

Republic of Zambia

NATIONAL HEALTH RESEARCH AUTHORITY

Regulations on Registration and Accreditation of Health Research Ethics Committees, Research Institutions and Health Researchers

2016

The National Health Research Act

(Act No. 2 of 2013)

National Health Research (registration and accreditation of health research ethics committees, research institutions and health researchers) Regulations, 2016.

IN EXERCISE of the powers contained in section <u>Sixty-three</u> of the National Health Research Act, the following regulations are made:

Title

1. These Regulations may be cited as National Health Research (registration and accreditation of health research ethics committees, research institutions and health researchers) Regulations, 2016.

Interpretation

- 2. In these regulations unless the context otherwise requires:
- "Authority" has the meaning assigned to it in the Act;
- "Certificate of accreditation" means an official document issued under section <u>eighteen</u> of the Act as formal recognition of competence to perform health research and health research related tasks.
- "Certificate of registration" means an official document issued under section <u>eighteen</u> stating that a health research ethics committee, research institution or health researcher has provided all the necessary information for a record of registration;
- "Register" means a book in which records of health research ethics committees, research institutions and health researchers are kept.
- "Standard operating procedures" means written instructions intended to document how to perform a routine activity.

Application for registration

3. (1) An application for registration of health research ethics committees, research institutions and health researchers shall be made in Form I set out in the First Schedule upon payment of a prescribed fee.

(2) The Authority shall, where it accepts an application, inform the applicant in Form II set out in the First Schedule within thirty days of receipt of the application.

- (3) The Authority shall, where it rejects an application, inform the applicant in Form III set out in the First Schedule within thirty days of receipt of the application.
- 4. The Authority shall issue the successful applicant with a certificate of registration in Form IV set out in the First Schedule.
- 5. (1) The Authority may, by stating reason(s) in writing, suspend the registration of a health research ethics committee, research institution or health researcher.
 - (2) Where the registration of a research institution or health researcher is suspended in accordance with sub-section (1), all research activities must cease forthwith.
 - (3) Where the registration of a health research ethics committee is suspended in accordance with sub-section (1), the Board shall transfer all research protocols under review of that committee to another accredited ethics committee.
- 6. (1) The Authority may, by stating reason(s) in writing, revoke the registration of a health research ethics committee, research institution or health researcher.
 - (2) Where the registration of a research institution or health researcher is revoked in accordance with sub-section (1), all research activities must cease forthwith.
 - (3) Where the registration of a health research ethics committee is revoked in accordance with sub-section (1), the Board shall transfer all research protocols under review of that committee to another accredited ethics committee.
- 7. A suspended or revoked registration certificate may be restored where the Authority is satisfied with the corrective and preventive actions undertaken by the registration certificate holder upon payment of a prescribed fee.
- 8. (1) An application for accreditation or renewal of accreditation of health research ethics committees, research institutions and health researchers

Certificate of registration
Suspension of certificate of registration

Revocation of certificate of registration

Restoration of certificate of registration

Application for accreditation or

renewal of accreditation

- shall be made in Form V set out in the First Schedule upon payment of a prescribed fee.
- (2) The validity period of accreditation shall be for a period not exceeding 3 years
 - (3) The Authority shall, where it accepts an application for accreditation or renewal of accreditation, inform the applicant in Form VI set out in the First Schedule within thirty days of receipt of the application.
 - (4) The Authority shall, where it rejects an application for accreditation or renewal of accreditation, inform the applicant in Form VII set out in the First Schedule within thirty days of receipt of the application.

Certificate of accreditation

 The Authority shall issue the successful applicant with a certificate of accreditation or renewal of accreditation in Form VIII set out in the First Schedule.

certificate of accreditation

Suspension of

- 10. (1) The Authority may, by stating reason(s) in writing, suspend the accreditation of a health research ethics committee, research institution or health researcher.
 - (2) Where the accreditation of research institution or health researcher is suspended in accordance with sub-section (1), all research activities must cease forthwith.
 - (3) Where the accreditation of a health research ethics committee is suspended in accordance with sub-section (1), the Board shall transfer all research protocols under review of that committee to another accredited ethics committee.

Revocation of certificate of accreditation

- 11. (1) The Authority may, by stating reason(s) in writing, revoke the accreditation of a research institution or health researcher.
 - (2) Where the accreditation of a research institution or health researcher is revoked in accordance with sub-section (1), all research activities must cease forthwith.
 - (3) Where the accreditation of a health research ethics committee is revoked in accordance with sub-section (1), the Board shall transfer all research protocols under review of that committee to another accredited ethics committee.

Restoration of certificate of accreditation

12. A suspended or revoked accreditation certificate may be restored where the Authority is satisfied with the corrective and preventive actions undertaken by the accreditation certificate holder upon payment of a prescribed fee.

Levels of accreditation

- 13. (1) The Authority shall, where the research institution or health establishment meets the requirements, issue an accreditation certificate according to the following levels:
 - (a) Level 1, for a Health Research Ethics Committee within one year of existence which shall review research protocols that are no more than minimum risk to research participants;
 - (b) Level 2, for a Health Research Ethics Committee which shall review all types of research protocols except clinical and vaccine trials; and
 - (c) Level 3, for a Health Research Ethics Committee which shall review all types of research protocols including clinical and vaccine trials.
 - (2) The Authority shall issue guidelines for each level of accreditation
 - (3) The Authority shall suspend or revoke, at any time, the accreditation of any Health Research Ethics Committee if they approve any research protocol outside the level of accreditation.

Variation of accreditation level

- 14. (1) A holder of an accreditation certificate may, at any time during the validity of the accreditation certificate, apply to the Authority for the variation of the level of accreditation.
 - (2) An application for a variation relating to an accreditation certificate shall be made in Form IX set out in the First Schedule and in accordance with the guidelines on variations as issued by the Authority from time to time upon payment of a prescribed fee.
 - (3) Where the Authority is satisfied with the application and accompanying information, the Authority may approve the variation and communicate to the holder of a certificate of accreditation within thirty days from date of receipt of the application.

(4) A holder of a certificate of accreditation shall not implement any variation relating to the record of the certificate of accreditation without notification and prior approval of the Authority.

Functions of Health Research 15. (1) A Health Research Ethics Committee shall:

(a) promote the rights, dignity and welfare of research participants

Ethics

Committee

(b) ensure that the terms and conditions of the Accreditation Certificates issued by the accredited Health Research Ethics

Committee on behalf of the Board are adhered to:

(c) review, approve or disapprove research protocols;

(d) maintain records of approved research protocols;

(e) monitor the conduct of research in the institution or field;

(f) submit annual reports to the Authority.

Certificate of appointment

16. The Authority shall provide an inspector with a certificate of appointment in Form X set out in the First Schedule.

Register of health research ethics

17. (1) The Authority shall keep and maintain a register of health research ethics committees and health researchers in the custody of the Director at the offices of the Authority.

committees and health researchers

- (2) The register referred to in sub-section (1) shall be open for inspection by the public during normal office hours of the Authority upon payment of such fee as the Authority may determine.
- (3) The Director may, upon application by any person, issue to the person a certified copy of the Register, or a copy of a certificate of registration, upon payment of such fee as the Authority may determine.

Fees

18. The fees set out in the Second Schedule are the prescribed fees for the matters specified in the schedule.



NATIONAL HEALTH RESEARCH AUTHORITY

Regulations on Registration and Accreditation of Health Research Ethics Committees, Research Institutions and Health Researchers

FIRST SCHEDULE

2016



Form I

(Act No. 2 of 2013)

Health Research (Registration and Accreditation of health research ethics committees, research institutions and health researchers) Regulations, 2016.

APPLICATION FOR REGISTRATION

1. APPLICANT DETAILS

PART A1. Health Research Ethics Committee

Name of Ethics Committee	
Institutional Affiliation	
Physical address	
Postal address	
Phone	
Fax	
Email	
Level applied for	
Chairperson	
	Title ($Tick[\ \ \]$ where applicable) Prof. Dr. Mr. Mrs. Ms.
	Surname
	Forename(s)
	Phone:
	Email:
	Address:
Administrator	Title ($Tick[\sqrt{]}$ where applicable)
	Prof. Dr. Mr. Mrs. Ms.
	Surname
	Forename(s)
	Phone:
	Email:
	Address:

A2. Supporting documents - REC

Document		Attached Yes/No	Comment
Registration Certificate			
List of the members of research ethics committee	tee		
Composition of research ethics committee as			
provided for in attachment 1			
Curriculum vitae of members of the research e	thics		
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 accord			
with the National Health Research Act No. 2 o	İ		
2013			
Declarations of conflict of interest			
Standard operating procedures Protocol and consent forms template			
Fee structure			
ree structure			
A3. Type of research to be reviewed Biomedical research			
Social research			
Other (Specify)			
B1. Health Research Institution			
Name of institution			
Type of institution I	Public	Private [
(Tick where applicable)			
Designation and the Co. DACDA LIDCZ			
Registration number (e.g. PACRA, HPCZ			
etc) Physical address			
Filysical address			
Postal address			
Phone			
Fax			
Email			
B2. Supporting documents for Research Insti	itution	1	
Document		Attached	Comment
		Yes/No/NA	
Registration Certificate			
Letter from accredited health research ethics			
committee			

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	

Title ($Tick[\[\]]$ where applicable)	Prof.	Dr. Mr.	Mrs. Ms.
Surname			
Forename(s)			
Nationality			
National identification number:			
Gender:	Male	Female	
Qualification(s)			
Institutional affiliation			
Physical address			
Postal address			
Phone			
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Email			
Document Professional registration certificate		Attached Yes/No/NA	Comment
Professional registration certificate			
Curriculum vitae	• .1		
Evidence of ethics training, undertaken with	nin the		
last three years			
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NHRA Researcher's Certificate (mandatory	7)		
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NHRA Researcher's Certificate (mandatory	Prof	Dr. Mr.	Mrs. Ms.
NHRA Researcher's Certificate (mandatory 1. Research Assistant Title (Tick[√] where applicable)		Dr. Mr.	Mrs. Ms.
NHRA Researcher's Certificate (mandatory 1. Research Assistant		Dr. Mr.	Mrs. Ms.
NHRA Researcher's Certificate (mandatory 1. Research Assistant Title (Tick[√] where applicable) Surname Forename(s)		Dr. Mr.	Mrs. Ms.
NHRA Researcher's Certificate (mandatory 1. Research Assistant Title (Tick[√] where applicable) Surname Forename(s) Nationality		Dr. Mr.	Mrs. Ms.
NHRA Researcher's Certificate (mandatory 1. Research Assistant Title (Tick[√] where applicable) Surname		Dr. Mr. Female	Mrs. Ms.
NHRA Researcher's Certificate (mandatory 1. Research Assistant Title (Tick[√] where applicable) Surname Forename(s) Nationality National identification number: Gender:	Prof.		Mrs. Ms.
NHRA Researcher's Certificate (mandatory 1. Research Assistant Title (Tick[√] where applicable) Surname Forename(s) Nationality National identification number:	Prof.		Mrs. Ms.
NHRA Researcher's Certificate (mandatory 1. Research Assistant Title (Tick[√] where applicable) Surname Forename(s) Nationality National identification number: Gender: Qualification(s)	Prof.		Mrs. Ms.
NHRA Researcher's Certificate (mandatory 1. Research Assistant Title (Tick[√] where applicable) Surname Forename(s) Nationality National identification number: Gender: Qualification(s) Institutional affiliation	Prof.		Mrs. Ms.
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NHRA Researcher's Certificate (mandatory 1. Research Assistant Title (Tick[√] where applicable) Surname Forename(s) Nationality National identification number: Gender: Qualification(s) Institutional affiliation Physical address	Prof.		Mrs. Ms.

D2. Supporting documents for Research Assistants

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		
NHRA Research Assistant's Certificate (mandatory)		
2. DECLARATION AND SIGNATURE		'

2. DECLARATION AND SIGNATURE
I declare that the information provided in this application and attachments containe therein, are true to the best of my knowledge. Further, I acknowledge that submission of false informatio 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 OFFICAL USE ONLY
Date of receipt of application: Registration number: Completeness of application: YES No
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		
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Profession	
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Qualification(s)	
Physical address	
Phone	
Email	



Form II

(Act No. 2 of 2013)

Health Research (Registration and Accreditation) Regulations, 2016.

NOTICE OF GRANT OF REGISTRATION

IN THE MA	TTER OF			
	ereby notified that your application for registration has been accepted on the conditions:			
(a)	This Registration is not transferrable in any way.			
(b)	There is adherence to the provisions in the Health Research Act No. 2 of 2013 National Health Research Authority Council Guidelines and other regulations.			
(c)	Failure to adhere to Guidelines and the Health Research Act No. 2 of 2013 and other regulations would lead to revocation of this certificate.			
(d)	In the event that the registration certificate is revoked, you are expected to surrende the certificate and this notice back to the National Health Research Authority.			
Dated th	nisday of			
Sign	ned:			
	ector Research			

Form III

(Act No. 2 of 2013)

Health Research (Registration and Accreditation) Regulations, 2016.

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:	
Lagath Besearch	
Director	

Form IV

(Act No. 2 of 2013)

CERTIFICATE OF REGISTRATION

This is to certify that	
 has been registered as a	
day of	
Signed:	
Director	



Form V

(Act No. 2 of 2013)

Health Research (Registration and Accreditation) Regulations, 2016.

APPLICATION FOR ACCREDITATION OR RENEWAL OF ACCREDITATION

[Pleas	se tick] Zambian Applicant L	JNon-Zambian ApplicantL
Гуре of	Application: 1. Initial 2. Ren	ewal
Level of	Accreditation applied for:	
Please w	vrite in BLOCK LETTERS	
3. AP	PLICANT DETAILS	
(a) ?	Head of Institution	
	Title ($Tick[\sqrt{]}$ where applicable)	Prof Dr. Mr. Mrs. Ms.
	Surname	
	Forename(s)	
	Qualification(s)	
	Physical address	
	Postal address	
	Phone	
	Fax	
	I = 11	

(b) Details of Research Institution

4.

to conduct research

Curriculum vitae of research staff

Name of institution							
Type of institution (Tick were applicable)	Public	Priv	rate	Other			
· · · · · · · · · · · · · · · · · · ·							
If other(please specify)			• • • • • • • • • • • • • • • • • • • •			• • • •	
Registration number of Institution							
Physical address							
Postal address							_
Phone							
Fax							
Email							
Name of Ethics Committee Physical address							
Postal address							
Phone							
Fax							
Email							
Biomedical research Social research							
Other (Specify)							
UPPORTING DOCUMENTATION Document	N	Attach	ad Va	s/No	Co	mment	
		Attach	leu 1 e	5/110	CO	mmem	
Covering letter Pagistration cartificate	-				\vdash		
Registration certificate	tho				-		
Signed statement of commitment by head of institution to conduct health							
research in accordance with the							
National Health Research Act No. 2	of						
2013	01						
Declarations of conflict of interest					+		
Adequate and appropriate infrastruc	ture				+		
Aucquaic and appropriate infrastruc	เนเบ				1		

5. In the preceding year

Number of Grants received	
Value of Grants received	
Number of publications	
Trainings	GCP Number conducted Ethics Number conducted Other Number conducted
	If other, please specify

6. DECLARATION AND SIGNATURE

applica	declare that the information provided in this ation and the attachments contained therein, are true to the best of my knowledge. Further, towledge that submission of false information shall render the application void, and may a fine or being banned from conducting research in Zambia.
Details	s of Person Signing the Application
Details	of Leison Signing the Application
d)	Name:
e)	Designation:
f)	Signature: d) Date:/
	(dd/mm/yyyy)

FOR OFFICAL 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	Researcy Parties	

(Act No. 2 of 2013)

Health Research (Registration and Accreditation) Regulations, 2016.

NOTICE OF GRANT OF ACCREDITATION TO ETHICS COMMITTEE

10
IN THE MATTER OF
You are notified that your application for accreditation has met requirements for accreditation.
Therefore, your institution has been granted LEVEL ACCREDITATION for the period From
(a) Renewal is done three months before the expiry date.
(b) This accreditation certificate is not transferrable.
(c) There is adherence to the provisions in the Health Research Act No. 2 of 2013, National Health Research Authority Council Guidelines and other regulations.
(d) Failure to adhere to Guidelines and the Health Research Act No. 2 of 2013 and other regulation would lead to revocation of this certificate.
(e) In the event that the certificate of accreditation is revoked, you are expected to surrender the certificate and this notice back to the National Health Research Authority.
Date thisday of
Signed:

Director



Form VII

(Act No. 2 of 2013)

NOTICE OF REFUSAL TO GRANT ACCREDITATION TO ETHICS COMMITTEE

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	



THE NATIONAL HEALTH RESEARCH AUTHORITY

Form VIII

The Health Research Act

(Act No. 2 of 2013)

$Health\ Research\ (Registration\ and\ Accreditation)\ Regulations,\ 2016.$

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
Signed:
Director
Director



Form IX

(Act No. 2 of 2013)

Health Research (Registration and Accreditation) Regulations, 2016.

APPLICATION FOR VARIATION OF ACCREDITATION

[Please tick] Zambian Applicant	Non-Zambian Applicant
1. Current level of Accreditation:	
N. I. and J. G. A. and J. L. L. and J. J. G. and	
2. Level of Accreditation applied for:	
Please write in BLOCK LETTERS	
3. APPLICANT DETAILS	
(a) Head of Institution	
Title ($Tick[N]$ where applicable)	Prof Dr. Mr. Mrs. Ms.
Surname	
Forename(s)	
Qualification(s)	
Physical address	
Postal address	
Phone	
Fax	
Email	
(b) Details of Research Institution	
Name of institution	
Type of institution (Tick were applicable)	Public Private Other
If other(please specify)	
Registration number of Institution	
Physical address	
Postal address	
Phone	

Fax		
Email		
etails of Research Ethics Committee		
Name of Ethics Committee		
Physical address		
Postal address		
Phone		
Fax		
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ype of research to be reviewed		
Biomedical research		
Social research		
Other (Specify)		
Other (Specify)	Attached Yes/No	Comment
Other (Specify) PPORTING DOCUMENTATION Document Covering letter	Attached Yes/No	Comment
Other (Specify) PPORTING DOCUMENTATION Document Covering letter Registration certificate	Attached Yes/No	Comment
Other (Specify) PPORTING DOCUMENTATION Document Covering letter Registration certificate Signed statement of commitment by the	Attached Yes/No	Comment
Other (Specify) PPORTING DOCUMENTATION Document Covering letter Registration certificate Signed statement of commitment by the head of institution to conduct health	Attached Yes/No	Comment
PPORTING DOCUMENTATION Document Covering letter Registration certificate Signed statement of commitment by the head of institution to conduct health research in accordance with the	Attached Yes/No	Comment
PPORTING DOCUMENTATION Document 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	Attached Yes/No	Comment
PPORTING DOCUMENTATION Document 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	Attached Yes/No	Comment
PPORTING DOCUMENTATION Document 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	Attached Yes/No	Comment
PPORTING DOCUMENTATION Document 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	Attached Yes/No	Comment
PPORTING DOCUMENTATION Document 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	Attached Yes/No	Comment
PPORTING DOCUMENTATION Document 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	Attached Yes/No	Comment
PPORTING DOCUMENTATION Document 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 the preceding year	Attached Yes/No	Comment
PPORTING DOCUMENTATION Document 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 the preceding year Number of Grants received	Attached Yes/No	Comment
Other (Specify) PPORTING DOCUMENTATION Document 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 the preceding year Number of Grants received Value of Grants received	Attached Yes/No	Comment
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PPORTING DOCUMENTATION Document 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 the preceding year Number of Grants received	GCP N Ethics N	Number conducted Number conducted
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Other (Specify) PPORTING DOCUMENTATION Document 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 the preceding year Number of Grants received Value of Grants received Number of publications	GCP N Ethics N Other N	Number conducted Number conducted

6. DECLARATION AND SIGNATURE

		declare that the information provided in this
	applica	tion and the attachments contained therein, are true to the best of my knowledge. Further,
	I ackno	owledge that submission of false information shall render the application void, and may
	result i	n a fine or being banned from conducting research in Zambia.
	Details	s of Person Signing the Application
	g)	Name:
	h)	Designation:
	i)	Signature: d) Date:/
		(dd/mm/yyyy)
		SE ONLY
For office u		
Date of reco		
Registration	n number:	Completeness of application: YES No No
General o	comments	3
•••••	••••••	
•••••	••••••	
Name of re	viewer	
Signature	••••••	
Date		



Form X

(Act No. 2 of 2013)

Health Research (Registration and Accreditation) Regulations, 2016.

INSPECTOR CERTIFICATE

This is to certify that
Has been APPOINTED by the
National Health Research Authority of Zambia as
for the period from January to December 20
Date thisday of
Signed:
Director



NATIONAL HEALTH RESEARCH AUTHORITY

 $\label{eq:condition} \mbox{ Health Research (Registration and Accreditation) Regulations} \\ \mbox{ SECOND SCHEDULE}$

FEES

2016

	REGI	STRATION AND ACC	CREDITATION FEES		
		ZAMBIAN		FOREIGN	
S/No.	Description	Application Fees (Fee Units)	Application Fees (Zambian Kwacha)	mbian Kwacha) (Fee Units)	
1.	Application for registration of a Researcher	3.400	1,020	6,800	2,040
2.	Application for registration of a Research Assistant	850	255	1,700	510
3.	Application for registration of a health research ethics committee	6,700	2,010	13,400	4,020
4.	Application for registration of a health research institution	6,700	2,010	13,400	4,020
5.	Inspection fee	23,400	7,020	46,800	14,040
6.	Re-inspection fee	23,400	7,020	46,800	14,040
7.	Application of accreditation of a Researcher	2,500	750	5,000	1,500
8.	Application for accreditation of a Research Assistant	625	188	1,250	376
9.	Application of accreditation of a health research ethics committee	8,350	2,520	16,700	5,040
10.	Application of accreditation of a research institution	8,350	2,520	16,700	5,040
11.	Application of renewal of accreditation of a researcher	1,000	300	2,000	600
12.	Application of renewal of accreditation of a health research ethics committee	5,000	1,500	10,000	3,000
13.	Application of renewal of accreditation of a research institution	5,000	1,500	10,000	3,000
14.	Restoration of suspended or revoked certificate	33,500	10,050	67,000	20,100
15.	Application for variation of accreditation certificate	23,400	7,020	46,800	14,040
16.	Inspection of register of health research ethics committees and health researchers	350	105	700	210
17.	Issue of certified copy of the register of health research ethics committees and health researchers	350	105	700	210

N.B: One Fee Unit = ZMW 0.30