-(1) The Regulator shall, in collaboration with other relevant authorities, initiate the establishment of the National Human DNA database and gene Bank for genetic information

(2) The Regulator shall ensure that the data is securely stored and remains confidential.

Disclosure  
of sample  
for  
Human  
DNA on  
research

60. Any person who, in the ordinary course of business stores or maintains private human genetic information shall be prohibited from allowing access to such information by researchers unless-

- (a) the Regulator has approved a program or study for non medical research and has been notified of the medical or pharmaceutical research; and
- (b) the sample source or the sample source's representative has specifically consented to the access or disclosure of such information under authorization which is in conformity with the provisions of sections 26 and 30.

Access to  
informa-  
tion for  
the  
purposes  
of  
inspection  
of genetic  
records

61. Notwithstanding the provisions of section 60, any person who stores or maintains human genetic information may grant access to such information solely for the purpose of inspection or review of records containing the information on condition that -

- (a) the inspection or review is for the purpose of compiling data for statistical or epidemiological studies;
- (b) private genetic information is not to be copied, removed from records or re-disclosed in any way;
- (c) the person conducting the inspection or review certifies in writing that conditions attached to the disclosure shall be complied with; and
- (d) that he is aware of the liability for any violation of the provisions of this Act.

62. Where analysis of sample for Human DNA permitted under Part IV determines that a relative of a deceased sample source is at risk of genetic disease which in reasonable medical judgment can be effectively ameliorated, prevented or treated, nothing in this Act shall be construed as prohibiting researchers from contacting such relatives and informing them of such risk.

Disclosure  
to  
relatives

63.-(1) An employer shall not be allowed to require from the employee or a person applying for employment to provide his genetic information or to undergo Human DNA test as a pre condition for the employment.

Preven-  
tion of  
discrimi-  
nation

(2) No insurer or an insurance agent or training institution or any organisation is allowed to set a condition to the insured or people applying for admission or insurances services to provide their genetic information or undergo Human DNA test.

(3) Any person who contravenes the provisions of subsections (1) and (2) commits an offence.

64.-(1) Any person who receives or access private genetic information in the performance of his duties or in the cause of his employment shall keep such information confidential and shall not divulge it to any body or make use of it during or after the tenure of employment without the written authorization of the sample source or the sample source representative.

Confiden-  
tiality

(2) A director of a designated laboratory, a researcher on Human DNA, a director of a research institution or hospital that conduct Human

DNA analysis shall take all reasonable measures to ensure that employees and anyone under their supervision maintain confidentiality of the matters brought to their knowledge in the course of discharge of their duties.

Non  
disclosure

65.-(1) The Regulator shall not disclose any genetic information obtained and kept under this Act, except to -

- (a) the criminal investigation section of police in the course of criminal investigation or proceedings;
- (b) the person from whom the genetic information was extracted and such genetic information is requested for his defence; and
- (c) a country making request, which is accepted by the Attorney General for mutual assistance in criminal matters pursuant to the provisions of the Mutual Assistance in Criminal Matters Act.

Cap. 251

(2) Any person who contravenes the provision of subsection (1) commits an offence and on conviction is liable to a fine of three million shillings or to imprisonment for a term of two years or to both.

## PART IX

### FINANCIAL PROVISIONS

Funds and  
sources

66.-(1) Funds for administration and regulation of Human DNA shall be drawn from the following sources -

- (a) such sums of money as may be appropriated by the Parliament for the Government Chemist Laboratory Agency;
- (b) fees imposed and other charges collected for the services rendered; and
- (c) such donations and grants bequests as may be given for the purposes of administration of this Act.

(2) The funds collected pursuant to subsection (1) shall be administered by the Regulator.

(3) The Regulator shall prepare and keep proper books of accounts and audit reports three months after the end of each financial year.



(4) The funds collected under this Act shall be audited by the Controller and Auditor General along the accounts of the Government Chemist Laboratory Agency.

## PART X

### OFFENCES AND PENALTIES

67.-(1). Without prejudice to any provisions of this Act, and any other written law, any person who-

Offences  
and  
penalties

- (a) collects sample without written authorization of the requesting authority;
- (b) deliberately swaps samples of Human DNA;
- (c) wilfully collects sample through intimate method while options for non intimate collection are easily available;
- (d) collects sample while not gazetted;
- (e) wilfully mislabel, or mismatches samples of Human DNA;
- (f) deliberately exposes sample for Human DNA and or processed genetic materials to the risks of destruction;
- (g) extracts genetic information more than what was requested,
- (h) divulges genetic information to unauthorized person or contrary to the intended purpose;
- (i) discloses wrong genetic information;
- (j) conducts research without permission of the relevant authority;
- (k) extraction of sample from minor and incompetent person without written authorization of a parent or guardian or representative; or
- (l) laboratory conducting analysis of samples for Human DNA without being registered and designated, commits an offence.

(2) Any person who commits an offence under subsection (1) shall on conviction be liable to a fine of five million shillings or to imprisonment for a term of three years or to both.

(3) Notwithstanding the provisions of subsection (1) any person, who knowingly, deliberately or wilfully-

- (a) swaps sample for Human DNA;
- (b) makes disclosure of wrong genetic information;
- (c) collects sample for Human DNA without the written authorization or permit from the relevant authority;
- (d) conducts research without the authorization of the relevant authority;
- (e) collects samples by means of undue influence, coercion or use of money;
- (f) extracts sample from an incompetent persons without a written authorization of a parent, guardian or a representative;
- (g) buys a sample for Human DNA from sample source or sample source's representative; or
- (h) sends sample for Human DNA analysis abroad without permission of the Regulator,

commits an offence, and upon conviction shall be liable to a fine of not less than five million shillings and not exceeding ten million shillings or to imprisonment for a term of not less than three years and not more than five years or to both.

(4) Any person who contravenes the provisions of Parts VI and VII commits an offence and on conviction, is liable to a fine of not less than five million shillings but not exceeding fifty million shillings or to imprisonment for a term of not less than three years but not exceeding seven years or to both.

(5) Any person who contravenes the provisions of section 56 of this Act commits an offence and upon conviction shall be liable to a fine of not less than ten million shillings but not exceeding fifty million shillings or to imprisonment for a term of not less than two years but not more than seven years or to both.

68. Where an offence is committed under this Act by a body corporate and it is proved to have been committed with the consent or connivance of, or to have been facilitated by any neglect on the part of any officer, a member of such body corporate or any person who purports to act in any such capacity, such officer, member or such other person as well as the body corporate commits an offence and upon conviction shall be liable to a fine of not less than five million shillings and not more than fifty million shillings.

Offences  
by body  
corporate

69. Where a person is convicted for contravention of any provision of this Act or any regulation made under this Act for which no specific penalty has been prescribed that person shall be liable to a fine of not less than three million shillings or to imprisonment for a term of not less than three years or to both.

General  
penalty

## PART XI MISCELLANEOUS PROVISIONS

70. Any thing done in good faith by a member, the Regulator or any person empowered to perform any function under this Act in execution of his function shall not render such member, the Regulator or that other person personally liable for the thing done.

Protec-  
tion for  
bona fide  
acts

71.-(1) The Minister may at any appropriate time make regulations for the effective carrying out of the objectives and purpose of this Act.

Power to  
make  
regula-  
tions

(2) In particular and without prejudice to the generality of subsection (1), the Minister shall make regulations prescribing for -

- (a) the fees to be paid under this Act;
- (b) various forms to be used under this Act;
- (c) procedures in which an application and registration of designated laboratory shall be made;
- (d) requirements of Human DNA sampling kit;
- (e) procedures for disposal of human biological materials, consumable wastes and their containers;
- (f) qualifications and duties of inspectors and analysts;

- (g) procedures for appointment of inspectors and designated laboratories;
- (h) procedure for record keeping;
- (i) prescribing mechanisms for establishing and management of Human DNA database;
- (j) management and regulatory procedures which are in conformity with international conventions and accreditation;
- (k) prevention and management of accidents; and any other matter which may be required for effective carrying into effect or implementation of this Act;
- (l) management and use of gene therapy;
- (m) research on paleontology and genealogy; and
- (n) anything or matter which needs to be prescribed under this Act.

Additional powers of Minister

72. The Minister shall, in addition to the general powers conferred upon him under this Act, declare by order in the *Gazette* sampling officers, inspectors, and designated laboratories.

Appeals

73. Any person aggrieved by the decision of the Regulator may appeal against that decision to the High Court within thirty days from the date of such decision.

Damages

74. Any person who suffers damages due to violations of his rights under this Act may seek civil remedies against the defendant in a court of competent jurisdiction.

Transitional provisions

75.-(1) Nothing in this Act shall prohibit or render liable to prosecution any person or body corporate which, at the date of coming into operation of this Act, was carrying on practice or business of Human DNA

Laboratory for continuing to carry on practice or business for six months from the date of coming into operation of this Act.

(2) The Minister may by notice in the *Gazette* extend the period of months provided for in subsection (1).

(3) Any person shall, before the expiry of the period provided in the notice issued pursuant to subsection (1) or (2), cause such Human DNA laboratory to be registered by the Regulator pursuant to the provisions of this Act.

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#### FIRST SCHEDULE

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*[Made under Section 8(3)]*

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#### TENURE AND PROCEDURES OF THE HUMAN DNA TECHNICAL COMMITTEE

1. A member of the Committee appointed under section 9(1) shall hold office for a period of three years from the date of his appointment, and shall be eligible for reappointment to the Committee at the expiration of such period.

2.-(1) In the absence of the Chairman, the Committee shall elect from amongst its members a Chairman who shall preside over the meeting.

(2) Any member who shall not attend the three consecutive meetings without adducing good reasons shall cease to be a member.

(3) Where any member ceases to be a member for any reason before the expiration of his term of office, the appointing authority may appoint another person in his place and the person so appointed shall hold office for the remainder of the term of office of the predecessor

3. The Committee shall ordinarily meet four times yearly at such times and places as it may deem necessary for the transaction of its business, and it shall convene ad hoc meetings upon request by the majority of members;

4. The Quorum at any meeting of the Committee shall be at least two thirds of the members in office.

5.-(1) The Committee shall cause to be recorded and keep minutes of all business conducted or transacted at its meetings, and the minutes of each meeting of the committee shall be read and confirmed or amended and confirmed at the next meeting of the committee and signed by the Chairman and Secretary of the meeting.

(2) Any minute purporting to be agreed by the Chairman at a meeting of the Committee shall, in the absence of proof of error, be deemed to be correct record of the meeting whose minutes they purport to be.

6. Matters proposed at a meeting of Committee shall be decided by a majority of the votes of the members present and voting and in the event of an equality of votes the person presiding shall have a second or casting vote in addition to his original or deliberative vote.

7. The Committee shall regulate its own proceedings.

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## SECOND SCHEDULE

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*[Made under section 28(1)]*

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### RIGHTS AND ASSURANCES FORM

(To be read or cause to be read to the sample source or sample source's representative before collection of sample for Human DNA for analysis)

1. Name of Sample source.....
2. Name of sample source's representative.....
3. Address .....
- Telephone.....email.....mobile.....
4. Date of birth.....
5. Nationality .....
6. The rights and assurances of the sample source/ sample source's representatives shall include the following information:-
  - (i) that the sample for Human DNA shall only be used as authorized in the written authorization;
  - (ii) that the sample for Human DNA is the property of the sample source or sample source's representative
  - (iii) unless specifically prohibited by the sample source or sample source's representative, researchers may be granted access to sample for Human DNA that cannot be linked to individual identification;
  - (iv) that the sample source or the sample source's representative has the right to order the destruction of the sample for Human DNA, genetic processed material at any time;
  - (v) that the sample for Human DNA shall be destroyed on completion of the analysis unless the sample source or the sample source's representative has previously directed otherwise in writing;
  - (vi) that the sample source may designate another individual as the person authorized to make decisions regarding the sample for Human DNA after the death of the sample

- source; and if any person is so designated, the sample source shall notify the facility in which the sample for Human DNA is stored;
- (vii) save for samples collected from criminal suspects the sample source's representative has the right to examine the records containing private genetic information, to obtain copies of such records;
  - (viii) the sample source or sample source's representative or criminal investigation authority may request for necessary corrections or amendments, if any, of the personal particulars of the sample source;
  - (ix) except for samples of Human DNA collected from dead bodies, criminal investigations and in compliance with court order, the sample source or sample source's representative have the right to refuse the collection of sample for Human DNA from him if the mode of collection is non intimacy or discovers that the consent is obtained through undue influence;
  - (x) the right to have copy of written authorization; and
  - (xi) counseling services may be available.

I..... sample source/ sample source's representative of P.O. BOX..... do hereby agree that I have read and understood the rights and assurances set in this form hence accept the collection, storage and destruction of my sample for Human DNA as directed in the Written Authorization by .....

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

I.....HEREBY CERTIFY that the rights and assurances were read and understood by..... in my presence this .....day of.....20.....

Signature..... Seal.....Qualification.....

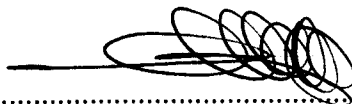
FOR OFFICIAL USE ONLY

Received/rejected by..... of.....this ..... day of.....2.....

Opinion of Receiving Officer.....

Signature..... Qualification..... Seal .....

Passed in the National Assembly on the 22nd April, 2009.



.....  
Clerk of the National Assembly