

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:

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| 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<br>“certificate of accreditation” means a certificate of accreditation issued under regulation 8; and<br>“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.<br><br>(2) The Board may, within thirty days of receipt of an application under subregulation (1), grant or reject the application.<br><br>(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.<br><br>(2) A certificate of registration shall remain valid unless suspended or cancelled under these Regulations.  | Certificate of registration                                      |

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Suspension,  
cancellation  
of  
registration

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

- (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.

(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.

(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.

(4) Where the certificate of registration of a health research ethics committee is suspended or cancelled

- (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

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.

Application  
for  
accreditation  
or renewal of  
accreditation

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.

(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

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.

(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.

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

14. (1) A certificate of accreditation for a health research ethics committee shall be issued according to the following levels:

- (a) level one, for a health research ethics committee which reviews research protocols that have minimum risks to research participants;
- (b) level two, for a health research ethics committee which reviews all types of research protocols except clinical and vaccine trials; and
- (c) level three, for a health research ethics committee which reviews all types of research protocols, including clinical and vaccine trials.

(2) A health research ethics committee shall comply with the guidelines issued by the Authority for each level of accreditation.

(3) The certificate of accreditation shall state the level of accreditation granted to a health research ethics committee.

(4) A health research ethics committee shall not approve a research protocol that is beyond the level of accreditation permitted by the Board.

(5) The Board shall revoke the certificate of accreditation of a health research ethics committee that does not comply with subregulation (4).

15. The functions of a health research ethics committee are to
- Functions of health research ethics committee
- (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.
16. (1) The Director shall keep and maintain a Register of persons registered and accredited under these Regulations.
- Registers
- (2) The Director shall enter the details and particulars relating to—
- (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.
- (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.
- (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.
17. The fees set out in the Second Schedule are payable for the matters specified therein.
- Fees