




ANIMAL ETHICS COMMITTEE

TERMS OF REFERENCE

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1. Preamble

- 1.1. The South African Institute for Aquatic Biodiversity (SAIAB) is a National Facility of the National Research Foundation (NRF).
- 1.2. The NRF-SAIAB Institutional Animal Ethics Committee (AEC) is a standing committee established in accordance with the requirements of the **NRF-SAIAB Animal Ethics Policy**.
- 1.3. The committee shall be known as the NRF-SAIAB Animal Ethics Committee (AEC).
- 1.4. The NRF-SAIAB Institutional Official (i.e., the person who is defined as such in the NRF-SAIAB Animal Ethics Policy) is the **NRF-SAIAB appointing authority** for NRF-SAIAB AEC membership.
- 1.5. The NRF-SAIAB AEC's Terms of Reference shall be publicly available.

2. Purpose

The purpose of the NRF-SAIAB AEC is to ensure that:

- 2.1. The care and use of animals for scientific purposes in NRF-SAIAB complies with the following minimum standards:
 - 2.1.1. The NRF-SAIAB Animal Ethics Policy
 - 2.1.2. The South African National Standard for the Care and Use of Animals for Scientific Purposes (**SANS 10386**: latest edition)
 - 2.1.3. Relevant national legislation and regulations.
 - 2.1.4. Other standards which may potentially be adopted by NRF-SAIAB at its own discretion.
- 2.2. All animal use for scientific purposes in NRF-SAIAB is justified in accordance with and complies with the core ethical principles of **Replacement, Reduction and Refinement** (the three Rs):
 - 2.2.1. **Replacement** of the use of animals by non-animal alternative methods, whenever possible
 - 2.2.2. **Reduction** of the number of animals to the minimum required to produce valid results
 - 2.2.3. **Refinement** of methods and procedures in order to minimise animal suffering (including discomfort, pain, fear, distress or lasting harm) and to improve animal welfare.
- 2.3. Competent, fair and timely review of applications and reports related to animal use is provided.
- 2.4. All proposals for the care and use of animals undergo rigorous scientific and ethical review.
- 2.5. All animal use is appropriately justified by a harms-benefit assessment, such that the expected benefits (to humans, animals or the environment) will outweigh the harms to the animals involved.
- 2.6. All persons who perform any procedure(s) on live animals, including euthanasia, should be confirmed to be practically competent in performing the procedure(s).
- 2.7. Animal use only commences after the NRF-SAIAB AEC has granted formal approval for the activities.
- 2.8. Appropriate oversight of approved studies is afforded, to ensure adherence to approval conditions.
- 2.9. Formal reporting to the NRF-SAIAB appointing authority is performed at the required frequency.

3. Composition

The membership composition of the AEC is dictated by the SANS 10386 (latest edition), as outlined below, and further informed by transformation imperatives.

3.1. The following members are required:

- 3.1.1. **Chairperson:** The chairperson should hold a senior position in NRF-SAIAB and is appointed *in addition* to the Category A-D members, below.
 - 3.1.1.1. The chairperson should ideally be independent of the care and use of animals for scientific purposes. If an independent chairperson cannot be appointed, there should be adequate provision for the appropriate management of conflict of interest.
 - 3.1.1.2. The chairperson is responsible for impartially guiding the operations of the AEC, resolving conflicts of interest related to the business of the AEC, and representing the AEC in any negotiations with NRF-SAIAB management.
 - 3.1.1.3. The chairperson should have experience in research methodology and training in animal ethics (or have previously served on the AEC for at least a year).
- 3.1.2. **Category A member(s):** At least one registered veterinarian with experience relevant to NRF-SAIAB's animal use or the ability to acquire the relevant knowledge.
- 3.1.3. **Category B member(s):** At least one suitably qualified person with recent and substantial experience in the use of animals for scientific purposes, relevant to NRF-SAIAB's care and use of animals for scientific purposes.
 - 3.1.3.1. Category B membership should include the NRF-SAIAB Chief Scientist, Collections Curator, and at least one Aquatic Scientist.
- 3.1.4. **Category C member(s):** At least one person with demonstrable commitment to, and established experience in furthering the welfare of animals, who is not employed by or otherwise associated with NRF-SAIAB, and who is not currently involved in the care and use of animals for scientific purposes. The person should be selected on the basis of active membership of, and endorsement by an animal welfare organisation. This member should bring an animal welfare perspective to AEC deliberations, with a special awareness of current community and broader animal welfare concerns.
- 3.1.5. **Category D member(s):** At least one independent person who does not currently and has not previously conducted scientific studies or teaching activities using animals, either in their employment or beyond their undergraduate education and who is not an employee of NRF-SAIAB. The Category D member should not fit any of the other Categories. They should be members of the wider community who can contribute different and independent perspectives to the AEC deliberations. It is envisaged that the Category D member will have no other association with the institution apart from his or her membership of the AEC. The Category D member should be viewed by the wider national community as bringing a completely independent view to the committee and might include people such as distinguished public figures, businesspeople, teachers, retirees, accountants, lawyers, persons with legal training, etc.
- 3.1.6. **Additional members:** Person(s) responsible for the routine care of animals within the institution should be appointed to the AEC, ensuring that they have up-to-date information of relevant facilities. Additional members with the necessary skills and background of value to the AEC may also be appointed.

- 3.1.7. Note: The AEC Chairperson may invite people with specific expertise to provide advice or input, as required.
- 3.1.8. **Ex officio members:** The following persons are included as AEC members, *ex officio*:
 - 3.1.8.1. The NRF-SAIAB Institutional Official (as defined in the NRF-SAIAB Animal Ethics Policy).
 - 3.1.8.2. The NRF-SAIAB Managing Director, if he/she is not also the Institutional Official.
- 3.2. The number of members appointed in each Category should consider the need to remain quorate and to retain adequate expertise to effectively conduct the committee's business including protocol reviews, in cases where there are recusals of members due to potential conflicts of interest.
- 3.3. **Balance of membership:** Categories C and D shall, together, represent at least one-third of the AEC membership.
- 3.4. A Deputy Chairperson may be appointed from among the AEC members.

4. Confidentiality

AEC members should maintain confidentiality regarding the content of applications and all deliberations of the AEC.

- 4.1. This is important to allow all committee members to speak freely and frankly during meetings and decision-making processes, as well as to protect intellectual property.
- 4.2. Guidance should be provided on how members may seek advice without breaching confidentiality, in cases where consultation external to the AEC is required regarding confidential matters.
- 4.3. Concerns regarding breaches of confidentiality should be raised with the AEC chairperson in the first instance and, if not addressed to the satisfaction of the complainant, thereafter with the NRF-SAIAB appointing authority.

5. Conflicts of Interest

Procedures for declaration of interests and management of perceived or actual conflicts of interest involving the AEC members and experts whose advice is sought by the AEC, shall require persons with a conflict of interest to recuse themselves from the AEC's discussion and decision making on the matters that relate to the conflict of interest.

6. Appointment of Members

The appointment process for AEC members is in compliance with the SANS 10386 (latest edition) and may be further informed by other relevant best practice guidelines.

- 6.1. All AEC members, including the chairperson, are appointed by the NRF-SAIAB appointing authority.
- 6.2. Before appointment, prospective members shall declare all potential conflicts of interests. Conflicts of interest shall be appropriately managed during the process of making appointments.

- 6.3. Before appointment, all members of the AEC shall acknowledge in writing their acceptance of the terms of reference of the AEC, as well as the requirement to maintain confidentiality regarding the content of applications and the deliberations of the AEC, in accordance with NRF-SAIAB requirements.
- 6.4. Appointment letters should be issued to each member, for each term of service on the committee, which includes the following information:
 - 6.4.1. Their term of service as committee members of the AEC (i.e., start and end dates).
 - 6.4.2. Where to find more information regarding the AEC, its Terms of Reference and processes.
 - 6.4.3. An indemnity statement which indicates that AEC members will not be held personally liable for decisions that are made in good faith while executing the business of the AEC.
 - 6.4.4. Indicate how relevant training in animal ethics will be provided by the institution.
 - 6.4.5. Signed by the NRF-SAIAB appointing authority.
- 6.5. Procedures should be developed for the reappointment and retirement of AEC members
 - 6.5.1. AEC members are appointed for a term of up to three (3) years, with possible renewal of their term.
 - 6.5.2. AEC members will generally be eligible for reappointment for a maximum of three (3) consecutive terms, whereafter they will need to take a sabbatical of at least one (1) year before they may be reappointed as AEC members.

7. Training of Members

- 7.1. All AEC members shall undergo appropriate animal ethics induction training, either prior to or as soon as possible after joining as members of the committee.
- 7.2. All AEC members shall have access to the SANS 10386 (latest edition).
- 7.3. AEC members shall have access to appropriate continuing education programmes and resources.
- 7.4. Appropriate continuing education training in animal ethics shall be provided to AEC members at least every three (3) years.
- 7.5. Where possible, training activities should have assessed outcomes and include certification, in order to confirm adequate comprehension of the concepts imparted during the training.

8. Meetings

- 8.1. The AEC shall convene formal committee meetings at frequencies that
 - 8.1.1. enable the committee to adequately support NRF-SAIAB's requirements for the care and use of animals for scientific purposes,
 - 8.1.2. promote the competent and timely ethical review of animal care and use, and
 - 8.1.3. ensure continued compliance with the AEC's Terms of Reference and Standard Operating Procedures, NRF-SAIAB Animal Ethics Policy, SANS 10386 (latest edition) and relevant legislation.
- 8.2. Formal meetings shall be convened at least four times per year, or more frequently as required.

- 8.3. *Ad hoc* or emergency meetings may be convened, which should adhere to quorum requirements.
- 8.4. Members shall attend meetings regularly, in accordance with NRF-SAIAB requirements. In cases where attendance is not possible, written comments on protocol reviews should be provided to the AEC.
 - 8.4.1. When AEC members are not able to attend any committee meeting, they should notify the chairperson in advance of their expected absence.
 - 8.4.2. If an AEC member is absent for two consecutive committee meetings without first notifying the chairperson of their absence, or if an AEC member is absent for three consecutive meetings having notified the chairperson in advance of their absence, that committee member may be seen to be in breach of their obligations and is liable to be removed from the committee, subject to AEC agreement and endorsement by the AEC chairperson.
- 8.5. Prior to any deliberations of the AEC, members shall confirm that they will maintain confidentiality regarding the content of applications and all deliberations of the AEC.
- 8.6. Prior to any deliberations of the AEC, members shall declare any potential conflict of interest that could influence the objectivity of their decision-making.
 - 8.6.1. Persons with a conflict of interest should recuse themselves from relevant discussions and decision-making on matters that relate to the conflict of interest.
- 8.7. Members should actively partake in deliberations of the committee discussions.
- 8.8. Each member is responsible for deciding whether, in their own judgement, an application or other matter under consideration by the AEC is ethically acceptable, meets the relevant NRF-SAIAB policies and the SANS 10386 (latest edition) standards. To fulfil this responsibility, members should be familiar with the SANS 10386 (latest edition) and should provide opinions on the ethical acceptability of matters under discussion.
- 8.9. Meeting documents should be distributed to AEC members in a timely manner before meetings.
- 8.10. Minutes of meetings should include information regarding discussions, the outcome of the review and approval of new and on-going protocols, studies or activities.
- 8.11. The AEC shall clearly communicate its decisions, the reasons for its decisions and any conditions attached for an approval to the investigators in writing as promptly as possible.
- 8.12. The AEC should consider face-to-face meetings with applicants to resolve issues, in cases where written communication does not adequately resolve differences or possible misunderstandings.
- 8.13. Financial compensation for meeting attendance by AEC members who are not affiliated with NRF-SAIAB, may include reimbursement for expenses directly related to travel to meetings, loss of income for professionals, or an honorarium.

9. Quorum

- 9.1. Quorate AEC meetings may be convened as face-to-face meetings, video conferencing or telephone-conferencing.
- 9.2. At least one AEC member from each of the membership Categories A, B, C and D shall be present throughout a meeting, in order to establish a quorum for the conduct of the meeting. Categories C and D together shall represent at least one-third of members present.
- 9.3. Applications for new projects and activities, as well as major amendments to AEC-approved projects and activities, may only be reviewed and approved at quorate AEC meetings.

- 9.4. Annual reports for existing projects and activities may only be reviewed and approved for further continuation at quorate AEC meetings.

10. Executive Committee

An AEC Executive Committee (the AEC Exco) may be established from among the members of the AEC.

- 10.1. Exco membership must include at least the chairperson, a Category A member (veterinarian), as well as at least one member from either Category C or Category D (to maintain independence). Other AEC members may also serve on the Exco.
- 10.2. Appointment letters should be issued to each Exco member, including the following information:
- 10.2.1. Their term of service as members of the AEC Exco (i.e., start and end dates).
- 10.2.2. An indemnity statement which indicates that Exco members will not be held personally liable for decisions that are made in good faith while executing the business of the Exco.
- 10.2.3. Signed by the NRF-SAIAB appointing authority.
- 10.3. The Exco has delegated authority to approve minor amendments to AEC-approved projects or to AEC-approved activities. The AEC should determine the types of changes that would qualify as a minor amendment, e.g., an amendment where the proposed change is not likely to cause harm to the animals, including fear, discomfort, pain, suffering, distress or lasting harm.
- 10.4. The AEC may establish procedures for expedited review by the Exco. The nature of research that may be expedited should be described in these procedures. Expedited review should apply, in principle, only to research that poses no more than minimal risk of harm to the animals involved.
- 10.4.1. Provision may thus be made for Exco review and approval for scientific activities involving rare events, in cases where such activities meet the requirements for expedited review.
- 10.5. The Exco may deal with urgent matters that may arise between meetings of the NRF-SAIAB AEC.
- 10.6. All decisions made by the Exco shall be reported to and be reviewed by the full AEC at the next quorate AEC meeting.

11. Responsibilities

The primary responsibility of the AEC is to ensure, on behalf of NRF-SAIAB, that all activities relating to the care and use of animals for scientific purposes are conducted in compliance with the minimum standards as prescribed in Clause 2 in this document (i.e., the Purpose of the AEC).

The AEC shall:

- 11.1. Review applications for animal care and use and approve only those applications that are ethically acceptable and conform to the requirements of the prescribed minimum standards, including the requirement that all persons who perform invasive or potentially harmful procedures on live animals should be confirmed competent,
- 11.2. Review applications for activities associated with the care and management of animals in facilities, including procedures relating to breeding animals, and approve only those activities that are ethically acceptable and conform to the requirements of the prescribed minimum standards,

- 11.3. Conduct follow-up review of approved projects and activities at scheduled times and when circumstances trigger additional follow-up review or inspections; and only allow the continuation of approval for projects and activities that are ethically acceptable and conform to the requirements of the prescribed minimum standards. Such follow-up review shall include:
 - 11.3.1. Review of applications for amendments to approved projects or activities.
 - 11.3.2. Review of annual progress reports for all on-going projects and activities.
 - 11.3.3. Review of final reports for projects or activities that have been completed or discontinued.
 - 11.3.4. Review of adverse events in a project or activity. Appropriate action should be taken to ensure that the issue is addressed promptly, animal well-being is not compromised, and activities that have the potential to adversely affect animal well-being cease immediately. Actions may include consultation or where necessary, suspending or withdrawing approval
 - 11.3.5. Review of reporting of concerns raised by any person.
 - 11.3.6. Review of potential non-compliance in approved projects or activities.
- 11.4. Monitor the care and use of animals to ensure compliance with standards and AEC decisions,
- 11.5. Take appropriate actions regarding concerns or serious adverse events,
- 11.6. Take appropriate actions regarding non-compliance,
- 11.7. Approve guidelines for the care and use of animals on behalf of NRF-SAIAB,
- 11.8. Provide advice and recommendations to NRF-SAIAB; and report on its operations to NRF-SAIAB,
- 11.9. Ensure that adequate consideration is given to biosecurity, biosafety and workplace safety.

12. Decision-making

- 12.1. Decision-making by the AEC should be in compliance with the requirements of the SANS 10386 (latest edition).
- 12.2. For decision-making, members with a conflict of interest shall recuse themselves from the relevant components or discussions of a meeting. Once such members have withdrawn from the deliberations, the remaining members shall still constitute a quorum as defined in this document.
- 12.3. Decisions should be made as promptly as possible.
- 12.4. The AEC may decide that:
 - 12.4.1. An application to commence a project or activity, or amend an approved project or activity, is approved with or without conditions, deferred for further review subject to modification, or rejected,
 - 12.4.2. For AEC-approved projects or activities: Approval is continued, suspended, modified or discontinued, following review by the AEC of the annual report for the project/activity or review by the AEC of other relevant reports or evidence pertaining to the project/activity,
 - 12.4.3. Any AEC approval is suspended, withdrawn, or that the period of said approval ends.
 - 12.4.4. Any animal is immediately given appropriate treatment, euthanased or otherwise removed from a study or activity.
- 12.5. AEC decisions should be based on a thorough, fair and inclusive process of discussion and deliberation by the AEC members.

- 12.6. Decisions should usually be made on the basis of consensus. If consensus cannot be reached after a reasonable effort has been made to resolve differences, the AEC should explore with the applicant ways of modifying the project or activity that may lead to consensus. Should consensus still not be achieved, the AEC should only proceed to a majority decision after members have been allowed a period of time to review their positions, followed by further discussion.
- 12.7. The following principles shall apply in cases where a matter is brought to a vote:
- 12.7.1. There is one vote per membership Category, i.e., one vote for each of the Categories A, B, C and D. There are thus four (4) votes in total, across the Categories.
 - 12.7.2. There may be no conflict of interest in any of the Categories voting.
 - 12.7.3. In the case of a split vote *within* a Category, the majority vote *within* the Category becomes the Category's vote; if there is a tie *within* a Category, the Category's vote is zero.
 - 12.7.4. The chairperson does not usually have a vote. However, in cases of a tie *across* Categories, the chairperson has a deciding vote. This may be the fifth (5th) vote in total.
 - 12.7.5. Additional members do not have a vote. However, their input is crucial in order to share specialised information whereby the Category A-D members can make informed decisions
- 12.8. In determining the duration of approval for individual projects or activities:
- 12.8.1. The AEC should take into account the number of years for which the project is funded, any milestones or stages outlined in the project, and any formal agreements between NRF-SAIAB and funding bodies.
 - 12.8.2. In all cases where AEC-approval is granted for multiple years, such approval should be conditional on the AEC formally granting reapproval for the project or activity annually, based on receipt and review by the AEC of a satisfactory annual status report.
 - 12.8.3. The AEC should remain mindful of the evolving nature of science, animal welfare science, ethical standards and legislation. Therefore, a relevant maximum duration of AEC approval should always be set, in order to ensure ongoing compliance with accepted current norms.

13. Monitoring

- 13.1. The AEC should monitor all activities relating to the care and use of animals on a regular and ongoing basis, in order to assess compliance with required standards and the decisions of the AEC. This should include the acquisition, transport, breeding, housing and husbandry of animals.
- 13.1.1. In cases where there are animal facilities, the AEC should formally review and approve the animal facility SOPs for all activities relating to animal care and use, including breeding.
 - 13.1.2. In cases where there are animal facilities, regular inspections by appropriate independent animal welfare organisations should be conducted, with reported concerns addressed appropriately and timeously.
- 13.2. The AEC (or appointed AEC members) should monitor animal care and use by physically inspecting animals, animal housing and the conduct of procedures, as well as by reviewing records and reports.
- 13.3. All Categories of AEC members should participate in site inspections or animal facility inspections
- 13.4. The frequency and timing of inspections may depend on the number and accessibility of sites and the number and types of projects and activities. The AEC may decide that certain projects or activities require more frequent inspection, e.g., due to the severity grade or historic audit results.

- 13.5. The AEC may delegate authority to suitably qualified persons to monitor animal care and use, e.g., for projects or activities conducted at remote sites. Procedures should include how reports of such monitoring should be provided to the AEC, including using e.g., audio-visual footage.
- 13.6. Inspections may be announced or unannounced.
- 13.7. The AEC should ensure that identified problems and issues receive appropriate follow-up.
- 13.8. Records of inspections should include the names of attendees, observations, any identified problems, recommended actions, on-going or outstanding issues and outcomes.

14. Documentation

14.1. Administrative responsibility

- 14.1.1. The AEC shall develop policies and procedures for the submission, receipt and processing of applications and reports to the AEC and make the policies/procedures readily available.
- 14.1.2. The AEC should ensure that forms for reporting of concerns, alleged non-compliance, severe adverse events and whistle-blowing are publicly accessible on the NRF-SAIAB website.

14.2. The AEC shall develop documentation for, *inter alia* the following:

- 14.2.1. Application form for review, in order to commence a project or activity using animals.
 - 14.2.1.1. All research projects should be submitted to the AEC using the relevant application form.
- 14.2.2. Follow-up relating to an AEC-approved project or activity, including:
 - 14.2.2.1. Application form for an amendment to an approved project or activity.
 - 14.2.2.2. Annual progress report form: for all on-going projects and activities.
 - 14.2.2.3. Final report form: for projects and activities that have been completed or discontinued.
 - 14.2.2.4. Reporting form for serious adverse events in a project or activity.
 - 14.2.2.5. Reporting form for potential non-compliance for approved projects or activities.
- 14.2.3. Template letter for the appointment of AEC members.
- 14.2.4. Confidentiality agreement for AEC members and reviewers.
- 14.2.5. Conflict of interest declaration for AEC members and reviewers.
- 14.2.6. Form for recording post-approval monitoring of a project or activity (i.e., onsite inspection).
- 14.2.7. Form for recording inspections of animal facilities by AEC members.

14.3. The AEC shall further develop Standard Operating Procedures (SOPs) which enable it to meet its responsibilities and functions as outlined in this document.

- 14.3.1. SOPs should be formally reviewed and approved by the AEC, for adoption by the NRF-SAIAB appointing authority.
- 14.3.2. Approved SOPs should be re-evaluated every few years, or more frequently as required.
- 14.3.3. The following SOPs should be established:
 - 14.3.3.1. SOP for preparation of agendas and minutes and distribution of documents prior to meetings.

- 14.3.3.2.SOP that describes the process for making an application to the AEC, the AEC review and approval process for proposals or amendments, including how prompt notification of decisions are made to applicants.
 - 14.3.3.2.1.The SOP may specify that different types of applications are handled differently by the AEC, including but not limited to different application forms, requirements for requisite documentation, review and approval processes, etc., as applicable.
- 14.3.3.3.SOPs that explain the process for reporting of allegations of misconduct, complaints or concerns, and how this will be investigated and acted upon by the AEC.
- 14.3.3.4.SOP for reporting of unanticipated problems, incidents or serious adverse events, and how this will be investigated and acted upon by the AEC.
- 14.3.3.5.SOP prescribing mechanisms for “whistle-blower” protection.
- 14.3.3.6.SOP detailing the AEC process for monitoring animal care and use, including routine animal facility inspections, site visits (i.e., onsite post-approval monitoring inspection of active studies) and review of annual and final reports; including the reporting of monitoring outcomes and potential identified problems to the AEC and NRF-SAIAB; and how this will be acted upon by the AEC.

15. Record-keeping

- 15.1. Accurate records relating to the AEC’s operations should be maintained in order to demonstrate ongoing compliance with the relevant standards, including the following records:
 - 15.1.1. A register of all applications to the AEC, including the outcomes of deliberations (i.e., date approved or rejected), study title, number and types of animals, severity grade of the study (i.e., the level of harm experienced by the animals: non-recovery, mild, moderate or severe), names and contact details of investigators, start and end dates of approval period.
 - 15.1.2. Minutes of meetings that accurately record decisions and other aspects of the AEC’s operation.
 - 15.1.2.1.Confirm attendance (specify membership Categories) and confirm quorum.
 - 15.1.2.2.Confirm conflict of interest declaration and confidentiality agreement at meeting start.
 - 15.1.2.3.Minutes should provide an audit trail from the date of initial submission to date of final approval or rejection of all applications (new protocols or amendments).
 - 15.1.2.4.Reports from animal facilities should be included where relevant (problems, etc.).
 - 15.1.2.5.Record relevant Exco decisions that were taken between AEC meetings.
 - 15.1.2.6.Final approved minutes should be signed by the AEC chairperson.
 - 15.1.3. Written communication between the AEC and Principal Investigators (PI), which document the review process from time of initial submission of the application/amendment, the AEC’s comments to the PI and the PI’s responses, up to the point of the protocol’s final approval, including the formal approval letter from the AEC to the PI.
 - 15.1.3.1.A final approval or rejection letter must be issued to the Principal Investigator for each application (new protocol or amendment) that confirms the AEC’s formal decision. The letter must be signed by the AEC chairperson.
 - 15.1.4. Copies of the final AEC-approved versions of all applications and amendments.

- 15.1.5. Records of all inspections and post-approval monitoring conducted by the AEC.
- 15.1.6. The outcomes of investigations into reports of potential non-compliance or adverse events.
- 15.1.7. The reports of review board findings from annual reviews of the AEC and from independent external reviews of the AEC's functioning.

16. Complaints and Non-Compliance

- 16.1. Procedures shall be established to investigate and address the following:
 - 16.1.1. Complaints related to AEC processes, irreconcilable differences between the AEC and investigators and conflict management between AEC members.
 - 16.1.1.1. The NRF-SAIAB Managing Director acts as chief arbitrator in the case of disputes or disagreements between scientists (or other persons) and the AEC. In cases where the Managing Director declares a conflict of interest, independent arbitration shall be sought.
 - 16.1.2. Reported, suspected or confirmed non-compliance relating to:
 - 16.1.2.1. NRF-SAIAB institutional policies or procedures, including AEC requirements.
 - 16.1.2.2. The conditions or details as specified in AEC-approved protocols.
 - 16.1.2.3. The SANS 10386 (latest edition), relevant national laws and regulations.
- 16.2. A whistle blower policy is required to protect whistle blowers. The NRF Whistle Blowing Policy applies.
- 16.3. In cases where projects or activities are detected that are in breach of the required standards or the AEC's requirements, the AEC should ensure that:
 - 16.3.1. Appropriate action is taken to ensure that the issue is addressed promptly, animal well-being is not compromised, and activities that have the potential to adversely affect animal well-being cease immediately. Actions may include suspending or withdrawing approval.
 - 16.3.2. Actions are taken to address the issues in consultation with the person(s) involved.
 - 16.3.3. When considered necessary, such matters are referred to NRF-SAIAB Institutional Official (as defined in the NRF-SAIAB Animal Ethics Policy) for action.
 - 16.3.4. Non-compliance receives appropriate follow-up.

17. Review of AEC functioning

- 17.1. An annual review of the operation of the AEC should be conducted, to ensure that it is effective and consistent with the SANS 10386 (latest edition) and institutional policies.
 - 17.1.1. This shall include but not be limited to, an assessment of the AEC's annual report and relevant AEC records, as well as a meeting with the AEC chairperson.
 - 17.1.2. The review should also assess the effectiveness of institutional processes regarding complaints and non-compliance relating to the care and use of animals.
 - 17.1.3. The review board should consist of the AEC chairperson, the NRF-SAIAB Managing Director (or their senior delegate) and one external reviewer, as a minimum composition.

17.2. An independent external review of the AEC should be conducted at least every four years, in order to assess institutional compliance with the SANS 10386 (latest edition) and to ensure the continued suitability, adequacy and effectiveness of the AEC's procedures (including AEC functioning and adherence to its Terms of Reference) in order to meet its responsibilities under the SANS 10386 (latest edition).

18. Reporting

The AEC should submit a written report on its operations to the NRF-SAIAB appointing authority, at least annually or more frequently as required. The report should include information and recommendations relating to *inter alia* the following:

- 18.1. The numbers and types of projects or activities that were reviewed, approved or rejected.
- 18.2. The number of AEC meetings held, composition of the committee, any challenges with quorum.
- 18.3. The number of Exco meetings held and the nature of decisions made.
- 18.4. The number of animals bred and used in NRF-SAIAB research in the year, per severity grade of study (i.e., the level of harm experienced by the animals: non-recovery, mild, moderate or severe).
- 18.5. Outcomes of facility inspections, monitoring of approved studies or activities, suspected or reported non-compliance, serious adverse effects, complains and investigations.
- 18.6. Any education or training that was performed or is required for AEC members, scientists, students or other persons involved in the care and use of animals for scientific purposes.
- 18.7. Administrative, funding or other challenges encountered or any relevant concerns of the AEC.
- 18.8. Any matters that may affect NRF-SAIAB's ability to maintain compliance with required standards.
- 18.9. Recommendations regarding the oversight of NRF-SAIAB's animal care and use programme.

19. Relationship to other Entities

19.1. Memoranda of Understanding (MoUs) may be entered into between NRF-SAIAB or the NRF-SAIAB AEC on the one hand; and other institutions or the AECs of other institutions on the other; in order to formalise agreements in terms of possible reciprocal review and approval agreements, to formalise the responsibilities of the various institutions/AECs for post-approval monitoring, etc., in cases where there are inter-institutional collaborative studies or activities being conducted.

19.1.1. The NRF-SAIAB Managing Director shall be a signatory to all such MoUs.

20. Monitoring and Evaluation

The NRF-SAIAB Managing Director is responsible for conducting a comprehensive review of this document at a minimum of every three years, or more frequently as required, in order to stay current with applicable legislation, ethical standards and NRF-SAIAB strategic objectives.

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