



**Guidelines for Registration and Accreditation of Health Research  
Ethics Committees, Research Institutions and Health Researchers in  
Zambia**

## **Abbreviations**

MOH-Ministry of Health

NHRA-National Health Research Authority

REC-Research Ethics Committee

IRB-Institutional Review Board

NHREB-National Health Research Ethics Board

PI-Principal Investigator

MTA- Material Transfer Agreement

SOP- Standard Operating Procedures

NHRA

## **1.0 Background**

The National Health Research Authority (NHRA) is a regulatory body established in Zambia by the Health Research Act of 2013. The Act provides for the functions and powers of the Authority including the registration and accreditation of health researchers, research institutions and Research Ethics Committees (RECs). The ACT further provides for the establishment of the National Health Research Ethics Board (NHREB) to ensure the development of consistent health research standards and guidelines for ethically sound health research; provide for the establishment of health research ethics committees and the regulation and management of research institutions, health researchers and health establishments involved in or undertaking research. These provisions of the Health Research Act have now been operationalized by Statutory Instrument No. 25 of 2020. These Guidelines provide further information on the processes and procedures required to put into effect the provisions of the Statutory Instrument.

## **2.0 Scope of the Guidelines**

This document sets out guidelines for the Registration and Accreditation of Research Ethics Committees, Research Institutions, and Health Researchers. The guidelines further provide procedures for suspension, revocation, renewal and restoration of registration and accreditation certificates.

The guidelines are intended to be used by NHRA, appropriate key stakeholders as defined by the Health Research Act of 2013 and the general public. They shall apply to all registration and accreditation certificates awarded by the Authority. These guidelines should be read in conjunction with the Health Research Act, the Statutory Instrument on Registration and Accreditation of Health Research Institutions, Researchers and Research Ethics Committees, NHREB Standard Operating Procedures, other guidelines and documents that govern health research in Zambia as provided by NHRA from time to time.

### 3.0 Objectives of the Guidelines

The objectives of these guidelines are to:

- 1) Describe application procedures for registration and accreditation of researchers, research institutions and Research Ethics Committees/Institutional Review Boards (IRBs);
- 2) Describe eligibility and evaluation criteria for the registration and accreditation of researchers, research institutions and Research Ethics Committees/Institutional Review Boards;
- 3) Prescribe procedures for suspension, cancellation and restoration of certificate of registration or accreditation;
- 4) Outline feedback procedures on applications for registration and accreditation of Research Ethics Committees, Research Institutions and Health Researchers.

### 4.0 Application Processes

#### 4.1 Application for registration: Research Ethics Committees, Research Institutions, and Health Researchers.

An application for registration of health research ethics committees, research institutions and health researchers shall be made to the authority through application forms provided by the Authority through its website. Applicants are required to satisfy the application requirements as stipulated by these guidelines. The Authority shall, where it **accepts** or **rejects** an application, inform the applicant in writing within thirty days of receipt of the application. The authority shall issue the successful applicant with a certificate of registration. All applications for registration and accreditation shall be processed upon the payment of a **non-refundable fee** as stipulated in these guidelines and related statutory instrument. See Annex 1 for a summary of the Application Process.

## **4.2 Eligibility Criteria For Registration**

### **a. Health Researcher**

The Health Research Act defines a Health Researcher as someone who conducts health research as defined by the same Act. Registration shall apply to all Health Researchers conducting any type of health research in Zambia. This registration shall also apply to PhD students and Masters students undertaking academic research in Zambia. However, Undergraduate students will conduct academic research under the guidance of a registered supervisor and are not required to be registered. Undergraduate students conducting non-academic research shall be required to be registered before engaging in such research. Academic research in this case refers to research undertaken as a requirement for the award of a particular qualification by an academic institution. Research Assistants, employed by a research establishment for purposes of undertaking research shall be deemed to be researchers and will need to be registered by NHRA. Research Assistants hired on part-time (up to six months) to collect research data will not need to be formally registered but the research establishment engaging such personnel should show evidence that the Research Assistant being engaged has undergone ethics training and training in the NHRA Research Assistants' basic training course.

### **b. Research Institution**

Registration shall apply to any organization whether public or private that undertakes health research in Zambia. This registration also includes both public and private universities that undertake health research.

### **c. Research Ethics Committee/Institutional Review Board**

Registration as REC/IRB shall apply to any organization or committee that intends to conduct ethical review of health research and meets the criteria in composition as described in the Health Research Act of 2013.

### **4.3 Eligibility For Accreditation**

Only registered Researchers, Research Institutions, or Research Ethics Committees are eligible to apply for Accreditation. A Researcher, Research Institution, or Research Ethics Committee may apply at any time after it has been duly registered subject to satisfying Accreditation Requirements.

Researchers, Research Institutions, or Research Ethics Committees or Institutional Review Boards shall be accredited based on assessment of the capacities of the institution by the Authority using a Checklist that will be developed by the Authority and will accompany the Application Form.

### **4.4 Levels of Accreditation: Research Ethics Committees**

Where the Research Ethics Committee meets the requirements, the Authority shall 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;
- c) Level 3: For a Health Research Ethics Committee which shall review all types of research protocols including clinical and vaccine trials.

The Authority reserves the right to suspend or revoke, at any time, the accreditation of any Health Research Ethics Committee if they approve any research protocol outside their level of accreditation.

### **5.0 Functions and Responsibilities of Accredited Health Research Ethics Committees**

Registered and accredited Research Ethics Committees/Institutional Review Boards shall promote the rights, dignity and welfare of research participants. Further, RECs/IRBs will ensure that the **terms and conditions** of the Accreditation Certificates issued by the NHRA are adhered to. Other functions of the RECs/IRBs will include:

- a. Review, approve or disapprove research protocols;
- b. Maintain records of approved research protocols;
- c. Monitor the conduct of all approved research in the institutions or the field;
- d. Submit Quarterly and Annual reports to the Authority.

#### **6.0 Register for health researchers, research institutions, and research ethics committees**

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. The register 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. 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.

#### **7.0 Suspension of Certificate of Registration: Research Ethics Committee, Research Institution or Health Researcher**

The Authority may, by stating reason(s) in writing, suspend the registration of a health research ethics committee, research institution or health researcher. Where the registration of a research institution or health researcher is suspended in accordance with the provisions of Statutory Instrument No. 25 of 2020, all research activities must cease forthwith. Where the registration of a health research ethics committee is suspended, the Board shall transfer all research protocols under review of that committee to another accredited ethics committee.

## **8.0 Revocation of Registration: Research Ethics Committee, Research Institution or Health Researcher**

The Authority may, by stating reason(s) in writing, revoke the registration of a health research ethics committee, research institution or health researcher. Where the registration of a research institution or health researcher is revoked, all research activities must cease forthwith. Where the registration of a health research ethics committee is revoked, the Board shall transfer all research protocols under review of that committee to another accredited ethics committee.

## **9.0 Renewal of Accreditation**

Accredited Researchers, Research Institutions and Research Ethics Committee shall be required to renew their accredited every after **two(2) years**. Application for renewal of accreditation shall be done to the Authority upon payment of fees as stipulated in the fees schedule below.

## **10.0 Restoration**

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 prescribed **non-refundable fees**.

## **11.0 FEES**

An application for the approval of research registration and accreditation shall attract fees as stipulated in the National Health Research (Registration and Accreditation of Research Ethics Committees, Research Institutions and Health Researchers) Statutory Instrument No. 25 of 2020. The fees are categorised by the type of application which an applicant is seeking approval for. The table below stipulates applicable fees for each category.



REGISTRATION AND ACCREDITATION FEES-APPROVED BY BRRA AND MINISTRY OF JUSTICE, MARCH 2020					
S/No.	Description	ZAMBIAN		FOREIGN	
		Application Fees (Fee Units)	Application Fees (Zambian Kwacha)	Application Fees (Fee Units)	Application Fees (Zambian Kwacha)
1.	Application for registration of a Researcher	3,400	1,020	6,800	2,040
1.	Application for registration of research institution or health research ethics committee	6,700	2,010	13,400	4,020
1.	Application of accreditation of Researcher	2,500	750	5,000	1,500
1.	Application of accreditation of research institution or health research ethics committee	8,350	2,520	16,700	5,040
1.	Application of renewal of accreditation of researcher	1,000	300	2,000	600
1.	Application for renewal of accreditation of research institution or health research ethics committee	5,000	1,500	10,000	3,000
1.	Restoration of suspended or revoked certificate	33,500	10,050	67,000	20,100
1.	Application for variation of accreditation certificate	23,400	7,020	46,800	14,040

## 10.1 Payment Procedures

All payments for an application for research registration and accreditation shall be made by making deposits into the National Health Research Authority bank account held with **Zambia National Commercial Bank**. An applicant shall attach the proof of payment to their application and await confirmation of receipt from NHRA. Upon confirmation, NHRA shall issue a Receipt to the applicant and further begin the process of reviewing the application.

### National Health Research Authority Basket Account

**ZANACO BANK**

**A/C NO.5586154300691**

**Woodlands Branch**

**National Health Research Authority**

## Annex 1: Summary of application process

