

Animal Health (National Animal Research Ethics Committee)
Regulations, 2021

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IT is hereby notified that the Minister of Lands, Agriculture, Fisheries, Water and Rural Development has, in terms of section 5 of the Animal Health Act [Chapter 19:01], as read with section 7 of the Scientific Experiments on Animals Act [Chapter 19:12], and as read with section 16 of the Prevention of Cruelty to Animals Act [Chapter 19:09], made the following regulations:—

PART I

PRELIMINARY

Title

1. These regulations may be cited as the Animal Health (National Animal Research Ethics Committee) Regulations, 2021.

Interpretation

2. In these regulations—

“certificate” means a certificate issued in terms of section 14;

“committee” or “NAREC” means the national research ethics committee;

“Director” means Director of Veterinary Services referred to in section 4 of the Animal Health Act [Chapter 19:01];

“foreign researcher” means a person who is—

(a) not a citizen of Zimbabwe wishing to conduct research in Zimbabwe; or

(b) any person being a citizen, wishing to conduct research in Zimbabwe on behalf of a foreign institution, foreign organisation or foreign person;

“registered veterinarian” means a veterinary doctor registered in terms of the Veterinary Surgeons Act [Chapter 27:15];

“research” means any systematic, critical or scientific study of, or inquiry into, any subject or matter for the extension of knowledge;

“researcher” means a person who carries out academic or scientific research.

PART II

NATIONAL ANIMAL RESEARCH ETHICS COMMITTEE

Establishment of national animal research ethics committee

3. (1) There is hereby established a committee to be known as the National Animal Research Ethics Committee.

(2) The committee shall consist of members appointed by the Minister as follows—

(a) the head of research in the Department of Veterinary Services as a designated by the Director of Veterinary Services (who shall be the chairperson);

(b) an animal scientist from the department responsible for livestock research;

(c) chairperson of the Agriculture Research Council livestock committee;

(d) one representative from the Zimbabwe Parks and Wildlife Authority;

(e) one representative from the Research Council of Zimbabwe;

(f) the secretary of the committee who shall be drawn from the Agricultural Research Council;

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- (g) one representative from livestock farmers;
- (h) an academic from an animal science department or faculty of a recognised University;
- (i) a representative from an Agriculture, Environment and Food systems faculty of a recognised University;
- (j) a laboratory scientist registered in terms of Veterinary Surgeons Act [*Chapter 27:15*];
- (k) a veterinary surgeon registered in terms of Veterinary Surgeons Act [*Chapter 27:15*];
- (l) the legal advisor of the Ministry or his or her representative.

(3) A member appointed in terms of subsections (2)(d) to (k) shall hold office for a period not exceeding three years and shall be eligible for reappointment for only one other term.

Functions of committee

4. The functions of the National Animal Research Ethics Committee shall be to—

- (a) receive and consider applications for research proposals and issue a research ethics certificate where appropriate;
- (b) carry out inspections as a regulatory mechanism of monitoring compliance of research with required ethics;
- (c) ensure that Consent/Agreement forms are signed by animal owners or government Competent Authorities (CA) before their animals are used as subjects for research activities;
- (d) ensure shipment of biological samples outside Zimbabwe shall be on the approval of the committee on case by case basis depending on the authenticity of reasons for shipment stated in the application form:

Provided that the committee shall prevent bio-piracy and unnecessary shipment of samples by reducing sample size and numbers as well as encouraging local sample testing;

- (e) ensure that research outputs of national interest are reported to the relevant Departments in the Ministry;
- (f) identify a secretariat for effective discharge of its duties, including determining certificate and inspection fees, collection of certificate and inspection fees, and accounting for expenditures according to treasury instructions;
- (g) formulate and review research ethics guidelines;
- (h) carry out awareness programmes;
- (i) develop a monitoring system for research protocols where animal models are used, which allows for routine and *ad hoc* inspections of animals at any stage of the protocols and make appropriate recommendations to safeguard animal welfare and safety of personnel and researchers;
- (j) maintain inventory of all research animal facilities in Zimbabwe for the purpose of registration and licensing to ensure ethically acceptable research and safety of animals, personnel and researchers;
- (k) promote local capacity building by encouraging development and adoption of modern advanced tests, research, methods and technologies.

Disqualification for appointment as member

5. Subject to these regulations, a person shall not be qualified for appointment as a member of the committee —

- (a) if he or she is not a citizen of Zimbabwe or ordinarily resident in Zimbabwe; or
- (b) if he or she has, in terms of a law in force in any country —
 - (i) been adjudged or otherwise declared insolvent or bankrupt and has not been rehabilitated or discharged; or
 - (ii) made an assignment or composition with his or her creditors which has not been rescinded or set aside;or

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- (c) within the period of five years immediately preceding his or her proposed appointment, he or she has been sentenced in any country by a competent court to a term of imprisonment imposed without the option of a fine, whether or not any portion thereof has been suspended, and has not received a free pardon; or
- (d) if he or she is a member of Parliament.

Expiry of appointment as member

6. On the expiry of the period for which a member has been appointed, he or she shall continue to hold office until he or she has been re-appointed or his or her successor has been appointed:

Provided that a member shall not continue to hold office in terms of this subsection for a period exceeding three months.

Vacation of office by members

7. (1) A member shall vacate his or her office and his or her office shall become vacant—

- (a) one month after the date he or she gives notice in writing to the Minister of his or her intention to resign his or her office or after the expiry of such other period of notice as he or she and the Minister may agree; or
 - (b) on the date he or she begins to serve a sentence of imprisonment, whether or not any portion has been suspended, imposed without the option of a fine—
 - (i) in Zimbabwe, in respect of any offence; or
 - (ii) outside Zimbabwe, in respect of conduct which, if committed in Zimbabwe, would have constituted an offence;
- or
- (c) if he or she becomes disqualified in terms of subsection 2 to hold office as a member.

(2) The Minister may require an appointed member of the committee to vacate his or her office if the member—

- (a) has been guilty of conduct which renders him or her unsuitable to continue to hold office as a member; or
- (b) has failed to comply with any condition of his or her office; or
- (c) is mentally or physically incapable of efficiently performing his or her duties as a member.

(3) The Minister, on the recommendation of the committee, may require a member to vacate his or her office if the Minister is satisfied that the member has been absent without the consent of the chairperson from three consecutive meetings of the committee, of which he or she has been given due notice in terms of section 10, and that there was no just cause for the member's absence.

Suspension of members

8. The Minister may suspend from office a member against whom criminal proceedings are instituted for an offence involving dishonesty and, whilst that member is so suspended, he or she shall not carry out any duties or be entitled to any remuneration or allowances as a member.

Filling of vacancies on committee

9. On the death of, or the vacation of office by a member his or her office shall be filled within three months.

Meetings and procedure of committee

10. (1) The committee shall hold its first meeting on a date and place fixed by the Minister, and thereafter shall meet for the dispatch of business and adjourn, close and otherwise regulate its meetings and procedure as it thinks fit:

Provided that the committee shall meet at least once every three months.

(2) Written notice of an ordinary meeting convened in terms of the proviso to subsection (1) shall be sent to each member not later than seven working days before the meeting, together with an agenda for the meeting.

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(3) The chairperson—

- (a) may convene a special meeting of the committee at any time; and**
- (b) shall convene a special meeting of the committee on the written request of the Minister or not fewer than two members, which meeting shall be convened for a date not sooner than seven days and not later than thirty days after the chairperson's receipt of the request.**

(4) Written notice of a special meeting convened in terms of subsection (3) shall be sent to each member no later than forty-eight hours before the meeting and shall specify the business for which the meeting has been convened.

(5) No business shall be discussed at a special meeting convened in terms of subsection (3) other than—

- (a) such business as may be determined by the chairperson, where he or she convened the meeting in terms of paragraph 3(a); or**
- (b) the business specified in the request for the meeting, where the chairperson convened the meeting in terms of paragraph 3(b).**

(6) The chairperson or, in his or her absence, the vice-chairperson shall preside at all meetings of the committee.

(7) A majority of members shall form a quorum at any meeting of the committee.

(8) All acts, matters or things, authorised or required to be done by the committee may be decided by a majority vote at any meeting of the committee at which a quorum is present:

Provided that in the event of an equality of votes the chairperson or person presiding at the meeting shall have a casting vote in addition to his or her deliberative vote.

(9) With the committee's approval, the chairperson of the committee may invite any person to attend a meeting of the committee, where the chairperson considers that the person has special knowledge or experience in any matter to be considered by the committee, as the case may be, at that meeting.

(10) A person invited to attend a meeting of the committee in terms of subsection (9) may take part in the proceedings of the committee as if he or she were a member thereof, but he or she shall not have a vote on any question before the committee, as the case may be.

(11) Any proposal circulated among all members and agreed to in writing by a majority of them shall have the same effect as a resolution passed at a duly constituted meeting of the members and shall be incorporated into the minutes of the next succeeding meeting of the committee:

Provided that if a member requires that such a proposal be placed before a meeting of the committee, this subsection shall not apply to the proposal.

Minutes of proceedings of committee

11. (1) The committee shall cause minutes of all proceedings of and decisions taken at every meeting of the committee to be entered in books kept for the purpose.

(2) Any minutes referred to in subsection (1) which purport to be signed by the person presiding at the meeting to which the minutes relate or by the person presiding at the next following meeting of the committee shall be accepted for all purposes as *prima facie* evidence of the proceedings and decisions taken at the meeting concerned.

(3) The committee shall cause copies of all minutes that have been signed as provided in subsection (2) to be sent to the Minister for his or her information.

Validity of decisions and acts of committee

12. No decision or act of the committee or act that is authorised by the committee shall be invalid solely because there was a vacancy in the membership of the committee or because a disqualified person purported to act as a member of the committee, as the case may be, at the time the decision was taken or the act was done or authorised.

PART III

RESEARCH ETHICS CERTIFICATE

Application for a research ethics certificate

13. (1) Subject to subsection (2) no person shall conduct animal research (whether it is collaborative or individual research) without the approval of the committee.

(2) Persons exempted from applying for approval shall be determined and listed by the committee from time to time as approved by the Minister in relation to research carried out by government:

Provided that where there is need for publication of any finding of the research such government official may make application to the committee for endorsement for publication certificate.

(3) Any person or institution wishing to conduct research on or involving an animal in Zimbabwe shall apply for a Research Ethics Certificate by submitting Form NR1 in the case of a primary application or in the case of an application for an extension of the duration of an existing certificate or a substantially similar form together with a prescribed fee to the secretary of the committee as specified in the Second Schedule.

(4) An application submitted in terms of subsection (2) must be accompanied by—

- (a) research proposal;
- (b) institutional approval where relevant;
- (c) relevant consent from persons or organisations in whose care the animals to be used for a research belong; and
- (d) any other information relevant to the application that the committee may require.

(5) In the case of collaborative research application must be submitted including an application for all parties in the research.

(6) After receiving an application for a certificate the secretary to the committee shall satisfy himself or herself that Form NR1 has been properly completed and if so satisfied shall transmit the application to the committee to consider the application within 14 days from the date of application, and make a decision on the application.

(7) If within the prescribed period the secretary to the committee finds that the Form NR1 has not been properly completed or he or she requires further information in connection with an application, he or she must notify the applicant to enable the applicant to furnish the additional information requested (in which event the 14 day period shall run from the date when the applicant retransmits the application back to the secretary of the committee.

(8) The committee shall, before granting a research ethics certificate, take into account the following—

- (a) the scientific competence and relevance of the research;
- (b) the national priorities and development agenda are observed in research protocols in the case of government institutions;
- (c) research protocols and amendments as required as aligned to animal welfare principles as provided for in the Prevention of Cruelty to Animals Act [*Chapter 19:09*] and international standards;
- (d) technical and financial capacity.

(9) Before granting a certificate the committee (through inspectors designated for the purpose) must satisfy itself that the facilities or sites intended to be used for the research are suitable for the purpose:

Provided that where the applicant is an institution, the relevant institutional review boards will ensure that animal ethics and welfare are observed at institutional level where they are used for research and teaching.

(10) As soon as possible after a decision on an application is made, the secretary of the committee shall notify the applicant of the granting or rejection of the application for a certificate by giving the applicant a copy of the application whereon it is indicated whether the application is granted or rejected and, if rejected the reasons for the rejection:

Provided that where an application is rejected or granted with conditions the secretary to the committee shall inform the applicant of his or her right of appeal under section 20.

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Issuance, surrender, duration and extension of certificates

14. (1) Every research ethics certificate shall be valid for the duration of the study, as stated in the certificate unless such approval is earlier terminated by the committee or the researcher.

(2) If an application for a research ethics certificate is successful (whether approved with or without conditions by the committee), the committee shall—

- (a) inform the applicant accordingly; and
- (b) issue to the applicant in Form NR2 (a research ethics certificate), upon payment by the applicant of the prescribed issuance fee;
- (c) endorse on the existing certificate in the case of an application for an extension of the duration of a certificate;
- (d) make an appropriate entry in the approved research data base.

(3) Upon receipt of an application for an extension of the duration of a certificate the committee shall satisfy itself—

- (a) the reason for the extension;
- (b) the progress report;
- (c) an indication of the extension period of the study.

(4) Where an applicant has made an application for an extension for the period of a research ethics certificate of such extension shall simply be an endorsement on the existing certificate.

(5) If a holder of a research ethics certificate terminates a research for which he or she has been granted he or she shall within 7 days of terminating such research surrender his or her research ethics certificate to the secretary of the committee.

(6) Any person who contravenes subsection (5) shall be guilty of an offence and liable to a fine not exceeding level 3 or to imprisonment for a period not exceeding 1 month or both such fine and such imprisonment.

Suspension or cancellation of research ethics certificate

15. (1) Subject to subsections (2) and (4), the committee may at any time suspend (for a period not exceeding sixty (60) days) or cancel any research ethics certificate if the committee has reasonable grounds for believing that—

- (a) the research ethics certificate was issued in error or through fraud or misrepresentation or non-disclosure of a material fact by the holder of certificate; or
- (b) the holder of a certificate has contravened any provision these regulations or any condition of his or her research ethics certificate; or
- (c) the holder of a certificate has terminated the research.

(2) The committee shall notify the holder of a certificate in writing of its intention to suspend or cancel his or her research ethics certificate and the reasons for doing so, and shall call upon the holder of a certificate to show cause, within 14 days from the date of the notice, why the research ethics certificate should not be suspended or cancelled, as the case may be:

Provided that if in the opinion of the committee the research ethics certificate needs to be immediately suspended or cancelled in the public interest or to avert an environmental emergency it can issue the notice requiring the holder of a certificate to show cause after suspending or cancelling the certificate.

(3) If, at the expiry of the period specified in the notice given in terms of subsection (2), and after considering any representations made by the holder of a certificate, the committee is satisfied for any reason specified in subsection (1) that the certificate concerned should be suspended or cancelled, the committee shall, by notice in writing to the holder of a certificate, suspend or cancel the certificate or take such other action as it considers appropriate.

(4) The penalty of suspension is only available where there has been a contravention of any provision these regulations or any condition of a research ethics certificate which, in the opinion of the committee, is a contravention that can be easily or speedily remediated by the holder of a certificate:

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Provided that—

- (a) if after the expiry of the period of suspension the holder of a certificate has not taken the remedial action, the committee shall forthwith cancel the certificate; or
- (b) on good cause shown by the holder of a certificate, the committee may extend the suspension for a period not exceeding fourteen (14) days to allow the holder of a certificate to take the required remedial action.

(5) The committee shall immediately make an appropriate entry in the data base of approved research established in terms of section 19 where it suspends or lifts a suspension of any certificate or cancels it in accordance with this section.

Amendment and replacement of licences

16. (1) A committee may at any time amend a certificate or any terms or conditions of a certificate—

- (a) to correct any error in the certificate; or
- (b) if the holder of a certificate requests the amendment; or
- (c) if the committee considers the amendment necessary to reflect the true nature of the approved activities; or
- (d) if for any other reason the committee considers the amendment necessary or desirable in the interests of the environment or in the public interest.

(2) The committee shall notify the holder of a certificate in writing of its intention to amend the certificate on a ground referred to in subsection (1)(a), (c) or (d) and shall call upon the holder of a certificate to show cause, within 14 days from the date of the notice, why the licence should not be amended.

(3) Where a holder of a certificate requests an amendment to his or her certificate, he or she shall make an application to the committee therefor, together with the prescribed fee.

(4) If in the opinion of the committee the amendment sought by the holder of a certificate is a material amendment section 6(2), (3), (4), (5) and (6) shall apply as if the application for the amendment is an application for a certificate.

(5) Where a certificate is lost or destroyed, the holder of a certificate may apply to the committee in writing, together with the prescribed fee, for a replacement certificate:

Provided that if the holder of a certificate finds the lost certificate he or she shall forthwith surrender it to the committee.

(6) Any person who contravenes the proviso to subsection (5) shall be guilty of an offence and liable to a fine not exceeding level 3 or imprisonment for a period not exceeding one month or both such fine and such imprisonment.

Conditions attaching to certificate

17. It shall be a condition that—

- (a) no holder of a research ethics certificate can transfer such certificate to another individual;
- (b) on completion of research every holder of a certificate must submit a finalisation of research report;
- (c) every holder of a certificate must strictly adhere to his or her research protocol as approved by the committee;
- (d) any holder of a certificate wishes to terminate his or her research must only do so after notifying the committee;
- (e) every holder of a certificate must ensure access of inspectors to all its research sites.

Database of approved research proposals

18. (1) There is hereby established a data base of approved research proposals to be known as the Data base of approved research proposals, in which the following shall be recorded—

- (a) the research proposal title;
- (b) the name and address of the principal investigator (PI);
- (c) date of approval;
- (d) duration of the study;
- (e) proposal approval number; and
- (f) such other particulars as the committee considers necessary.

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- (2) Any person may—
- (a) inspect the data base of approved research proposals at all reasonable times at the premises of the secretary to the committee or at such other place that the secretary to the committee may direct upon payment of the prescribed fee; or
 - (b) obtain copies of or extracts from the data base upon payment of the prescribed fee.
- (3) The committee shall keep and maintain the data base in both material and electronic form.

Funds of committee

19. For the avoidance of doubt monies accrued by the committee in the exercise of its functions shall form part of the funds of the committee in order to allow it to perform its functions in terms of these regulations and in terms of relevant treasury instructions.

PART IV

GENERAL

Appeals

20. (1) Any person who is aggrieved by a decision of the committee in respect of any application for a certificate under these regulations may, within thirty (30) days after receipt of the committee's decision, apply to the Minister for a review of the decision.

(2) Any person who is aggrieved by a decision of the Minister or the committee under these regulations, may seek a review of such decision by the Administrative Court.

(3) Upon a review of the Minister or committee's decision the Administrative Court may—

- (a) uphold the decision of the Minister or committee;
- (b) refer the decision back to the Minister or committee for reconsideration (whether with or without directions on how the decision is to be reconsidered) on any one or more of the following grounds—

- (i) allowing extraneous or irrelevant considerations to affect the decision;
- (ii) failure to take into account relevant considerations in arriving at the decision;
- (iii) any material mistake of fact or law that tainted the decision;
- (iv) interest in the cause, bias, malice or corruption on the part of any person involved in making or contributing to the decision;
- (v) gross irregularity in the proceedings or the decision of any person involved in making or contributing to the decision.

Offences

21. (1) It shall be an offence for a holder of a research ethics certificate or any person (as the case may be) to—

- (a) conduct research without a valid certificate;
- (b) conduct research without complying with the principles of animal welfare;
- (c) falsify information when carrying out the research when submitting any application or on the submission of the final report on completion of the research;
- (d) make changes to the research protocol without the approval of the committee;
- (e) obstruct inspectors from performing their duties;
- (f) conduct research outside the scope of the approved research proposal;
- (g) ship or transport biological samples outside Zimbabwe without approval of the committee;
- (h) failure to report termination of research;

(2) Any person who forges or tampers with a research ethics certificate receipt shall be guilty of an offence.

(3) Any holder of a certificate who contravenes subsection (1) shall be guilty of an offence and liable to a fine not exceeding level 10.

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FIRST SCHEDULE

FORMS



**Registration of Scientific Animal Research Facility complying with
the National Animal Research Ethics Committee (Animal Health)
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NR1

Application form for Research Ethics Certificate

APPLICATION FOR A CERTIFICATE

**The Minister of Lands, Agriculture, Fisheries, Water and Rural
Development**

PART I

1. Full name of applicant:
2. Address:
3. Profession and qualification of applicant:
4. Number and nature of experiments to be performed:
5. Number and classes of animals to be used:
6. Premises at which experiment are to be performed:
7. Period during which experiments are to be performed:
- 8.—
 - (a) purpose for which experiments are to be performed (e.g. medical research, higher education e.t.c)
 - (b) full reasons why the performance of experiments is necessary for this purpose.....
- 9.—
 - (a) will the object of the experiments, or any of them, necessarily be frustrated if the provisions of subsection (2) of section 6 of the Scientific Animal

Experiments Act (1963) are complied with?
..... ;

(b) if so give full reasons.....
.....

I, the undersigned hereby apply for the issue of a Certificate under subsection (1) of section 5 of the Scientific Animal Experiments Act, 1963, authorising the performance, subject to the provisions of the Act of scientific animal experiments as:

.....
.....
.....
.....

.....
Signature of applicant

Date.....

PART II

This part of the application must be completed by two independent sponsors of the applicant. A sponsor should be a person of some standing who is qualified for, and has personal experience of, the performance of experiments on animals.

1. Full name:
2. Address:
3. Profession qualifications and experience:.....
4. Do you consider that the experiment to which the application relates are necessary for the purpose for which they are to performed?
.....
.....
5. Do you consider that the applicant is a fit and proper person and is qualified to perform the experiments to which this application relates?
.....
.....

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6. Do you consider that the object of the experiments or any of them, to which this application relates would necessarily be frustrated if the provisions of subsection (2) of section 6 of the Act were complied with?.....
.....
.....

7. Remarks (Include here any reservations you wish to make concerning the application, and any special conditions which you consider should be imposed if a Certificate is issued to the applicant).
.....
.....
.....
.....
.....
.....
.....
.....
.....

.....
Signature of applicant

Date.....

RESEARCH ETHICS CERTIFICATE

NR2

 <p>ARC AGRICULTURAL RESEARCH COUNCIL</p>		
<h2>National Animal Research Ethics Certificate</h2>		
<p>This is to certify that research project registration certificate number NRREC/2021/Year submitted by Principal Investigator (PI) (Name) has been reviewed and approved for implementation by the National Animal Research Ethics Committee</p>		
<p>Chief Director of Veterinary Services 01 8394</p>	<p>Director Veterinary Professional Services 01 8394</p>	<p>Animal Research Council CEO 01 8394</p>

2021	2021	Electronic copy of the register of research certificates
2021	2021	Hard copy of the register of research certificates
2021	2021	Research facility or site inspection

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SECOND SCHEDULE

FEES (Section 2)

<i>Section</i>	<i>Description</i>	<i>Form number</i>	<i>Fees (\$ZWL)</i>
13	Application for research ethics certificate Student Postgraduate PhD Local researcher Foreign researcher	NR1	1 000,00 2 000,00 4 000,00 4 000,00 10 000,00
	Issuance of research ethics certificate Student Postgraduate PhD Local researcher Foreign researcher		2 000,00 10 000,00 20 000,00 20 000,00 100 000,00
13	Application for duplicate of research ethics certificate	NR 2	2 000,00
	Application for amendment of certificate of approval to research	NR 3	2 000,00
	Inspection of data base of approved research		200,00
	Electronic copy of the register of researches		200,00
	Hard copy of the register of certificate s		200,00
20	Appeals		2 000,00
	Research facility or site inspection fee		4 000,00

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