GOVERNMENT OF ZAMBIA

STATUTORY INSTRUMENT NO. 24 OF 2020

The National Research Act, 2013

(Act No. 2 of 20131)

The National Health Research (Bio-Banking) Regulations, 2020

Regulation

Copies of this Statutory Instrument can be obtained from the Government Printer, P.O. Box 30136, 10101 Lusaka, Price K68.00 each

IN EXERCISE of the powers contained in sections 49, 51 and 63 of the National Health Research Act, 2013, and in consultation with the Authority, the following Regulations are made:

Title

1. These Regulations may be cited as National Health Research (Bio banking) Regulations, 2020.

Interpretation

2. In these Regulations, unless the context otherwise requires

" biological material integrity " means the unimpaired and unmarred condition of biological material;

" designation " means designation of a research institution, site or health establishment as a bio bank and designate shall be construed accordingly;

" licence " means a licence issued under regulation 6;

" licensee " means a holder of a licence issued under regulation 6;

"standard operating procedure " means a written instruction specifying the manner of consistently performing a complex routine activity; and

" Zambia Environmental Management Agency " means the Zambia Environmental Management Agency established by the Environmental Management Act, 2011.

Act No. 12 of 2011

Application for licence

3. (1) A research institution, site or health establishment that is designated as a bio bank under section 51 of the Act shall apply to the Minister for a licence to store biological material in Form I set out in the First Schedule on payment of the fee set out in the Second Schedule.

(2) The Minister shall, within thirty days of receipt of the application refer the application to the Authority for consideration.

(3) The Authority shall, within ninety days of receipt of the application from the Minister, recommend to the Minister to grant or reject the application.

(4) The Minister shall, within thirty days of receipt of the recommendation of the Authority, notify the applicant of the Minister's decision.

(5) The Minister shall, where the Minister approves the bio bank application, inform the applicant in Form II set out in the First Schedule.

Request for additional information

4. The Authority may request an applicant to submit additional information in relation to an application in Form III set out in the First Schedule.

Rejection of application

5. (1) The Minister shall reject an application for a licence if the—

(a) applicant fails to comply with any condition precedent for the grant of the licence; or

(b) the applicant was earlier issued with a licence under these Regulations which was revoked by the Minister within a period of five years preceding the date of the application.

(2) The Minister shall, where the Minister rejects an application under subregulation (1), inform the applicant within thirty days of the decision in Form IV set out in the First Schedule.

Issuance of licence

6. (1) The Minister shall issue a licence to a designated research institution, site or health establishment in Form V set out in the First Schedule.

(2) A licence shall be valid for three years.

Application for renewal of licence

7. (1) A licensee who intends to renew a licence shall apply to the Minister, ninety days before the expiry of the licence, in Form I set out in the First Schedule, on payment of the fee set out in the Second Schedule.

(2) The Minister shall, within thirty days of receipt of the application for the renewal of a licence, refer the application to the Authority for consideration.

(3) The Authority shall, within ninety days of the receipt of the application from the Minister, recommend to the Minister the renewal of a licence if the applicant meets the requirements of the Act.

(4) The Minister shall, where the Minister renews a licence, issue a new licence to the applicant.

(5) A licence that is not renewed by the Minister lapses on the date of its expiry.

Designation not transferable

8. A designation is not transferrable to any other person.

Amendment of licence

9. (1) The Minister may amend a licence where—

(a) the name of the research institution, site or health establishment of the licence changes; or

(b) the location of the bio bank changes.

(2) A licensee may apply to the Minister to amend a licence in Form VI set out in the First Schedule, on payment of the fee set out in the Second Schedule.

(3) The Minister shall, within thirty days of receipt of the application for amendment of the licence, notify the applicant of the decision.

(4) The Minister shall, where the licence is amended, issue the applicant with a new licence for the remaining validity period of the initial licence.

(5) The Authority shall not pay compensation that may arise in relation to the amendment of a licence.

Duplicate licence

10. (1) A licensee whose licence is lost, damaged or defaced, shall apply to the Minister for a duplicate licence in Form VII set out in the First Schedule on payment of the fee set out in the Second Schedule.

(2) The Minister shall, within thirty days of receipt of an application under sub-regulation (1), issue a duplicate licence in Form VIII set out in the First Schedule.

Suspension or revocation of licence

11. (1) The Minister shall suspend a licence if the licensee violates the conditions of the licence.

(2) The Minister shall, before suspending a licence, give notice to the licensee and request the licensee to show cause, within a specified period, why the licence should not

be suspended.

(3) A notice of intention to suspend a licence shall be in Form IX set out in the First Schedule.

(4) The Minister shall suspend a licence if the

licensee fails to take remedial measures within the period specified in the notice of intention to suspend the licence.

(5) A notice of suspension of a licence shall be in Form X set out in the First Schedule.

(6) A bio bank whose licence is suspended shall maintain the integrity of biological materials in the bio bank, but shall not receive new biological materials.

Revocation of licence to operate bio bank

12. (1) The Ministry shall revoke a licence of the licensee if that licensee—

(a) contravenes the provisions of the Act or any other relevant written law or breaches the terms and conditions of the licence;

(b) fails to take corrective measures following the suspension of the licence within the specified period;

(c) changes the location of the bio bank without authorisation; or

(d) obtained the licence by fraud negligence of misrepresentation or consentient of a material fact.

(2) The Minister shall, before revoking a licence, give notice to the licensee of the intention to revoke the licence and request the licensee to show cause, within a specified period, why the licence should not be revoked.

(3) A notice of intention to revoke a licence shall be in Form XI set out in the First Schedule.

(4) The Minister shall revoke a licence if the licensee fails to take remedial measures during the period specified by the Minister.

(5) A notice of revocation of a licence shall be in Form XII set out in the First Schedule.

(6) A bio bank whose licence is revoked shall at its cost—

(a) transfer biological materials in its custody to another bio bank approved by the Minister in consultation with the Authority; or

(b) destroy biological materials in its custody under the supervision of the Authority on behalf of the Minister.

Restoration of licence

13. A suspended or revoked licence may be restored if the Minister is satisfied with the remedial measures taken by the research institution, site or health establishment, on payment of the fee set out in the Second Schedule.

Failure to maintain biological material integrity

14. (1) Where a licensee is unable to maintain the integrity of biological materials for any reason, the licensee shall apply to the Minister to transfer the biological material to another designated bio-bank or destroy the biological materials under the supervision of the Authority.

(2) The Minister shall, within thirty days of receipt of the application under sub-regulation (1), authorise the transfer of the biological material on terms and conditions that the Minister may determine on the advice of the Authority.

Change of office

15. (1) A licensee shall, where the licensee intends to change its registered office, notify the Minister sixty days before the intended change, in Form XIII set out in the First Schedule, on payment of the fee set out in the Second Schedule.

(2) The notice to change its registered office under sub-regulation (1)shall be accompanied by—

(a) an application to amend the licence;

(b) site plan of the new location including set up of equipment and materials;

(c) the manner of transportation of the biological material that shall ensure integrity of the biological material; and

(d) the approval of the site by the Zambia Environmental Management Agency or any other relevant authority.

Closure of bio-bank

16. (1) Where a licensee intends to close a bio bank, the licensee shall within sixty days before closure, notify the Authority in Form XIV set out in the First Schedule on payment of the fee set out in the Second Schedule.

(2) The notice to close a bio-bank under subregulation (1), shall be accompanied by a—

(a) biological materials disposal plan;

(b) biological materials transfer plan where the biological materials are to be transferred to another approved bio bank; and

(c) material transfer agreement with a bio bank approved by the Authority.

Transfer of biological materials

17. A transfer of stored biological materials shall be accompanied by an approved material transfer agreement.

Fees

18. The fees set out in the Second Schedule are payable for the matters specified therein.

FIRST SCHEDULE

(*Regulations* 3, 4, 5, 6, 7, 9, 10, 11, 12, 15 *and* 16)

Form I

(*Regulation* 3(2) and 7 (1))

THE NATIONAL HEALTH RESEARCH AUTHORITY

The National Health Research Act

(Act No. 2 of 2013)

The National Health Research (Bio-banking) Regulations, 2020

APPLICATION FOR LICENCE OR RENEWAL OF LICENCE FOR THE STORAGE OF BIOLOGICAL MATERIAL

Please write in BLOCK LETTERS		Dated	
Information Required		*Information Provided*	√
Type of Application: 1. Initial [ ] 2. Renewal [ ]			
Type of Application: 1. National [ ] 2. International [ ]			
1.	**APPLICANT'S DETAILS**		
	(a) **Head of Institution responsible for the Bio-bank**		
	Title: (Tick (√) where applicable	Prof. ☐ Dr. ☐ Mr. ☐ Mrs. ☐ Ms. ☐	
	Surname:		
	Forename(s):		
	Qualification(s):		
	Physical address:		
	Postal address:		
	Phone:		
	Fax:		
	Email:		
	(b) **Institution responsible for the bio-bank**		
	Name of Institution:		
	Type of Institution: (Tick (√) where applicable	Public ☐ Private ☐ Others ☐	
	If others (please specify):	....	
	Registration Number:		
	Physical address:		
	Postal address:		
	Phone:		
	Fax:		
	Email:		
2.	**PARTICULARS OF THE BIO-BANK**		
	Name of Bio-bank:		

	Physical address:				
	Type of Bio-bank *(Tick (√) where applicable)*				
	☐ Bio-bank at Public Health Establishment ☐ Bio-bank at Private Health Establishment ☐ Bio-bank at Public Research Institution ☐ Bio-bank at Private Research Institution ☐ Other types of Bio-banks (please describe characteristics and contents)				
	Bio-bank purpose *(Tick (√) where applicable)*				
	☐ Clinical Research ☐ Therapeutic purposes ☐ Diagnostic purposes ☐ Quality Assurance ☐ Education ☐ Product development ☐ Other activities, please describe in detail				
	If affiliated to an existing approved Bio-bank give details				
	Name:				
	Physical address:				
	Bio-bank scope of work *(Tick (√) one of more applicable option(s))*				
	Tick (√)	**Type of biological material**	**Estimated number of samples per year**		
		Organ			
		Tissue			
		Cell/cell lines			
		Genomic materials			
		Blood and blood products			
		Urine			
		Saliva			
		Others, please list:			
3.	**PERSONNEL REQUIREMENTS**				
	Do you have personnel employed to perform the following responsibilities?			Yes	No
	(a)	Overseeing the operations of the bio-bank			
	(b)	Quality control			
	(c)	Sample collection, storage, transportation and handling or biological material			
	(d)	Data and information management			
4.	**QUALITY MANAGEMENT**				
				Yes	No
	Does the Bio-bank have in place a Quality Management System that complies with its manual of operations and Standard Operating Procedures				
5.	**SPECIMEN COLLECTION, PROCESSING, RETRIEVAL AND TRANSPORTATION**				
	A Bio-bank shall:			Yes	No
	(a)	Ensure sample collection is conducted by trained personnel			
	(b)	Develop protocols for stabilization and preservation of the samples during transit			
6.	**SUPPORTING INFORMATION**				
	Ethical Issues		Yes/No	Comments	
	Comply with local and international procedures, conventions, protocols, regulations, agreements relating to bio-banks as approved by the Authority; and				
	Ensure that any research done on materials in their possession has received appropriate ethical clearance.				
	Samples access and utilisation				
	Procedures for sample access and utilization which provide reasonable access to researchers and research institution				

	Procedures for determining what constitutes appropriate research use of the sample and data				
	Registers to record sample access requests and utilisation				
	Donor confidentiality shall be maintained where bio-bank biological materials are used in research publications				
	Data and information security				
	Ensure that data and information is transmitted securely in order to minimise the possibility of interception or unauthorised use				
	Anonymise data in such a way that it cannot be traced to the donor of the biological material unless there is a written consent by the donor or approval by the health research ethics committee				
	Establish a secure data and information management system which provides for back up, audit trail and a data recovery plan				
	Disposal of Bio-bank material				
	Assess the state of the samples				
	Keep record of the disposal of samples				
	Dispose of samples in line with the Zambia Environmental Management Act 2013 and The Public Health Act				
	A health researcher shall destroy or deposit left over samples arising from research into an approved bio-bank upon the expiry of the ethical approval				
	Biological materials stored for more than two months after analysis in the context of routine medical practice should be submitted to a licenced bio-bank				
	Risk Management				
	Does the bio-bank have a risk management policy approved by the Authority				
	Emergency Preparedness				
	Does the bio-bank have a written emergency preparedness plan				
	Safety				
	Have an established a safety plan				
	Have a safety officer responsible for implementing, monitoring and updating the safety plan				
	Have a plan of informing employees of potential hazards associated with biological material and sign an agreement that indicates that the employee shall handle biological material with necessary safety methods				
	Have a plan for use, storage ,transport or disposal of radioactive material in accordance with the provisions of the Ionizing Radiation Protection Act No. 16 of 2005				
	Stakeholders interest Does the bio-bank have a plan on how to engage the community and other stakeholders on the research activities that involve them				
7.	**APPENDICES - SUPPORTING DOCUMENTATION**				
				Yes/No	**Comment**
	Appendix 1	Proof of registration of institution			
	Appendix 2	Organogram			
	Appendix 3	Curriculum vitae of Principal Officers			
	Appendix 4	Comprehensive Policies/Protocols/Procedures			
	Appendix 5	International Air Transport Association (IATA) Certification			
	Appendix 6	Good Clinical Laboratory Practice (GCLP) Certification			
	Appendix 7	Certification from a competent Institution			
	Appendix 8	Accreditation certificate (for health research institutions)			
	Appendix 9	Funding source *(Tick (√) where applicable)*			
		Grant	Private funding		
		Public	End user payment		
		Donor			
		Other (specify)			

Appendix 10	List of key storage equipment				
Appendix 11	Floor plan of the bio-bank				
Appendix 12	Floor plan of bio-bank				

DECLARATION AND SIGNATURE

I ..... declare that the information provided in this application and attachments contained therein, are true to the best of my knowledge. Further, I acknowledge that submission of false information shall render the application void, and may result in a fine or being banned from conducting research in Zambia.

....

Applicant's Name Designation

..../...../20.....

Signature Date

FOR OFFICIAL USE ONLY

Received by: ..... Signature: .....

Officer (Name)

Bio-bank Application No.: ..... RECEIPT No.: .....

Completeness of application: Yes ☐ No ☐

General Comments: .....

.....

Date Received: ...../...../20.....

OFFICIAL STAMP

Form II
(*Regulation* 3(6))

THE NATIONAL HEALTH RESEARCH AUTHORITY
The National Health Research Act
(Act No. 2 of 2013)

The National Health Research
(Bio-banking) Regulations, 2020

NOTICE OF GRANT OF BIO-BANK LICENCE

To: ……..……

IN THE MATTER OF ……..……..…

You are notified that your application for designation as a bio-bank has been approved pending the issuance of the licence.

Dated this …….....…… day of ……..……, 20…….

Signed: ……..……..
Minister

Form III
(*Regulation* 4)

THE NATIONAL HEALTH RESEARCH AUTHORITY
The National Health Research Act
(Act No. 2 of 2013)

The National Health Research (Bio-banking) Regulations, 2020

REQUEST FOR ADDITIONAL INFORMATION

To…………………………………………………………………..…………...........…………......

IN THE MATTER OF…………………………….............……………………………..........….

You are hereby requested to provide the following information:

(a) ……………………………………………………………………………………...........…
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……………………………………………………………………………………...........…
………………………………..
………………………………..
………………………………..
………………………………..

Date this ………......................……..day of……………….....................…………,20……….

Signed:

………………………..
Minister

Form IV
(*Regulation* 5(2))

THE NATIONAL HEALTH RESEARCH AUTHORITY
The National Health Research Act
(Act No. 2 of 2013)

The National Health Research
(Bio-banking) Regulations, 2020

NOTICE OF REJECTION OF APPLICATION TO BE LICENSED AS BIO-BANK

To: ……

In the matter of ……

You are notified that your application for ……..

has been rejected on the following grounds: …….....

…….....…

…….....……

Dated this ……..... day of ……..……, 20…….

Signed:

……..……..
Minister

Licence No.

Form V
(*Regulation* 6(1))

THE NATIONAL HEALTH RESEARCH AUTHORITY
The National Health Research Act
(Act No. 2 of 2013)

The National Health Research
(Bio-banking) Regulations, 2020

LICENCE

…….....…….……

has been granted a licence to operate a bio-bank on the conditions specified overleaf

……....…….……..... for the period

…….....….. to ……..……..…….....….

Dated this …….....…… day of …….....……, 20…….

Signed: ……..
Minister

Overleaf

(a) This licence is not transferrable in any way.

(b) The licensee is expected to adhere to guidelines, Regulations and the provisions of the Act.

(c) Failure to adhere to guidelines, Regulations and the Act, may lead to the revocation of this licence.

(d) In the event that the licence is revoked, you are expected to surrender the licence to the National Health Research Authority