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THE HUMAN DNA REGULATION ACT,
(CAP.73)

REGULATIONS

(Made under section 71)

THE HUMAN DNA (GENERAL) REGULATIONS, 2019

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GN NO. 582 (contd)

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THE HUMAN DNA REGULATION ACT,
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REGULATIONS

(Made under section 71)

THE HUMAN DNA (GENERAL) REGULATIONS, 2019

PART I
PRELIMINARY PROVISIONS

Citation

1. These Regulations may be cited as the Human DNA (General) Regulations, 2019.

Interpretation

2. In these Regulations, unless the context otherwise requires-

"accredited proficiency test provider" means an organisation providing DNA proficiency testing (PT) schemes and accredited under ISO/IEC 17043 standards for demonstration of competence through formal compliance to a set of internationally recognized requirements for the planning and implementation of proficiency testing programs;

Cap.73

"Act" means the Human DNA Regulation Act;

"analyst" has the meaning ascribed to it under the Act;

"inspector" has the meaning ascribed to it under the Act;

"licence" has the meaning ascribed to it under the Act;

"Human DNA" has the meaning ascribed to it under the Act;

"Human DNA database" has the meaning ascribed to it under the Act;

"category I Human DNA laboratory" means a laboratory dealing with sample collection, storage, extraction, amplification and detection of Human DNA;

"category II Human DNA laboratory" means a hospital Human DNA laboratory dealing with sample collection, storage, extraction and amplification of Human DNA;

"category III Human DNA laboratory" means a hospital Human DNA laboratory dealing with sample collection, storage and extraction of Human DNA;

"category IV Human DNA laboratory" means a laboratory dealing with collection and storage of Human DNA criminal related samples;

"low copy number" means a Human DNA sample with low amount of DNA (less than 500 picograms of template DNA) including aged, extremely degraded or touch samples obtained from crime scenes;

Cap.152 "medical practitioner" has the meaning as ascribed to it under the Medical, Dental and Allied Health Professionals Act;

"Minister" has the meaning ascribed to it under the Act;

"proficiency test" means inter laboratory test which compares results within acceptable standards;

"Regulator" has the meaning ascribed to it under the Act;

"sample" means a specimen or an exhibit submitted for laboratory analysis;

"sample source's" has the meaning ascribed to it under the Act;

"sampling officer" has the meaning ascribed to it under the Act;

"sample source representative" has the meaning ascribed to it under the Act; and

"sample for Human DNA" has the meaning ascribed to it under the Act.

PART II
REGISTRATION AND MANAGEMENT OF DESIGNATED HUMAN DNA LABORATORY

Human DNA designated laboratory registration requirements

3.-(1) A Human DNA designated laboratory shall be registered for issue or renewal of a licence in accordance with the provisions of the Act.

(2) Notwithstanding the requirements of subregulation (1), a Human DNA designated laboratory shall be in the following categories-

(a) category I Human DNA laboratory;

(b) category II Human DNA laboratory;

(c) category III Human DNA laboratory; and

(d) category IV Human DNA laboratory.

(3) An application for registration of Human DNA

designated laboratory shall be-

(a) made by filling in the form set out in the First Schedule;

(b) accompanied by documents specified in the Second Schedule; and

(c) submitted to the Regulator for registration.

Assessment of application documents

4.-(1) Where the Regulator observes, upon assessment of the application documents submitted that there is non-compliance, he shall-

(a) notify the applicant of the non-compliance in writing; and

(b) give the applicant fourteen days to comply.

(2) The applicant shall upon full compliance notify the Regulator in writing of the manner of compliance.

Qualifications of laboratory analyst

5.-(1) An applicant for a Human DNA designated laboratory shall ensure that he has qualified laboratory staff with the following qualifications-

(a) in case of categories I and II, an in charge of a laboratory with at least a Masters degree in either, molecular biology biochemistry, biotechnology, chemistry, microbiology, genetics, forensic biology, laboratory technology, or its equivalent qualification from an accredited institution with at least three years working experience;

(b) in the case of categories III and IV, an in-charge of a laboratory with at least a diploma in either, molecular biology biochemistry, biotechnology, chemistry, microbiology, genetics, forensic biology, laboratory technology, or its equivalent qualification from an accredited institution with at least three years working experience;

(c) in case of categories I and II, an analyst with at least a Bachelor of Science degree in either, molecular biology biochemistry, biotechnology, chemistry, microbiology, genetics, forensic biology, laboratory technology, or its equivalent qualification from an accredited institution; and

(d) in case of categories III, an analyst with at least a diploma in either, molecular biology biochemistry, biotechnology, chemistry, microbiology, genetics, forensic biology, laboratory technology, or its equivalent

qualification from an accredited institutions.

(2) Notwithstanding the requirements of subregulation (1), an incharge and analyst of the Human DNA laboratory shall be required to attend special training on Human DNA and data management provided by the Regulator and shall be issued with a certificate.

(3) Subject to the requirements of subregulations (1) and (2), the incharge and analyst of every Human DNA laboratory shall be required to attend laboratory quality assurance training.

(4) In case the incharge or analyst is no longer an employee of a laboratory, the owner of the Human DNA laboratory shall notify the Regulator within seven days from the date of his absence from employment.

(5) Subject to the provisions of this regulation every incharge and analyst of the Human DNA laboratory shall be required to pay the training fees and charges prescribed under the Sixth Schedule to these Regulations.

Requirement for proficiency test

6. A Human DNA designated laboratory under category I shall-

(a) be required to undertake a proficiency test at least once a year from an accredited proficiency test provider; and

(b) submit evidence and test results on proficiency test to the Regulator within fourteen working days after receipt of results from the accredited proficiency test provider;

(2) Any Human DNA designated laboratory which fails to comply with the requirements of subregulation (1) or whose score fails to meet the required proficiency test results, shall have its operations suspended; and

(3) Any Human DNA designated laboratory whose operations has been suspended, shall be reinstated after undertaking another proficiency test and score within the required proficiency test results.

Standards of categorised Human DNA laboratory

7.-(1) Every category I and II Human DNA designated laboratory shall establish, follow and maintain quality assurance standards that are appropriate to the testing activities for Human DNA analysis documented in a manual which contains details as set out in the Third Schedule to these Regulations.

(2) Subject to the requirement of subregulation (1), a

Human DNA designated laboratory under category I, shall participate and keep records on proficiency tests from an accredited proficiency test provider at least once a year.

(3) Every Human DNA designated laboratory shall be required to meet the following minimum standards-

(a) a premise or facility of at least-
  (i) four working rooms or compartments for category I Human DNA laboratory;
  (ii) three working rooms or compartments for category II Human DNA laboratory; or
  (iii) two working rooms or compartments for category III and IV Human DNA laboratory, to allow for unidirectional operations;
(b) having adequate laboratory equipment and instruments to allow Human DNA laboratory analysis to be undertaken;
(c) having adequate space and conducive environment to allow Human DNA laboratory analysis to be undertaken without compromising quality of results;
(d) being secured but easily accessible to authorised persons;
(e) having necessary utilities available to ensure quality of services, health and safety; and
(f) having an emergency response plan including environment, health and safety management systems.

Licensing and designation of Human DNA laboratory

8. Upon fulfilment of registration requirements under the Act and these Regulations, every registered Human DNA designated laboratory shall be issued with a licence by the Regulator in the manner set out in the Fourth Schedule to these Regulations..

Duties of laboratory analyst

9. An analyst in the performance of his duties shall-
(a) conduct Human DNA designated laboratory analysis on various samples;
(b) condemn and order destruction or disposal of biological samples consumables;
(c) prepare reports on Human DNA designated laboratory analysis; and
(d) adduce evidence before the court when required to.

Laboratory analysis and issuance of report

10.-(1) Every category I and II Human DNA laboratory shall conduct analysis and issue laboratory analysis reports.

(2) Pursuant to section 25 of the Act, the laboratory analysis report shall only be issued to the requesting authority.

Human DNA laboratory analysis for criminal investigation

11.-(1) A sample and genetic information generated by category I Human DNA laboratory on criminal investigation shall be submitted to the Regulator for reference before issuance of laboratory analysis report to the requesting authority.

(2) Where low copy number samples for criminal investigation cannot be divided, the category I designated Human DNA laboratory shall submit the whole law copy number sample to the Regulator for laboratory analysis.

Cessation of Human DNA designated laboratory operations

12.-(1) Any designated Human DNA designated laboratory intending to cease operations as a Human DNA designated laboratory shall-

(a) notify the Regulator within three months prior and surrender the licence, any unprocessed samples, processed genetic information and Human DNA profiles to the Regulator; and

(b) safely dispose of all materials, equipment and instruments.

(2) Any designated Human DNA laboratory which fails to meet the requirements under subregulation (1), commits an offence and shall, on conviction, be liable to a fine of not less than three million shillings or to imprisonment for a period of not less than twelve months or to both.

PART III
INSPECTION OF HUMAN DNA DESIGNATED LABORATORY

Types of inspection

13.-(1) A Human DNA designated laboratory shall be inspected.

(2) The following are the types of inspection to be conducted for every Human DNA designated laboratory-

(a) assessment or pre-business inspection;

(b) routine inspection; or

(c) special inspection.

Qualifications of inspectors

14. A person appointed as an inspector of Human

DNA designated laboratory shall-

(a) possess at least a Bachelor degree specialised in either, molecular biology, biochemistry, biotechnology, chemistry, microbiology, genetics, forensic biology, laboratory technology, or equivalent qualification from an accredited institution;

(b) have at least two years of working experience as an analyst in Human DNA laboratory; or

(c) have attended a special Human DNA or laboratory inspector's course issued by the Regulator.

Functions and powers of inspectors

15.-(1) In the performance of his functions an inspector shall-

(a) verify availability and adequacy of laboratory equipment and instruments to allow Human DNA designated;

(b) laboratory analysis to be undertaken;

(c) assess the adequacy of space and conduciveness of the environment to allow Human DNA designated laboratory analysis to be undertaken without compromising quality of results;

(d) assess the security and accessibility of the Human DNA designated laboratory;

(e) verify for availability of necessary utilities to ensure quality of services, health and safety; and

(f) check and verify the presence of emergency response plan including environment, health and safety management systems.

(2) An inspector may issue directives on areas requiring improvement.

Manner of conducting inspection

16.-(1) Pursuant to section 13 of the Act and regulation 15, when conducting inspection of Human DNA designated laboratory, an inspector shall adhere to the following procedures-

(a) give self introduction by producing an identity card or introduction letter from the Regulator;

(b) use respective Human DNA designated laboratory inspection checklist as prescribed under the Fifth Schedule to these Regulations;

(c) ensure that the inspection checklist is duly filled, signed by both parties and stamped with an official stamp of a Human DNA designated

laboratory; and

(d) notify the in charge of the Human DNA designated laboratory on the inspection findings.

(2) The inspection conducted under these Regulations shall be subject to a fee prescribed in the Sixth Schedule to.

(3) Upon inspection of the Human DNA designated laboratory, if non compliance is observed, the Regulator shall-

(a) notify the owner of the Human DNA designated laboratory in writing within fourteen working days from the date of inspection;

(b) for minor non-compliance, give the owner thirty days to rectify the shortfalls observed; and

(c) for major non-compliance, the Regulator shall suspend operations of such Human DNA designated laboratory pending to rectification of the shortfalls observed.

Registers and record keeping requirements

17.-(1) Every Human DNA designated laboratory shall register and keep records on Human DNA laboratory analysis.

(2) The information to be kept shall include-

(a) results of Human DNA laboratory on proficiency tests;

(b) type and number of samples received and analysed;

(c) reports and genetic information generated as per analysis for-

(i) parentage;

(ii) civil matters;

(iii) mass disaster;

(iv) medical cases;

(v) population genetics studies;

(vi) Human DNA research activities; or

(vii) other cases.

(d) reagents and chemicals used;

(e) written authorization for collection and processing of Human DNA samples as set out in Seventh Schedule to these Regulations;

(f) standard operating procedures for reagents preparation, analysis methods;

(g) rights and assurance forms; and

(h) destruction of genetic samples, processed materials and genetic information in accordance

with the Act.

(3) In addition to information required to be kept under subregulation (2), a Human DNA laboratory designated to conduct analysis under category I and II on criminal investigation samples shall keep records on-

(a) Human DNA samples;

(b) generated genetic information;

(c) processed genetic material; and

(d) analysis report;

(4) The Regulator may, from time to time, prescribe that additional registers be kept as may be deemed necessary to ensure good laboratory practice.

PART IV
SAMPLE COLLECTION, MANAGEMENT AND CHAIN OF CUSTODY

Qualifications of sampling officers

18.-(1) A person appointed as Human DNA sampling officer shall possess at least a diploma in, molecular biology biochemistry, biotechnology, chemistry, microbiology, genetics, forensic biology, laboratory technology, or equivalent qualification from an accredited institution.

(2) A person shall be appointed as a sampling officer for Human DNA samples after having an experience of at least six months of working as an analyst in a Human DNA laboratory.

(3) Every person to be appointed as a sampling officer shall attend a special Human DNA sampling course issued by the Regulator.

Procedures for collection of Human DNA samples

19.-(1) A sampling officer in discharging his duties he shall observe the following procedures-

(a) verbally inform the sample source or sample source's representative of his rights and assurance and sign the rights and assurance form as set out under the Second Schedule to the Act;

(b) label and ensure proper packaging of Human DNA samples;

(c) ensure proper sample preservation and storage in appropriate conditions; and

(d) transport a Human DNA sample to the Human DNA laboratory or a designated Human DNA laboratory, for laboratory analysis.

(2) A sampling officer involved in the collection, re-

collection, packaging, storage, transportation, submission or receiving of Human DNA samples shall fill a sample management form set out in the Eighth Schedule to these Regulations.

Recollection of Human DNA samples

20. A Human DNA laboratory or a designated Human DNA laboratory may request the recollection of Human DNA samples from the requesting authority by filling the form set out in Ninth Schedule to those Regulations.

Destruction of Human DNA sample

21.-(1) Pursuant to section 58 of the Act, a biological Human DNA sample shall be destroyed by incineration.

(2) A non-biological sample shall be destroyed according to the nature of the sample upon approval by the Regulator.

(3) A designated Human DNA laboratory shall keep record of the destroyed Human DNA sample.

Disposal of consumables, reagents, chemicals and their containers

22.-(1) Any obsolete or expired chemicals, reagents, consumables and packaging materials shall be disposed as prescribed in their respective materials safety data sheet.

(2) The disposal and disposal methods for obsolete or expired chemicals, reagents, consumables and packaging materials shall be approved by the Regulator.

(3) Every approval and supervision for disposal of obsolete or expired chemicals, reagents, consumables and packaging materials shall be accompanied with a fee set out in the Sixth Schedule to these Regulations.

PART V
MANAGEMENT OF THE NATIONAL HUMAN DNA DATABASE

Information contained in the Human DNA database Cap.177

23. Pursuant to sections 59(1) of the Act, and section 32 and the Fifth Schedule of the Government Chemist Laboratory Authority Act, the Human DNA database shall contain such information including-

(a) crime scene index;
(b) new born;
(c) civil index;
(d) medical index;
(e) convicted offender index;
(f) remandees;
(g) violent offender;

(h) sexual offender;
(i) disaster victims index;
(j) missing person index;
(k) elimination database;
(l) information on national identification;
(m) defense force and police force;
(n) research index; and
(o) special or executive index.

Submission of information

24.-(1) A designated Human DNA laboratory under categories I and II shall on a quarterly basis for each calendar year submit generated genetic information to the Regulator specified in the Tenth Schedule to these Regulations.

(2) Any category I and II Human DNA laboratory which contravenes the requirements provided for under subregulation (1) commits an offence.

(3) Any employee of a designated Human DNA laboratory who knowingly or intentionally submits false information to the requesting authority, the Human DNA laboratory or Regulator commits an offence and shall, on conviction, be liable to a fine of not less than three million shillings or to imprisonment for a period of not less than twelve months or to both.

PART VI
RESEARCH ON HUMAN DNA

Authorisation from Commission Cap. 226

25. Notwithstanding the provisions of section 38 of the Act, a person intending to conduct Human DNA research activities shall first secure an authorisation from the Commission in accordance with the provisions of the Tanzania Commission for Science and Technology Act.

Application of Human DNA research permit

26.-(1) Any person who wishes to apply for a research permit shall fill in and submit an application form set out under the Eleventh Schedule to these Regulations;

(2) An application for research permit shall be accompanied by a fee set out under Sixth Schedule to these Regulations.

(3) A duly filled application form for research permit shall be accompanied by the following documents-

(a) introduction letter (from an individual or institution);
(b) research proposal;
(c) consent from supervisor or an institution to conduct research;
(d) proof of payment of application fee;
(e) curriculum vitae and composition of research team;
(f) research questionnaire or checklist (if applicable); and
(g) list of sample collection tools.

(4) An analysis of a research sample shall be conducted at the Human DNA laboratory or a designated Human DNA laboratory.

Issuance and validity of Human DNA research permit

27.-(1) Upon satisfaction of the information submitted under regulation 26, the Regulator shall issue a research permit in the manner prescribed in Twelfth Schedule to these Regulations.

(2) The research permit issued under subregulation (1), shall be valid for twelve months.

(3) A person conducting Human DNA research shall be required to acquire the ethical clearance permit from the National Institute for Medical Research.

Renewal of research permit

28.-(1) A renewal of a research permit issued under regulation 27, may be applied within three months before expiration.

(2) An application for renewal of a research permit, shall be accompanied by a fee prescribed under Sixth Schedule to these Regulations.

Non-transferability of research permit

29. The research permit issued shall not be transferrable.

Submission of research report and genetic information

30.-(1) A person granted with research permit, shall submit certified copy of the research report upon completion of research.

(2) A person granted with a research permit shall submit the generated genetic information to the Regulator in the manner prescribed under the Tenth Schedule to these Regulations.

Requirements for publication

31.-(1) A publication on the research findings relating to Human genetic information shall be authorized by the Regulator in consultation with the relevant authorities.

(2) The authorization for publication shall be granted upon submission of a proposed manuscript for publication to the Regulator.

PART VII
GENERAL PROVISIONS

Requirements for genetic counseling

32.-(1) A designated Human DNA laboratory may provide genetic counseling to a sample source or sample source's representative prior to the collection of sample for Human DNA analysis.

(2) A designated Human DNA laboratory may have in place an officer who has knowledge and skills related to genetic counseling.

Professional misconduct

33.-(1) For the purposes of these Regulations, an employee of the Human DNA laboratory shall be considered to have committed professional misconduct where he-

(a) contravenes the provision of the Act, regulations or guidelines;
(b) fails to abide by the terms, conditions of service;
(c) has a conflict of interest which affects the client;
(d) practices analysis of Human DNA without having relevant qualifications;
(e) collects of Human DNA samples without being *gazetted* or authorised by the Regulator;
(f) fails to abide to the conditions and requirements of sample management;
(g) abets and aids the illegal practice on Human DNA sample collection or analysis; or
(h) furnishes false information or document to the requesting authority, designated Human DNA laboratory or the Regulator.

(2) Any employee of a designated Human DNA laboratory who knowingly or intentionally destroys, varies or alters a document or laboratory analysis report generated in the process of carrying activities under the Act and these Regulations commits an offence and shall, on conviction, be liable to a fine of not less than five million shillings or to imprisonment for a period of not less than twelve months or to both.

Fees

34. All fees payable under these Regulations on services provided under the Act and these Regulations shall be-

(a) as provided in Sixth Schedule to these Regulations;
(b) non transferable; and
(c) non refundable.

Revocation GN. No. 520 of 2010

35. The Human DNA (Sample Management, Human DNA Laboratories, Qualifications of Analysts and Inspectors) Regulations are hereby revoked.

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FIRST SCHEDULE

(Made under regulation 3(3)(a))

GOVERNMENT CHEMIST LABORATORY AUTHORITY

Application form for registration of Human designated DNA laboratory

1. Particulars of the applicant:

1.1 Name: ……1.2 Address: .....……1.3 Telephone: …….....
1.4. E-mail: ….....……...…1.5 Certificate of Incorporation No: ….....…….....
1.6 Business Licence No: ……..…….....

2. Physical Address:

2.1 Plot No: ……2.2 Street No…….....
2.3 Ward: .....2.4 District: ……..…….....
2.5 Region: ……

3. Proprietor of the Human DNA designated laboratory (if different from (1) above):

3.1 Name: ……3.2 Physical address: ..…….....
3.3 Telephone: ……3.4 E-mail: ……...…….

4. Category of Human DNA designated laboratory (indicate accordingly)

4.1 Category I ☐
4.2 Category II ☐
4.3 Category III ☐
4.4 Category IV ☐

5. Requirements for Registration

5.1 Name and qualifications of the in-charge of Human DNA Designated laboratory.....
(Attach CVs and copies of certification)
5.2 Names and qualification of Human DNA designated laboratory analysts ……..
(Attach CVs and copies of certification)
5.3 List of equipment that is used or intended to be used
5.4 List of all tests and activities carried out or intended to be carried out

Declaration

I …… (applicant), hereby declare that the above statements are true and correct to the best of my knowledge and understanding.

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Signature:……..…….…… Date:……..…….……

FOR OFFICIAL USE ONLY:

Application No.: …….....…

Name:…….. Signature:…….....…Date:….....…
Stamp.....

SECOND SCHEDULE

(Made under regulation 3(3)(b))

GOVERNMENT CHEMIST LABORATORY AUTHORITY

Documents required for registration of Human DNA designated laboratory

1. Introduction letter.
2. Business licence.
3. Filled application form for registration of Human DNA designated laboratory.
4. Evidence and results on proficiency test.
5. Proof of payment for application fee.
6. Certified true copies of academic qualifications of the in-charge and analyst(s) of Human DNA designated laboratory.
7. Certified true copy of Identity Card (National ID, passport, voters ID, or driving licence) and coloured passport size photograph of the laboratory owner.
8. Certified true copy of Certificate of Incorporation: (*if applicable*) .....
9. Copies of manuals and standard operating procedures.
10. Copies of materials safety data sheet.
11. Copies of quality assurance program.

THIRD SCHEDULE

(Made under regulation 7(1))

GOVERNMENT CHEMIST LABORATORY AUTHORITY

Details contained in the manual for quality assurance standards

Minimum requirements for category I and II designated Human DNA laboratories

1. Goals and objectives.
2. Organization and management.
3. Personnel.
4. Facilities.
5. Control of Human DNA samples and genetic information.
6. Validation.
7. Analytical procedures.
8. Equipment calibration and maintenance.
9. Reports.
10. Review.
11. Proficiency testing.
12. Corrective action.
13. Audits.
14. Safety.
15. Outsourcing.

Minimum requirements for category III and IV designated Human DNA laboratories

1. Goals and objectives.
2. Organization and management.
3. Personnel.
4. Facilities.
5. Control of Human DNA samples and genetic information.
6. Validation.
7. Analytical procedures.
8. Equipment.
9. Corrective action.
10. Audits.
11. Safety.
12. Outsourcing.

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FOURTH SCHEDULE

(Made under regulation 8)

GOVERNMENT CHEMISTY LABORATORY AUTHORITY

Licence to operate Human DNA designated laboratory

I hereby certify that (*Human DNA laboratory)*……..... of (*Address)*…..... in (*Region)*……..has been registered and LICENCED to operate as a designated Human DNA laboratory (*category)* …….. under The Human DNA Regulation Act, Cap. 73 and granted Registration No. .....

The special conditions attached to this LICENCE are: (*Category details*)

.....

.....

.....

This LICENCE remains valid from .... (*day*) of ..... (*month*) ..... *(year)* to .... (*day*) of ..... (*month*) ..... *(year)*

Granted on .... (*day*) of ..... (*month*) ..... *(year)*

Name:.....

Signature: ……

REGULATOR

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FIFTH SCHEDULE

(Made under regulation 16(1)(b))

GOVERNMENT CHEMIST LABORATORY AUTHORITY

Human DNA designated laboratory inspection checklist

Section I: General particulars

1.0 Name of Laboratory: _____ Name of Proprietor(s) _____ 1.1 Establishment of the Human DNA designated lab: _____							
1.2 Ward: _____ 1.3 District:_____ 1.4 Plot No: _____							
1.5 Tel No: _____							
1.6 Email address: _____ 1.7 Website:_____							
2.0 Physical address: _____							
3.0 Type of inspection: Assessment routine Special ☐☐ 3.1 Date of inspection:_____ 3.2 Type and date of last inspection:_____							
4.0 Laboratory registration certification No:		4.1 Valid ☐		4.2 Not valid ☐			
5.0 Category of laboratory							
5.1 Collection, Extraction, Amplification and Detection (Category I)	*(indicate accordingly)*	5.2 Collection, Extraction and Amplification (Category II)	*(indicate accordingly)*	5.3 Collection and Extraction (Category III)	*(indicate accordingly)*	5.4 Collection (Category IV)	*(indicate accordingly)*

Section II: Information of technical personnel TOTAL SCORE 25

S/N	Requirements	

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A	Human DNA designated laboratory in-charge				
1	Name of Human DNA designated laboratory in-charge :			Qualifications and type:	
			Total weight	Score	Remarks
2	Evidence on attending special training on Human DNA and data management from Regulator	Yes (*copy of certificate*)	3		
3	Evidence of participating in proficiency testing (PT) (*where applicable*)	Number and results of PT	5		
4	Evidence of work experience (*where applicable)*	Copy of updated CV	2		
5	Job description	Copy of job description	2		
6	Evidence on laboratory quality assurance training	Copy of Certificate (s)	2		
			Total score		
B	Laboratory analyst(s)				
1	Names of other laboratory analyst(s):			Qualification and type:	
			Total weight	Score	Remarks
2	Evidence on attending special training on Human DNA and data management from Regulator	Yes (*copy of certificate*)	3		
3	Evidence of participating in proficiency testing (*where applicable*)	Number and results of PT	4		
4	Job description	Copy of job description	2		
5	Evidence on laboratory quality assurance training	Copy of Certificate (s)	2		
			Total Score		

Section III: Laboratory standard TOTAL SCORE 50

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S/N	Requirement		Total weight	Score	Remarks
1	Evidence of quality assurance standards	Available (*copy of quality assurance manual*)	3		
		Suitable	1		
		Being Used	1		
2	Evidence control	Available (*Standard Operating Procedures (SOPs)*)	2		
		Suitable	1		
		Being used	1		
3	Protocol for method validation	Available (*SOPs*)	2		
		Suitable	1		
		Schedule & Records	1		
4	Analytical procedures	Available (*SOPs*)	3		
		Suitable	1		
		Being used	1		
5	Evidence showing equipment calibration and maintenance	Available (schedule)	3		
		Reports	1		
6	Evidence of participating in proficiency testing (*where applicable*)	Number and results of PT			
7	Facility for separate storage of reagents and samples	Available	3		
		Suitable	1		
		Being used	1		
8	Safety policy	Available	1		
		Suitable	1		
		Being used	1		
9	Number of rooms?	Adequate	2		
		Inadequate	1		
10	Space and conducive environment to allow Human DNA designated laboratory analysis	Adequate	2		
		Inadequate	1		
11	Is there a Uni-	Yes	3		

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	directional laboratory workflow?	No	0		
12	Restriction to unauthorized persons to access the Human DNA designated laboratory	Controlled doors or restriction protocol	2		
13	Hygiene (floor and working bench are clean and free from debris, spills, etc)	Yes	1		
		No	0		
12	Chemical and biological waste collection and disposal systems are properly working (*drainages, fumes, etc*)	Available	1		
		Suitable	1		
		Being used	1		
14	Utilities: water, hand washbasins, emergency showers, WC	Available	1		
		Suitable	1		
15	Cooling System (*working condition, suitable temperatures*)	Available	1		
		Suitable	1		
16	Walls, ceilings: sooth, easy to wash, clean or decontaminate; resistant to corrosion	Yes	1		
		No	0		
			Total score		

		Name	Quantity	Application	Storage conditions	Expiry date
17	List reagent/chemicals					

Section IV: Laboratory Equipment Information

S/N	Requirement	Name	Quantity	Version	Application	Being used (Y/N)
1	Equipment/instruments used or in place					

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2	Software		N/A			

Section V: Health and Safety TOTAL SCORE 25

	Are health and safety issues addressed in respect of-				
S/N	Requirement		Total weight	Score	Remarks
1	Personal protective equipment or gears suitable, available and being used (*eg. gloves, lab coat, musk*)	Available	5		
		Suitable	2		
		Being used	2		
2	Availability and accessibility of emergency kit/items (*e.g. firefighting equipment, Alarms, First aid*)	Available	3		
		Suitable	2		
		Being used	1		
3	Availability of Signage (*e.g. written emergency procedures, signs and safety posters*)	Available	3		
		Suitable	1		
		Being used	1		
4	Availability of material safety data sheet	Available	2		
		Suitable	1		
		Being used	1		
			Total Score		

Section VI: Any other observations:

S/N	Observation	Remarks

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Section VII: Agreement on Way forward

S/N	Items requiring attention	Agreed way forward	Timeframe

Section VIII: Owner(s)/Supervisor(s) Declaration
I/we ..... as supervisor/owner(s) of the said Human DNA designated laboratory, certify that, the information and observations made in this form during the inspection of the laboratory are true and correct.

Name: Signature:_____ Date: _____ and Official Stamp: .....

Section IX:
For official Use; Inspector's recommendations

Does the Human DNA designated laboratory qualify for registration?				
YES/NO	Yes, with minor improvement	State such conditions	No	State the reasons

_____

SIXTH SCHEDULE

_____

(Made under regulations 5(5),16(2), 22(3), 26(2), 28(2) and 34(a))

_____

GOVERNMENT CHEMIST LABORATORY AUTHORITY

Fees

S/N	ITEMS	AMOUNT
1.	Application or renewal fee for category I & II	200,000

GN NO. 582 (contd)

	registration	
2.	Application or renewal fee for category III & IV registration	150,000
3.	Pre registration inspection fee for category I & II	250,000
4.	Pre registration inspection fee for category III & IV	125,000
5.	Routine inspection fee for category I & II	100,000
6.	Routine inspection fee for category III & IV	70,000
7.	Special inspection fee for category I & II	350,000
8.	Special inspection fee for category III & IV	175,000
9.	Consultation fee (*general*)	20,000
10.	Consultation fee for approval of disposal	100,000
11.	Disposal supervision fee	100,000 per day
12.	Special training on Human DNA and data management	200,000 per person
13.	Research permit fee (*local*)	250,000
14.	Research permit fee (*international*)	500,000 (*its equivalent in USD*)

SEVENTH SCHEDULE

(Made under regulation 17(2)(e))

GOVERNMENT CHEMIST LABORATORY AUTHORITY

Authorization for Analysis of Human DNA Samples

1. I ..... of ..... (*physical address*) being a requesting authority for Human DNA sample collection and analysis, grant an authority to ..... (*sampling officer/laboratory*) to collect sample(s) for Human DNA analysis from:

.....	.....	
.....	.....	
.....	.....	
Name (*sample source(s))*	Signature (*sample source(s) /representative*)	Date

2. The analysis will be conducted at the Government Chemist Laboratory Authority or at ..... (*Human DNA designated laboratory*).
3. Purpose for which sample is collected
   (a) Personal parentage ☐
   (b) Legal parentage ☐
   (c) Criminal investigation ☐
   (d) Mass disaster ☐
   (e) Medical cases ☐
   (f) Research ☐
   (g) Any other (*specify*) .....
4. Description of all authorized uses of the sample for Human DNA
   .....
   .....
5. The Human DNA sample(s) collected shall or shall not be used for research or commercial purposes.

GN NO. 582 (contd)

Name of authorizing officer .....

Designation .....

Institution .....

Signature .....

Date and official stamp .....

EIGHTH SCHEDULE

(Made under section regulation 19(3))

GOVERNMENT CHEMIST LABORATORY AUTHORITY

Sample Management Form

PART A

COLLECTION, PACKAGING AND STORAGE OF SAMPLES FOR HUMAN DNA

1. Name of sampling officer …… ID No. ……
   a. Address ……
   b. Phone ……
2. Name of the requesting authority ……..……
   a. Address ……
   b. Phone …….. Email address ……
3. Name of the sample source/crime scene ……
   a. Address ……
   b. Phone ……
4. Purpose for the collection of the sample for Human DNA
   ……
   ……
5. Description and No. of the samples packaged

S/N	Sample Code No./ Reg. No.	Sample description	No. of samples	Package used	Condition of package
	Official seal Yes/No				
	Packaging intact Yes/No				

6. Explanation on whether reasonable force was used to collect the sample
   ……..
   ……...
7. Storage of a packed sample for Human DNA
   a. Condition of package ……
   b. Description of packaging (*Type of packaging, any labels on the packaging*)
   ……
8. Brief description of the package being used ……

DECLARATION

GN NO. 582 (contd)

I …… do hereby declare that I have collected, pack and stored the sample for Human DNA analysis.

…… …… …….. ……..……
Institute Signature Designation Date

PART B
TRANSPORTATION OF SAMPLE FOR HUMAN DNA

1. Samples handed to:
    a. Name of sampling officer …… ID No. ……....
    b. Designation ……
    c. Signature …….
    d. Date ……
2. Name of sampling officer ……...……....……
    a. Address ……
    b. Phone ……
3. Description of the samples

S/N	Sample Code No./ Reg. No.	No. of samples	Package used	Mode of transportation (*e.g., air, road, etc*)
	Seal intact: Yes/No			

Signature …… Designation …….
Date …… Time ……

PART C
HUMAN DNA SAMPLE RECEIVING FORM

1. Samples received by:
    a. Name of receiving officer …… ID No. …….
    b. Designation ……
    c. Signature …….
    d. Date ……

2. Received from:
    a. Name of sampling officer …… ID No. …….
    b. Institution …… Address ……..
    c. Designation ……
    d. Signature …….
    e. Date ……

3. Description and No. of the samples received

GN NO. 582 (contd)

S/N	Sample Code No./ Reg. No.	Sample description	No. of samples	Package used	Condition of package
	Packaging intact : Yes/No				
	Signs of tampering Yes/No				
	Any comments				

Signature …… Designation ……
Date …… Time ……

I …… do hereby declare that I have received the sample for Human DNA analysis.

……. …… …….. ……
Institute Signature Designation
Date

NINTH SCHEDULE

(Made under regulation 20)

GOVERNMENT CHEMIST LABORATORY AUTHORITY

Recollection of Human DNA Samples

I ..... of ..... (*physical address*) being the in-charge of the Human DNA laboratory or a designated Human DNA laboratory request the recollection of Human DNA sample(s) from .... (*sample source*) which was previously collected on ..... (*date)* of ..... (*Code No./sample reference No.*).

Purpose for sample recollection:

(a) spoiled ☐
(b) inadequate ☐
(c) non-compliant with set principles and procedures for sample management ☐

GN NO. 582 (contd)

(d) contaminated ☐

(e) decomposed ☐

Name of the laboratory in-charge .....

Designation .....

Institution .....

Signature .....

Date and official stamp.....

_____

TENTH SCHEDULE

_____

(Made under regulation 24(1) and 30(2))

_____

GOVERNMENT CHEMIST LABORATORY AUTHORITY

Checklist for Submission of Information

Category I and II Human DNA laboratories

(a) Copies of duly filled rights and assurance form
(b) Details of sample analysis;

(i) Names of analysts and laboratory in-charge

(ii) Methods used (*extraction, amplification and detection*)

(iii) Instrumentation and data analysis software used

(iv) Results and reports of generated genetic information

Category III and IV Human DNA laboratories

(a) Copies of duly filled rights and assurance form
(b) Details of sample analysis (*category III*);

(i) Names of analysts and laboratory in-charge

(ii) Extraction methods used

(iii) Instrumentation

(iv)

_____

ELEVENTH SCHEDULE

_____

GN NO. 582 (contd)

(Made under regulation 26(1))

GOVERNMENT CHEMIST LABORATORY AUTHORITY

Application for Research Permit

1. Particulars of the applicant:
1.1 Name: ……..... 1.2 Telephone:…….....
1.3 E-mail address: .....… 1.4 Institution: .....
1.5 Co-researchers:

.....	.....	.....	.....
.....	.....	.....	.....
.....	.....	.....	.....
Name	Qualifications	Institution	CV (attach)

2. Physical Address:
2.1 Plot No: …… 2.2 Street: …….....
2.3 Ward: ..... 2.4 District: ……..……..…….....
2.5 Region: ……..……..…….....

3. Ethical Clearance Permit No.:..... (attach copy) dated .....
4. Designated Human DNA laboratory Reg. No. where the research is to be conducted
.....
.....
5. Purpose of the research .....
.....
6. Details of the research location .....
.....
.....
7. Sample size .....
8. Estimated starting and ending dates of research .....

DECLARATION

I ....., the applicant, HEREBY CERTIFY that the above particulars are correct to the best of my knowledge, understanding and accept any liability arising thereon.

....
Date Signature of the applicant

TWELFTH SCHEDULE

GN NO. 582 (contd)

_____

(Made under regulation 27(1))

_____

GOVERNMENT CHEMIST LABORATORY AUTHORITY

Research Permit

I ..... (name of the Regulator) hereby certify that .... (applicant(s)) of ……..... (address) ..... (Region) has been granted a PERMISSION to conduct Human DNA research on ..... (research title) at ..... (research location) from ..... (commencement date) to ..... (ending date).

The special conditions attached to this PERMIT are:

1. The research shall be conducted as per the submitted and approved research proposal.
2. Publication of research results shall be upon permission of the Regulator.
3. Copies of final publications shall be submitted to the Regulator.
4. The Regulator may determine other conditions depending on the nature of the research.

This PERMIT remains valid from ..... (day) of ..... (month) ..... (year) to ..... (day) ..... of (month) ..... (year)

Granted on this ..... (day) of ..... (month) ..... (year)

Signed: ……..
REGULATOR

Dodoma,
1st July, 2019

UMMY A. MWALIMU
Minister for Health, Community Development, Gender, Elderly and Children