

GOVERNMENT OF ZAMBIA

STATUTORY INSTRUMENT NO.25 OF 2020

The National Health Research Act, 2013

(Act No. 2 of 2013)

**The National Health Research
(Registration and Accreditation) Regulations 2020**

IN EXERCISE of the powers contained in sections 18 (3), 19 and 63 of the National Health Research Act, 2013, the following regulations are made:

- | | |
|---|--|
| 1. These Regulations may be cited as the National Health Research (Registration and Accreditation) Regulations, 2020. | Title |
| 2. In these Regulations, unless the context otherwise requires

“certificate of accreditation” means a certificate of accreditation issued under regulation 8; and

“certificate of registration” means the certificate of registration issued under regulation 4. | Interpretation |
| 3. (1) A research institution or health establishment at which health research is conducted shall apply to the Board for the registration of a health research ethics committee in Form I set out in the First Schedule on payment of the fee set out in the Second Schedule.

(2) The Board may, within thirty days of receipt of an application under subregulation (1), grant or reject the application.

(3) The Board shall, where it rejects an application, inform the applicant in Form II set out in the First Schedule. | Application for registration of health research ethics committee |
| 4. (1) The Board shall, where it approves an application for registration, issue an applicant with a certificate of registration in Form III set out in the First Schedule.

(2) A certificate of registration shall remain valid unless suspended or cancelled under these Regulations. | Certificate of registration |

Suspension, cancellation of registration	<p>5. (1) The Board may suspend or cancel a certificate of registration of a health research ethics committee if the certificate of the health research ethics committee</p> <ul style="list-style-type: none"> (a) obtained the certificate of registration by fraud, negligence, misrepresentation, or concealment of a material fact; (b) is found guilty of misconduct under the written Act; (c) contravenes the Act or any other relevant written law; or (d) is disqualified based on circumstances arising against the health research ethics committee. <p>(2) The Board shall before suspending or cancelling the certificate of registration of a health research ethics committee, give notice to the holder of the certificate of registration to show cause within a specified period why the certificate of registration should not be suspended, cancelled or revoked in Form IV set out in the First Schedule.</p> <p>(3) The Board shall suspend or cancel a certificate of registration if the health research ethics committee fails to take remedial measures during the period specified by the Board in Form V set out in the Schedule.</p> <p>(4) Where the certificate of registration of a health research ethics committee is suspended or cancelled</p> <ul style="list-style-type: none"> (a) holder of a certificate of registration shall cease research activities; (b) the Board shall transfer research protocols under the review of a health research ethics committee to another accredited health research ethics committee; (c) the Board shall transfer research materials of the health researcher or research institution; and (d) the certificate of registration of the health research ethics committee shall be surrendered to the Authority and the registration shall be cancelled.
Restoration of certificate of registration	<p>6. A suspended or cancelled certificate may be restored if the Board is satisfied with the remedial measures taken by the health research ethics committee, on payment of the fee set out in the Second Schedule.</p>
Application for accreditation or renewal of accreditation	<p>7. (1) A health researcher, research institution or health research ethics committee shall apply to the Authority for accreditation or renewal of accreditation in Form VI set out in the First Schedule on payment of the fee set out in the Second Schedule.</p>

(2) The Board shall, within thirty days of receipt of the application under subregulation (1) grant or reject an application for accreditation or renewal of accreditation.

(3) The Board shall, where it grants an application for accreditation or renewal of accreditation, notify the applicant in Form VII set out in the First Schedule.

(4) The Board shall, where it rejects an application for accreditation or renewal of accreditation, notify the applicant in Form VIII set out in the First Schedule.

8. The Board shall issue a certificate of accreditation in Form IX set out in the First Schedule. Certificate of accreditation

9. A health researcher, research institution or health research ethics committee shall display the certificate of accreditation in a conspicuous place at their respective registered place of business or office. Display of certificate of accreditation

10. (1) The Minister shall revoke the certificate of accreditation of a health researcher, research institution or health research ethics committee if the health researcher, research institution or health research ethics committee Revocation of certificate of accreditation

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

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

(c) changes location of its place of business or office without authorisation; or

(d) obtained the certificate of registration by fraud, negligence, misrepresentation, or concealment of a material fact.

(2) The Minister shall, before revoking a certificate of accreditation, give notice to the health researcher, research institution or health research ethics committee of the intention to revoke the certificate and request the health researcher, health research ethics committee or research institution, to show cause, within a specified period, why the certificate should not be revoked.

11. (1) The Minister may restore a suspended or cancelled certificate of accreditation if the Minister is satisfied with the remedial measures taken by a health researcher, research institution, or health research ethics committee. Restoration of accreditation certificate

	(2) A health researcher, research institution or health research ethics committee may apply for the restoration of a suspended or revoked certificate of accreditation in Form VI set out in the First Schedule on payment of the fee set out in the Second Schedule.
Duplicate certificate of accreditation or registration	<p>12. (1) A health researcher, research institution or health research ethics committee whose certificate of registration or accreditation is destroyed or lost may apply to the Board for a duplicate certificate in Form X set out in the First Schedule on payment of the fee set out in the Second Schedule.</p> <p>(2) The Board may, within thirty days of receipt of an application under this regulation, issue a duplicate certificate of accreditation or registration in Form XI or XII set out in the First Schedule, respectively.</p>
Prohibition of transfer of certificate of registration or accreditation	13. A certificate of registration or accreditation issued under these Regulations is nontransferrable to a third party.
Levels of accreditation for health research ethics committee	<p>14. (1) A certificate of accreditation for a health research ethics committee shall be issued according to the following levels:</p> <p>(a) level one, for a health research ethics committee which reviews research protocols that have minimum risks to research participants;</p> <p>(b) level two, for a health research ethics committee which reviews all types of research protocols except clinical and vaccine trials; and</p> <p>(c) level three, for a health research ethics committee which reviews all types of research protocols, including clinical and vaccine trials.</p> <p>(2) A health research ethics committee shall comply with the guidelines issued by the Authority for each level of accreditation.</p> <p>(3) The certificate of accreditation shall state the level of accreditation granted to a health research ethics committee.</p> <p>(4) A health research ethics committee shall not approve a research protocol that is beyond the level of accreditation permitted by the Board.</p> <p>(5) The Board shall revoke the certificate of accreditation of a health research ethics committee that does not comply with subregulation (4).</p>

- | | |
|--|--|
| <p>15. The functions of a health research ethics committee are to</p> <ul style="list-style-type: none"> (a) promote the rights, dignity and welfare of research participants; (b) ensure that a certificate of accreditation is adhered to; (c) review, approve or disapprove research protocols; (d) maintain records of approved research protocols; (e) monitor the conduct of research by a health researcher, research institution or health research ethics committee; (f) submit annual reports to the Board; and (g) perform other functions conferred on a health research ethics committee under the Act. | <p>Functions of health research ethics committee</p> |
| <p>16. (1) The Director shall keep and maintain a Register of persons registered and accredited under these Regulations.</p> <p>(2) The Director shall enter the details and particulars relating to—</p> <ul style="list-style-type: none"> (a) registered health researchers, research institutions and health research ethics committees; (b) the holders of certificates of registration and accreditation, and person whose certificates have been cancelled; (c) the applications rejected and the reasons for the rejection; and (d) any other information that the Authority may determine. <p>(3) The Register shall be kept in the custody of the Director at the offices of the Authority and shall be open for inspection by members of the public during normal office hours on payment of the fee set out in the Second Schedule.</p> <p>(4) The Director may, on an application by any person, issue to the person a certified extract from the Register of a copy of a certificate of registration or accreditation, on payment of the fee set out in the Second Schedule.</p> | <p>Registers</p> |
| <p>17. The fees set out in the Second Schedule are payable for the matters specified therein.</p> | <p>Fees</p> |

SCHEDULE

(Regulations 3, 4, 5, 7, 8 and 12)

Form I

(Regulation 3 (1))

**THE NATIONAL HEALTH RESEARCH AUTHORITY****The National Health Research Act, 2013**

(Act No. 2 of 2013)

**The National Health Research
(Registration and Accreditation) Regulations 2020**

APPLICATION FOR REGISTRATION**1. APPLICATION DETAILS****PART A`. Research Institution**

Name of Ethics Committee	
Institutional Affiliation	
Physical address	
Postal address	
Phone	
Fax	
Email	
Level applied for	
Chairperson	<p>Title (Tick["] where applicable)</p> <p>Prof. <input type="checkbox"/> Dr <input type="checkbox"/> Mr. <input type="checkbox"/> Mrs. <input type="checkbox"/> Ms. <input type="checkbox"/></p> <p>Surname</p> <p>Forename(s)</p> <p>Phone:</p> <p>Email:</p> <p>Address:</p>
Administrator	<p>Title (Tick["] where applicable)</p> <p>Prof. <input type="checkbox"/> Dr <input type="checkbox"/> Mr. <input type="checkbox"/> Mrs. <input type="checkbox"/> Ms. <input type="checkbox"/></p> <p>Surname</p> <p>Forename(s)</p> <p>Phone:</p> <p>Email:</p> <p>Address:</p>
Type of Certificate (Registration/Accreditation):	
Certificate No:	
Affidavit (Attach):	

A2. Supporting documents

Document	Attached Yes/No	Comment
Registration Certificate		
List of the members of research ethics committee		
Composition of research ethics committee as provided for in attachment 1		
Curriculum vitae of members of the research ethics committee		
Evidence of ethics training, undertaken within the last three years		
Signed statement of commitment by the head of institution to conduct health research in accordance with the National Health Research Act No. 2 of 2013		
Declarations of conflict of interest		
Standard operating procedures		
Protocol and consent forms template		
Fee structure		

A3. Type of research to be reviewed

Biomedical research	
Social research	
Other (Specific)	

B1. Health Establishment

Name of institution	
Type of institution (Tick where applicable)	Public <input type="checkbox"/> Private <input type="checkbox"/>
Registration number (e.g. PACRA, HPCZ etc)	
Physical address	
Postal address	
Phone	
Fax	
Email	
Type of Certificate(Registration/Accreditation)	
Certificate No:	
Affidavit (Attach)	

B2. Supporting documents for Research Institution

Document	Attached Yes/No/NA	Comment
Registration Certificate		
Composition of research ethics committee as provided for in attachment		
Curriculum vitae of members of the research ethics committee		
Evidence of ethics training, undertaken within the last three years		
Signed statement of commitment by the head of institution to conduct health research in accordance with the National Health Research Act No. 2 of 2013		
Declarations of conflict of interest		
Curriculum vitae of research staff		
Standard operating procedures		
Protocol and consent forms template		
Fee Structure		

2. 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.

Details of Person Signing the Application

(a) Name:

(b) Designation:

(c) Signature:

(d) Date:/...../..... (dd/mm/yyyy)

FOR OFFICIAL USE ONLY

Date of receipt of application:	<input type="text"/>	Payment receipt number:	<input type="text"/>
Registration number:	<input type="text"/>		
Completeness of application:	YES <input type="checkbox"/>	No <input type="checkbox"/>	

General comments

.....

Name of reviewer.....

Signature.....

Date.....

Attachment 1: Composition of Research Ethics Committee

Name of person	
Profession	
Institutional affiliation	
Qualification(s)	
Physical address	
Phone	
Email	

Name of person	
Profession	
Institutional affiliation	
Qualification(s)	
Physical address	
Phone	
Email	

Name of person	
Profession	
Institutional affiliation	
Qualification(s)	
Physical address	
Phone	
Email	

Name of person	
Profession	
Institutional affiliation	
Qualification(s)	
Physical address	
Phone	
Email	

Name of person	
Profession	
Institutional affiliation	
Qualification(s)	
Physical address	
Phone	
Email	

Name of person	
Profession	
Institutional affiliation	
Qualification(s)	
Physical address	
Phone	
Email	

Name of person	
Profession	
Institutional affiliation	
Qualification(s)	
Physical address	
Phone	
Email	

Name of person	
Profession	
Institutional affiliation	
Qualification(s)	
Physical address	
Phone	
Email	

Name of person	
Profession	
Institutional affiliation	
Qualification(s)	
Physical address	
Phone	
Email	

Name of person	
Profession	
Institutional affiliation	
Qualification(s)	
Physical address	
Phone	
Email	

Name of person	
Profession	
Institutional affiliation	
Qualification(s)	
Physical address	
Phone	
Email	



Form II
(Regulation 3 (3))

THE NATIONAL HEALTH RESEARCH AUTHORITY

The National Health Research Act, 2013

(Act No. 2 of 2013)

**The National Health Research
(Registration and Accreditation) Regulations 2020**

NOTICE OF REJECTION OF REGISTRATION

To.....

In the matter of.....

You are notified that your application for..... has been
rejected on the following grounds:.....

.....

Dated thisday of..... 20.....

Signed:

.....

Director



Form III
(Regulation 4 (1))

THE NATIONAL HEALTH RESEARCH AUTHORITY

The National Health Research Act, 2013

(Act No. 2 of 2013)

**The National Health Research
(Registration and Accreditation) Regulations 2020**

CERTIFICATE OF REGISTRATION

This is to certify that

.....
has been registered as a

.....

Dated thisday of..... 20.....

Signed:

.....
Director



Form IV
(Regulation 5 (2))

THE NATIONAL HEALTH RESEARCH AUTHORITY

The National Health Research Act, 2013

(Act No. 2 of 2013)

**The National Health Research
(Registration and Accreditation) Regulations 2020**

**NOTICE OF INTENTION TO SUSPEND/CANCEL/REVOKE CERTIFICATE OF
REGISTRATION**

<p>(1) Here insert the full names and address of holder</p> <p>(2) Here insert the conditional authority No./ designation No.</p>	<p>TO (1)</p> <p>.....</p> <p>IN THE MATTER OF (2) you are notified that the Authority intends to *suspend/cancel/revoke your Certificate of Registration on the following grounds:</p> <p>(a)</p> <p>(b)</p> <p>(c)</p> <p>Accordingly, you are requested to show cause why your Certificate of Registration should not be *suspended/cancelled/revoked and to take action to remedy the breaches set out in paragraphs (above) within (3) days of receiving this notice. Failure to remedy the said breaches shall result in the *suspension/cancellation/revocation of your Certificate of Registration.</p> <p>Dated this day of 20.....</p> <p>.....</p> <p style="text-align: center;"><i>Board Chairperson</i></p> <p>*Delete as appropriate</p>
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**OFFICIAL
STAMP**



Form V
(Regulation 5 (3))

THE NATIONAL HEALTH RESEARCH AUTHORITY

The National Health Research Act, 2013

(Act No. 2 of 2013)

**The National Health Research
(Registration and Accreditation) Regulations 2020**

**NOTICE OF SUSPENSION, CANCELLATION OR REVOCATION OF CERTIFICATE
OF REGISTRATION**

To.....

IN THE MATTER OF.....

you are notified that your certificate of registration No.

..... is suspended, cancelled or revoked on the
following grounds:

.....

.....

.....

.....

Date thisday of..... 20.....

Signed:

.....

Board Chairperson



Form VI
(Regulation 7 (1)) and 11 (2))

THE NATIONAL HEALTH RESEARCH AUTHORITY

The National Health Research Act, 2013

(Act No. 2 of 2013)

**The National Health Research
(Registration and Accreditation) Regulations 2020**

**APPLICATION FOR ACCREDITATION, RENEWAL OR RESTORATION OF
ACCREDITATION FOR RESEARCH INSTITUTION/HEALTH RESEARCH ETHICS
COMMITTEE/RESEARCHERS**

To be completed in triplicate

1. Original to the minister
2. Duplicate to the
3. Triplicate to be retained by applicant

[Please tick] **Zambian Applicant** ☐ **Non-Zambian Applicant** ☐

Type of Application: **1. Initial** ☐ **2. Renewal** ☐

Level of Accreditation applied for.....

Please write in BLOCK LETTERS

3. APPLICANT DETAILS

(a) Research Institutions

(i) Details of Head of Institution

Title (Tick["] where applicable)	Prof. <input type="checkbox"/> Dr. <input type="checkbox"/> Mr. <input type="checkbox"/> Mrs. <input type="checkbox"/> Ms. <input type="checkbox"/>
Surname	
Forename(s)	
Qualification(s)	
Physical address	
Postal address	
Phone	
Fax	
Email	

(ii) Details of Research Institution

Name of institution	
Type of institution (Tick where applicable) If other (please specify)	Public <input type="checkbox"/> Private <input type="checkbox"/> Other <input type="checkbox"/>
Registration number of Institution	
Physical address	
Postal address	
Phone	
Fax	
Email	

(iii) Funding and training in preceding year

Number of Grants received	
Value of Grants received	
Number of publications	
Trainings	GCP <input type="checkbox"/> Number conducted <input type="checkbox"/> Ethics <input type="checkbox"/> Number conducted <input type="checkbox"/> Other <input type="checkbox"/> Number conducted <input type="checkbox"/> If other, please specify.....

(iv) Supporting Documents for Research Institution

Document	Attached Yes/No	Comment
Covering letter		
Registration certificate		
Signed statement of commitment by the head of institution to conduct health research in accordance with the National Health Research Act No. 2 of 2013		
Declarations of conflict of interest		
Adequate and appropriate infrastructure to conduct research		
Curriculum vitae of research staff		

(b) Research Ethics Committee**(i) Details of the Health Research Ethics Committee**

Name of Ethics Committee	
Institutional Affiliation	
Physical address	
Postal address	
Phone	
Fax	
Email	
Level applied for	
Chairperson	Title (<i>Tick["] where applicable</i>) Prof. <input type="checkbox"/> Dr. <input type="checkbox"/> Mr. <input type="checkbox"/> Mrs. <input type="checkbox"/> Ms. <input type="checkbox"/>
	Surname
	Forename(s)
	Phone:
	Email:
	Address:
Administrator	Title (<i>Tick["] where applicable</i>) Prof. <input type="checkbox"/> Dr. <input type="checkbox"/> Mr. <input type="checkbox"/> Mrs. <input type="checkbox"/> Ms. <input type="checkbox"/>
	Surname
	Forename(s)
	Phone:
	Email:
	Address:

(ii) Type of Research to be reviewed

Biomedical research	
Social research	
Other (Specify)	

(iii) Funding and training in preceding year

Number of Grants received	
Value of Grants received	
Number of publications	
Trainings	GCP <input type="checkbox"/> Number conducted <input type="checkbox"/> Ethics <input type="checkbox"/> Number conducted <input type="checkbox"/> Other <input type="checkbox"/> Number conducted <input type="checkbox"/> If other, please specify.....

(iv) Supporting Documents for REC

Document	Attached Yes/No	Comment
Covering letter		
Registration certificate		
Signed statement of commitment by the Research Ethics Committee to conduct health research in accordance with the National Health Research Act No. 2 of 2013		
Declarations of conflict of interest		
Adequate and appropriate infrastructure to conduct research		
Curriculum vitae of research staff		

C Health Researcher**(i) Details of Health Researcher**

Title (Tick[“] where applicable)	Prof. <input type="checkbox"/> Dr. <input type="checkbox"/> Mr. <input type="checkbox"/> Mrs. <input type="checkbox"/> Ms. <input type="checkbox"/>
Surname	
Forename(s)	
Nationality	
National identification number:	
Gender:	Male <input type="checkbox"/> Female <input type="checkbox"/>
Qualification(s)	
Institutional affiliation	
Physical address	
Postal address	
Phone	
Fax	
Email	

(ii) Supporting documents for health researchers

Document	Attached Yes/No/NA	Comment
Professional registration certificate		
Curriculum vitae		
Evidence of ethics training, undertaken within the last three years		
Declarations of conflict of interest		

4. DECLARATION AND SIGNATURE

I.....declare that the information provided in this application and the 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.

Details of Person Signing the Application

(a) Name:
 (b) Designation:
 (c) Signature: (d) Date:/...../..... (dd/mm/yyyy)

FOR OFFICIAL USE ONLY*For office use only*

Date of receipt of application: Payment receipt number:
 Registration number: Completeness of application: YES ☐ NO ☐

General comments

.....

Name of reviewer

Signature.....

Date.....



Form VII
(Regulation 7(3))

THE NATIONAL HEALTH RESEARCH AUTHORITY

The National Health Research Act, 2013

(Act No. 2 of 2013)

**The National Health Research
(Registration and Accreditation) Regulations 2020**

**NOTICE OF GRANT OF ACCREDITATION/RENEWAL OF
ACCREDITATION**

- (1) Here inset the full names and addresses of applicant To (1):.....
.....
- (2) Here inset the reference No. of the application IN THE MATTER OF (2).....
.....
- (3) Here inset the type of application You are hereby notified that your application for (3).....
has been approved on the following *conditions:
(a).....
(b).....
(c).....
(d).....
- (4) Signature of Secretary for the Board Dated this..... day of20.....
(4)
Director



Form VIII
(Regulation 7(4))

THE NATIONAL HEALTH RESEARCH AUTHORITY

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

**The National Health Research
(Registration and Accreditation) Regulations 2020**

**NOTICE OF REJECTION TO GRANT ACCREDITATION OR RENEWAL OF
ACCREDITATION**

To.....

IN THE MATTER OF.....

You are notified that your application for..... has been
rejected on the following grounds:.....

.....
.....

Dated thisday of..... 20.....

Signed:

.....

Director



Form IX
(Regulation 8)

THE NATIONAL HEALTH RESEARCH AUTHORITY

The National Health Research Act, 2013

(Act No. 2 of 2013)

**The National Health Research
(Registration and Accreditation) Regulations 2020**

CERTIFICATE OF ACCREDITATION

This is to certify that

.....

is **ACCREDITED** by the

National Health Research

Authority of Zambia as a

.....

for the period from January to December 20

Date thisday of..... 20.....

Signed:

.....

Director



Form X
(Regulation 12(1))

THE NATIONAL HEALTH RESEARCH AUTHORITY

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

**The National Health Research
(Registration and Accreditation) Regulations 2020**

**APPLICATION FOR DUPLICATE CERTIFICATE OF REGISTRATION OR
ACCREDITATION**

5. APPLICANT DETAILS

PART A. Health Research Ethics Committee

Name of Ethics Committee	
Institutional Affiliation	
Physical address	
Postal address	
Phone	
Fax	
Email	
Level applied for	
Chairperson	<p>Title (<i>Tick[“] where applicable</i>) Prof. <input type="checkbox"/> Dr. <input type="checkbox"/> Mr. <input type="checkbox"/> Mrs. <input type="checkbox"/> Ms. <input type="checkbox"/></p> <p>Surname</p> <p>Forename(s)</p> <p>Phone:</p> <p>Email:</p> <p>Address:</p>
Administrator	<p>Title (<i>Tick[“] where applicable</i>) Prof. <input type="checkbox"/> Dr. <input type="checkbox"/> Mr. <input type="checkbox"/> Mrs. <input type="checkbox"/> Ms. <input type="checkbox"/></p> <p>Surname</p> <p>Forename(s)</p> <p>Phone:</p> <p>Email:</p> <p>Address:</p>
Type of Certificate (Registration/Accreditation):	
Certificate No:	
Affidavit (Attach) :	

PART B. Health Research Institution

Name of institution	
Type of institution (Tick where applicable)	Public <input type="checkbox"/> Private <input type="checkbox"/>
Registration number (e.g. PACRA, HPCZ etc)	
Physical address	
Postal address	
Phone	
Fax	
Email	
Type of Certificate (Registration/Accreditation):	
Certificate No.:	
Affidavit (Attach):	

PART C. Health Researcher

Title (Tick["] where applicable)	Prof. <input type="checkbox"/> Dr. <input type="checkbox"/> Mr. <input type="checkbox"/> Mrs. <input type="checkbox"/> Ms. <input type="checkbox"/>
Surname	
Forename(s)	
Nationality	
National identification number:	
Gender:	Male <input type="checkbox"/> Female <input type="checkbox"/>
Qualification(s)	
Institutional affiliation	
Physical address	
Postal address	
Phone	
Fax	
Email	
Type of Certificate (Registration/Accreditation):	
Certificate No:	
Affidavit (Attach):	

6. 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.

Details of Person Signing the Application

(a) Name:

(b) Designation:

(c) Signature: (d) Date:/...../..... (dd/mm/yyyy)

FOR OFFICIAL USE ONLY

Date of receipt of application: Payment receipt number:
 Registration number:
 Completeness of application: YES ☐ NO ☐

General comments

.....

Name of reviewer

Signature Date.....

Attachment 1: Composition of Health Research Ethics Committee

Name of person	
Profession	
Institutional affiliation	
Qualification(s)	
Physical address	
Phone	
Email	

Name of person	
Profession	
Institutional affiliation	
Qualification(s)	
Physical address	
Phone	
Email	

Name of person	
Profession	
Institutional affiliation	
Qualification(s)	
Physical address	
Phone	
Email	

Name of person	
Profession	
Institutional affiliation	
Qualification(s)	
Physical address	
Phone	
Email	

Name of person	
Profession	
Institutional affiliation	
Qualification(s)	
Physical address	
Phone	
Email	

Name of person	
Profession	
Institutional affiliation	
Qualification(s)	
Physical address	
Phone	
Email	

Name of person	
Profession	
Institutional affiliation	
Qualification(s)	
Physical address	
Phone	
Email	

Name of person	
Profession	
Institutional affiliation	
Qualification(s)	
Physical address	
Phone	
Email	

Name of person	
Profession	
Institutional affiliation	
Qualification(s)	
Physical address	
Phone	
Email	

Name of person	
Profession	
Institutional affiliation	
Qualification(s)	
Physical address	
Phone	
Email	

Name of person	
Profession	
Institutional affiliation	
Qualification(s)	
Physical address	
Phone	
Email	



Form XI
(Regulation 12(2))

THE NATIONAL HEALTH RESEARCH AUTHORITY

The National Health Research Act, 2013

(Act No. 2 of 2013)

**The National Health Research
(Registration and Accreditation) Regulations 2020**

DUPLICATE CERTIFICATE OF ACCREDITATION

This is to certify that

.....

is **ACCREDITED** by the

National Health Research

Authority of Zambia as a

.....

for the period from January to December 20

Date thisday of 20.....

Signed:

.....

Director



Form XII
(Regulation 12(2))

THE NATIONAL HEALTH RESEARCH AUTHORITY

The National Health Research Act, 2013

(Act No. 2 of 2013)

**The National Health Research
(Registration and Accreditation) Regulations 2020**

DUPLICATE CERTIFICATE OF REGISTRATION

This is to certify that

.....

is **REGISTERED** by the

National Health Research Authority of

Zambia as a

.....

for the period from January to December 20

Date thisday of 20.....

Signed:

.....

Director

SECOND SCHEDULE
(Regulation 17)

Prescribed Fees

S/No.	Description	ZAMBIAN Application Fees (Fee Units)	FOREIGN Application Fees (Fee Units)
1.	Application for registration as researcher	3,400	6,800
2.	Application for registration of research institution or health research ethics committee	6,700	13,400
3.	Application of accreditation of researcher	2,500	5,000
4.	Application of accreditation of research institution or health research ethics committee	8,350	16,700
5.	Application for renewal of accreditation of researcher	1,000	2,000
6.	Application for renewal of accreditation of research institution or health research ethics committee	5,000	10,000
7.	Restoration of suspended or revoked certificate	33,500	67,000
8.	Application for variation of accreditation certificate	23,400	46,800

LUSAKA
[25th March , 2020]
[MOH/101/23/10]

C.CHILUFYA,
Minister of Health

