GOVERNMENT OF ZAMBIA

STATUTORY INSTRUMENT NO. 92 OF 2018

The National Health Research Act
(Act No. 2 of 2013)

The National Health Research (Material Transfer) Regulations, 2018

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

Title

1. These Regulations may be cited as the National Health Research (Material Transfer) Regulations, 2018.

Interpretation

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

ñAuthorityò has the meaning assigned to the word in the Act;

ñbenefitò means a financial, health or other advantage or profit gained from research;

ñbiological materialò has the meaning assigned to the words in the Act;

ñclinical trialò has the meaning assigned to the words in the Act;

ñmaterial transfer agreementò has the meaning assigned to the words in the Act; and

ñstandard operating procedureò means a written instruction intended to document how to perform a routine activity.

Application for transfer of biological materials for research purposes

3. (1) A person who wishes to transfer a biological material for research purposes shall apply to the Authority for approval in Form I set out in the First Schedule, on payment of the prescribed fee.

Copies of this Statutory Instrument can be obtained from the Government Printer, P.O. Box 30136, 10101, Lusaka, Price K24.00 each

(2) The Authority shall consider the application for transfer of biological materials for research purposes within ninety days of the date of receipt of the application.

(3) The Authority shall, where it approves an application for the transfer of biological materials for research purposes, inform the applicant within seven days of approval of the application in Form II set out in the First Schedule.

(4) The Authority shall, where it rejects an application for transfer of biological materials for research purposes, notify the applicant in Form III set out in the Schedule within seven days of the decision.

Application for transfer of biological materials for quality assurance

4. (1) Where an application for transfer of biological materials is required for quality assurance, the application shall be accompanied by the following:

(a) standard operating procedures for the planned tests;

(b) a statement of agreement between the two laboratories; and

(c) a plan for scheduled shipments of quality assurance samples.

(2) The Authority shall consider the application for transfer of biological materials for quality assurance within thirty days from the date of receipt of the application.

(3) The Authority may determine the number of shipments for each approval for quality assurance samples.

(4) Each shipment shall bear the seal of the Authority.

(5) The Authority shall, where it approves an application for transfer of biological materials for quality assurance purposes, notify the applicant in Form II set out in the First Schedule within seven days of the decision.

(6) The Authority shall, where it rejects an application for transfer of biological materials for quality assurance purposes, notify the applicant in Form III set out in the First Schedule within seven days of the decision.

Material transfer agreement

5. (1) A person who intends to import or export biological materials for research purposes shall fill out a material transfer agreement in Form IV set out in the First Schedule.

(2) The parties to a material transfer agreement shall ensure that confidentiality is maintained by withholding identities of participants.

(3) Where a material transfer agreement has been terminated, the parties shall destroy the samples unless the analysis is one which cannot be abandoned.

(4) The Authority shall require a publication to acknowledge the source of the material.

Rights of parties to material transfer agreement

6. (1) The material transfer agreement shall include terms relating toð

(a) intellectual property rights;

(b) rights to authorship;

(c) benefits to the health researcher, community or individual where applicable; and

(d) access to data generated from the study.

(2) Despite subregulation (1) an agreement made on intellectual property rights, rights to authorship, sharing benefits and access to data shall not be inconsistent with any other written law.

Fees

7. The fees set out in the Second Schedule are payable for the matters specified in that Schedule.

FIRST SCHEDULE

(*Regulations* 3,4 and 5)

FORM I
(*Regulation* 3(1))

The National Health Research Authority

The National Health Research Authority
(Act No. 2 of 2013)

National Health Research (Material Transfer) Regulations, 2018

APPLICATION FOR MATERIAL TRANSFER		
Please write in BLOCK LETTERS	Shaded fields for official use only	Application No.
		Date/Time
PART I		
Information Required	*Information Provided*	
A. Details of Head of Institution (PROVIDER SCIENTIST)		
Title (*Tick ["] where applicable)*	Prof. ☐ Dr. ☐ Mr. ☐ Mrs ☐ Ms. ☐	
(a) Surname:		
(b) Forename(s):		
(c) Qualification(s):		
(d) Email:		
(e) Phone number:		
(f) Name of institution:		
(g) Registration number:		
(h) Physical address:		
(i) Postal address:		
(j) Official phone number:		
(k) Fax:		
(l) Signature:		
(m) Date:		

B. Details of Local Principal Investigator (PROVIDER SCIENTIST)	
Title (*Tick ["] where applicable)*	Prof. ☐ Dr. ☐ Mr. ☐ Mrs ☐ Ms. ☐
(a) Surname:	
*(b)*Forename(s):	
(c) Qualification(s):	
(d) Email:	
(e) Phone:	
(f) Title of study:	
(g) Name of institution:	
(h) Registration number:	
(i) Physical address:	
(j) Postal address:	
(k) Phone number:	
(l) Fax:	
(f) Signature:	
(g) Date:	
1.Material to be transferred	
2.Purpose of export or import	
3.Name of study site(s)	

PART 2

A. DETAILS OF HEAD OF INSTITUTION (RECIPIENT SCIENTIST)	
Title (*Tick ["] where applicable)*	Prof. ☐ Dr. ☐ Mr. ☐ Mrs ☐ Ms. ☐
*(a)*Surname:	
*(b)*Forename(s):	
(c) Qualification(s):	
(d) Email:	
(e) Phone number:	
(f) Name of Organization/Laboratory	
(g) Physical Address:	
(h) City:	

*(i)*Country:		
(j) Website:		
(k) Signature:		
Attachments	**Attached Yes/No**	**Comment**
Research protocol (including budget, questionnaires, consent form, timelines, curriculum vitae)		
Letter of approval from the REC		
Letter of authority to conduct research		
Material transfer agreement signed by both parties		
Proof of payment of prescribed fee		
I certify that the recipient organisation has accepted and signed a copy of the material transfer agreement and shall not outsource the biological material to another organisation/laboratory without written approval of the Authority. I have read and understood the conditions outlined in this Agreement and I agree to abide by them in the receipt and use of the biological material.		
Signature:		
Date:		
B. DETAILS OF RECIPIENT SCIENTIST		
Title (*Tick ["] where applicable)*	Prof. ☐ Dr. ☐ Mr. ☐ Mrs ☐ Ms. ☐	
(a) Surname:		
(b) Forename(s):		
(c) Qualification(s):		
(d) Email:		
(e) Phone number:		
(f) Title of study:		
(g) Signature:		
(h) Date:		
(i) Name of Organization/ Laboratory		

(j) Physical Address:
(k) City:
(l) Country:
(m) Email:
(n) Website:
I certify that the recipient organisation has accepted and signed a copy of the material transfer agreement and shall not outsource the biological material to another organisation/laboratory without written approval of the Authority. I have read and understood the conditions outlined in this Agreement and I agree to abide by them in the receipt and use of the biological material.
Signature:
Date:

FOR OFFICIAL USE ONLY

Status:	**Tick [√]**	**Comments**
Recommended		
Not Recommended		
Deferred		

BOARD VICE-CHAIRPERSON:_____

Signature:_____

Date:_____

BOARD CHAIRPERSON:_____

*Signature:*_____

*Date:*_____

Approved ☐ **Not approved** ☐ **Deferred** ☐

FORM II
(*Regulation* 3 (3) and 4 (5))

The National Health Research Authority

The National Health Research Authority
(Act No. 2 of 2013)

National Health Research (Material Transfer) Regulations, 2018

NOTICE OF APPROVAL TO TRANSFER BIOLOGICAL MATERIALS FOR RESEARCH/QUALITY ASSURANCE PURPOSES

1. Here insert the full names and address of the applicant

To (1) .....

.....

.....

2. Here insert the reference No. of the application

IN THE MATTER OF (2).....

You are notifed that your application for material transfer has been approved on the following conditions:

(a) approval is not transferrable in any way;

(b) there is adherence to the provisions of the National Health Research Act No. 2 of 2013, Council Guidelines and other regulations; and

(c) failure to adhere to Council Guidelines and the National Health Research Act No. 2 of 2013 and other regulations shall result in the revocation of this approval.

Dated this.....day of..... 20.....

Signed: é é é é é é é é é é é é é ..

Board Chairperson

OFFICIAL STAMP

FORM III
(*Regulation* 3 (4) and 4 (6))

The National Health Research Authority

The National Health Research Authority
(Act No. 2 of 2013)

National Health Research (Material Transfer) Regulations, 2018

NOTICE OF APPROVAL TO TRANSFER BIOLOGICAL MATERIALS FOR RESEARCH/QUALITY ASSURANCE PURPOSES

1. Here insert the full names and address of the applicant

2. Here insert the reference No. of the application

To (1)é é é é é é é é é é é é é é é é é .é é .é é é é é é é ..é ..
é .é é é é é é é é é ..
é .é .
IN THE MATTER OF (2) é é é é é é é é é é é é é é é é é é ..é ....

You are notified that your application to transfer biological materials for research/ quality assurance purposes has been rejected on the following grounds:

*(a)*é .é ..
(b)............é .é é ..
(c).............é .é é é ..

Dated this é é é é é .é é é . day ofé é é é ..é é é é .. 20 é é .é ..é ..

é é é é é é é é é é .é é é é é é é é .é é ..
Board Chairperson

OFFICIAL STAMP

FORM IV
(*Regulation* 5)

The National Health Research Authority

The National Health Research Authority
(Act No. 2 of 2013)

National Health Research (Material Transfer) Regulations, 2018

MATERIAL TRANSFER AGREEMENT

This AGREEMENT made this.....day of.....,Two Thousand and .....BETWEEN.....of.....in é é é é é é é é é .(country and city) (herein after called ñthe exporter/importerò) of the one party, andé é é é é é é é é é of é é é é é é é é é é é (country and city) (hereinafter called ñthe exporter/importerò) of the other party WHEREBY IT IS AGREED that the exporter/ importer shall transfer biological materials mentioned in the accompanying application form to the importer/exporter for purposes of é é é é é é é upon the stated terms and conditions as set out in the schedule attached hereto.

IN WITNESS whereof the parties or their duly authorised agents have set their hands this day and year first before written.

SIGNED by: é é é é é .é é é é é é é .é é é é é ..)

in the presence of: é é é é é é é é é é .é é é é ...)

WITNESS

Name: é ..)

Physical address: é)

Occupation: é ..)

SIGNED by: é é é é é é é é é é é ..é é é ..)

in the presence oné é é é é é é é é é é é ...)

WITNESS

Name: é

Physical address: é ...

Occupation: é

CONDITIONS

1. These biological materials are transferred subject to the National Health Research Authority general conditions so far as the same are not inconsistent with or varied by these special conditions.

GENERAL CONDITIONS

2. The parties shall state the following:

(a) exported or imported research materials shall be used only for the purpose indicated in the research protocol;

(b) the biological materials shall not be transferred to a third party without written permission from the Authority;

(c) intellectual property rights and patents;

(d) rights to authorship;

(e) rights of ownership of the biological materials;

(f) benefits to the health researcher, community or individual(s) where applicable;

(g) access to data generated from the study;

(h) shipping of biological materials;

(i) disposal of biological materials; and

(j) termination of the agreement.

SPECIAL CONDITIONS

The parties may agree to any other conditions in addition to the above conditions.

Please return a filled in copy of this Agreement to: The National Health Research Authority, P. O. Box 30075, LUSAKA.

The purpose of this agreement is to provide a record of the biological material transfer, to memorialise the agreement between the provider scientist and the recipient scientist to abide by all terms and conditions of the Material Transfer Agreement and to certify that the recipient organisation has accepted and signed a copy of the Material Transfer Agreement. All materials collected from Zambia shall remain the property of the Government of the Republic of Zambia. For any commercial product derived from the exported materials, the person from whom the samples were collected shall receive royalties. The recipient agrees to acknowledge the source of the material in any publications reporting use of it. The recipient agrees to use the material in compliance with statutes and regulations.

SECOND SCHEDULE

(*Regulations* 7)

Prescribed Fees

No.	Item	Fee Units
1.	Application to transfer biological materials (students)	3,400
2.	Application to transfer biological materials (locally funded protocol)	8,350
3.	Application to transfer biological materials (internationally funded protocol)	16,700

DR C. CHILUFYA,
Minister of Health

LUSAKA
7th December, 2018
[MH.71.3/8]