Liselo Animal Research Ethics Committee (LAREC)
Terms of Reference (ToR)

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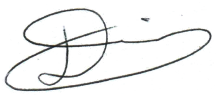
Approval signature:	
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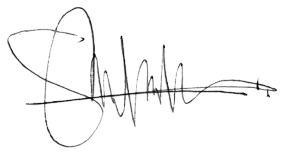
Approval signature:	

LAREC Terms of Reference Contents

1. Preamble

Liselo Labs recognizes that the advancement of biological, medical, agricultural and ecological knowledge and the development of improved means for the protection of the health and well-being both of man and of animals require the use of animals of a wide variety of species in research and teaching activities. These types of activities come with the implied responsibility to ensure that all animals, i.e., “live, sentient non-human vertebrate, including fertilized eggs, foetuses and embryos, that is; fish, amphibians, reptiles, birds and mammals, and encompassing domestic animals, purpose-bred animals, farm animals, wildlife and higher invertebrates such as the advanced members from the Cephalopoda and Decapoda” (SANS 10386:2021) used in research and teaching are cared for and used in ways judged to be scientifically, technically, and humanely appropriate. This policy is based on the 2021 Animal Ethics Policy of the National Research Foundation - South African Institute for Aquatic Biodiversity (NRF-SAIAB) and complies with the South African National Standard for the Care and Use of Animals for Scientific Purposes (SANS 10386:2021) produced by the South African Bureau of Standards, as well as the South African Department of Health’s Guidelines for Ethics in Health Research (2015 or latest version).

1.1. The Liselo Animal Ethics Research Committee (LAREC) is a standing committee established in accordance with the requirements of the LAREC Animal Ethics Policy.

1.2. The committee shall be known as the Liselo Animal Research Ethics Committee (LAREC).

1.3. The LAREC Institutional Official (i.e. the person who is defined as such in the Liselo Labs Ethics Policy) is the LAREC appointing authority for LAREC membership.

1.4. The LAREC’s Terms of Reference (ToR) shall be publicly available.

2. Purpose

2.1. LAREC is mandated to function as an independent Animal Research Ethics Committee (AREC) for the purpose of reviewing and approving applications for research involving animals, taking into consideration ethical and welfare aspects as well as scientific or educational value in accordance with accepted and applicable national and international normative and procedural standards.

2.2. The care and use of animals for scientific purposes in LAREC complies with the following minimum standards:

2.2.1. The Liselo Labs Animal Ethics Policy

2.2.2. The South African National Standard for the Care and Use of Animals for Scientific Purposes (SANS 10386:2021)

2.2.3. South African Department of Health, Ethics in Health Research Guidelines, 2015 or latest version

2.2.4. Relevant national legislation and regulations

2.2.5. Other standards which may potentially be adopted by LAREC at its own discretion.

2.3. All animal use for scientific purposes in LAREC is justified in accordance with and complies with the core ethical principles of Replacement, Reduction, Refinement, and Responsibility (the four Rs):

2.3.1. Replacement of the use of sentient animals by non-animal alternative methods, whenever possible.

2.3.2. Reduction of the number of animals to the minimum required to produce valid results.

2.3.3. Refinement of methods and procedures in order to minimise animal suffering (including discomfort, pain, fear, distress or lasting harm) and to improve animal welfare.

2.3.4. Responsibility to obtain animals and tissues ethically and provide animals with dignity, enrichment, and opportunity to engage in natural behaviours to the greatest extent possible; and to design, conduct, monitor, and report findings ethically.

2.4. Competent, fair and timely review of applications and reports related to animal use is provided (SOP-LRC-005).

2.5. All proposals for the care and use of animals undergo rigorous scientific and ethical review.

2.6. 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.

2.7. All persons who perform any procedure(s) on live animals, including euthanasia, should be confirmed to be practically competent in performing the procedure(s).

2.8. Animal use only commences after the LAREC has granted formal approval for the activities.

2.9. Appropriate oversight of approved studies is afforded by LAREC, to ensure adherence to approval conditions.

2.10. Formal reporting to the LAREC appointing authority or Institution Official (IO) is performed at the required frequency.

2.11. The LAREC, or chairperson on its behalf, can suspend or terminate any study where the committee considers that any relevant legislation is being

breached. The Chairperson shall investigate any suspected or alleged non-compliance with the SANS 10386:2021, relevant legislature, or protocol requirements and conditions and report it to the Institutional Official. Actions may also include the reporting of activities or projects in breach of the SANS 10386:2021 or other legislature, to animal welfare organizations.

3. Composition

The membership composition of the LAREC is dictated by the SANS 10386:2021, as outlined below, consisting of members who collectively have the qualifications, expertise and experience to review and evaluate the science and ethics of the proposed research.

It is worth noting that while the current SANS 10386 is the 2021 version, it is anticipated that the updated SANS guidelines, currently in draft form, will be promulgated late 2023 or early 2024 and ***3. Composition*** will need to be reviewed, amended and the LAREC committee membership structure may need changing.

3.1. The following members are required:

3.1.1. Chairperson: The chairperson should hold a senior position in Liselo Labs 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 LAREC, resolving conflicts of interest related to the business of the LAREC, and representing the LAREC in any negotiations with Liselo Labs management.

3.1.1.3. The chairperson should have experience in research methodology and training in animal ethics (or have previously served on the LAREC for at least a year).

3.1.1.4. The LAREC chairperson shall have the authority to immediately terminate or suspend any experiment on behalf of the committee if the chairperson considers that any relevant legislation is being breached.

3.1.2. Category A member(s): At least one person with qualifications in veterinary science, who is registered and/or authorised as a veterinarian in terms of the relevant national council (in South Africa, this is the South African Veterinary Council (SAVC)), and with

experience relevant to the institution's activities or the ability to acquire 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 Liselo Labs. This shall include possession of a higher degree in research or equivalent experience.

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 Liselo Labs, 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 LAREC 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 Liselo Labs. 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 LAREC 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 LAREC. 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 or persons with legal training.

3.1.6. Additional members: Person(s) responsible for the routine care of animals within the institution should be appointed to the LAREC, ensuring that they have up-to-date information of relevant facilities. Additional members with the necessary skills and background of value to the LAREC may also be appointed.

3.1.7. Note: The LAREC Chairperson may invite people with specific expertise to provide advice or input, as required.

3.1.8. The LAREC may consult external experts to assist them with the review of a particular protocol, when and if necessary. External experts will also be required to sign a non-disclosure agreement when approached to assist in the review of protocols (SOP-LRC-005).

3.2. The number of members appointed in each Category should be considered in order 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 LAREC membership and for each quorate meeting.

3.4. A Deputy Chairperson may be appointed from among the LAREC members.

4. Confidentiality

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

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 by the Principal Investigator (PI) on a case by case basis, on how members may seek advice without breaching confidentiality, in cases where consultation external to the LAREC is required regarding confidential matters.

4.3. Concerns regarding breaches of confidentiality should be raised with the LAREC chairperson in the first instance and, if not addressed to the satisfaction of the complainant, thereafter with the LAREC appointing authority (IO).

5. Conflicts of Interest

Declaration of interests and management of perceived or actual conflicts of interest involving the LAREC members and experts whose advice is sought by the LAREC, shall require persons with a conflict of interest to recuse themselves from the LAREC's discussion and decision making on the matters that relate to the conflict of interest. Guidelines are provided in the Standard Operating Procedure SOP-LRC-001 and SOP-LRC-009.

6. Appointment of Members

The appointment process for LAREC members is in compliance with the SANS 10386:2021 and may be further informed by other relevant best practice guidelines. Guidelines are provided in the Standard Operating Procedure SOP-LRC-001 and SOP-LRC-006.

6.1. All LAREC members, including the chairperson, are appointed by the Liselo Labs Institutional Officer.

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 LAREC shall acknowledge in writing their acceptance of the terms of reference of the LAREC, as well as the requirement to maintain confidentiality regarding the content of applications and the deliberations of the LAREC, in accordance with LAREC requirements. LAREC members should maintain confidentiality regarding the content of applications and all deliberations of the LAREC.

6.3.1. Each member of the committee will sign a non-disclosure agreement on appointment to the committee.

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 LAREC (i.e., start and end dates).

6.4.2. Where to find more information regarding the LAREC, its Terms of Reference and processes.

6.4.3. An indemnity statement which indicates that LAREC members will not be held personally liable for decisions that are made in good faith while executing the business of the LAREC.

6.4.4. Indicate how relevant training in animal ethics will be provided by the institution.

6.4.5. Signed by the Liselo Labs IO.

6.5. Procedures should be developed for the reappointment and retirement of LAREC members

6.5.1. LAREC members are appointed for a term of up to three (3) years, with possible renewal of their term.

6.5.2. LAREC 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 LAREC members.

7. Training of Members

7.1. All LAREC 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 LAREC members shall have access to the SANS 10386:2021.

7.3. LAREC members shall have access to appropriate continuing education programmes and resources.

7.4. Appropriate continuing education training in animal ethics shall be provided to LAREC 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

Guidelines are provided in the Standard Operating Procedure SOP-LRC-001 and SOP-LRC-004.

8.1. The LAREC shall convene formal committee meetings at frequencies that:

8.1.1. enable the committee to adequately support LAREC'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 LAREC's Terms of Reference and Standard Operating Procedures, LAREC Animal Ethics Policy, SANS 10386:2021 and relevant legislation.

8.2. Formal meetings shall be convened at least once every two months, 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 person or virtually), in accordance with LAREC requirements. In cases where attendance is not possible, written comments on protocol reviews should be provided to the LAREC.

8.4.1. When LAREC 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 LAREC member is absent for two consecutive committee meetings without first notifying the chairperson of their absence, or if an LAREC 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 LAREC agreement and endorsement by the AEC chairperson.

8.5. Prior to any deliberations of the LAREC, members shall confirm that they will maintain confidentiality regarding the content of applications and all deliberations of the LAREC.

8.6. Prior to any deliberations of the LAREC, members shall declare any potential conflict of interest that could influence the objectivity of their decision-making (SOP-LRC-009).

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, unless otherwise stated in the SOP for Conflicts of interest.

8.7. All 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 LAREC is ethically acceptable, meets the relevant LAREC policies and the SANS 10386:2021 standards. To fulfil this responsibility, members should be familiar with the SANS 10386:2021 and should provide opinions on the ethical acceptability of matters under discussion.

8.9. Meeting documents should be distributed to LAREC 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 and include a Harms-Benefits Analysis.

8.11. The LAREC 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 (SOP-LRC-004).

8.12. The LAREC 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 LAREC members who are not affiliated with LAREC, may include reimbursement for expenses directly related to travel to meetings, loss of income for professionals and/or inconvenience.

9. Quorum

Guidelines are provided in the Standard Operating Procedure SOP-LRC-001.

9.1. Quorate LAREC meetings may be convened as face-to-face meetings, video conferencing or telephone-conferencing.

9.2. At least one LAREC 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 LAREC-approved projects and activities, may only be reviewed and approved at quorate LAREC meetings.

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

10. Executive Committee

An LAREC Executive Committee (the LAREC Exco) may be established among the members of the LAREC. Guidelines are provided in the Standard Operating Procedure SOP-LRC-001 and SOP-LRC-006.

10.1. Exco composition must include at least the chairperson (or deputy chairperson), a Category A member (veterinarian), as well as at least one member from either Category C or Category D (to maintain independence). Other LAREC 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 LAREC 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 LAREC IO.

10.3. The Exco has delegated authority to approve minor amendments to LAREC-approved projects or to LAREC-approved activities. The LAREC 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 LAREC 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 (SOP-LRC-005).

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 LAREC.

10.6. All decisions made by the Exco shall be reported to and be reviewed by the full LAREC at the next quorate LAREC meeting.

11. Responsibilities

The primary responsibility of the LAREC is to ensure, on behalf of Liselo Labs, 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 LAREC). Guidelines are provided in the Standard Operating Procedure SOP-LRC-0011.

The LAREC 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 authorized as competent by an SAVC registered veterinarian, or be an SAVC registered veterinarian.

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 LAREC 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 in any facility used for LAREC-approved projects,

11.8. Provide advice and recommendations to facilities and report on their operations,

11.9. Ensure that adequate consideration is given to biosecurity, biosafety and workplace safety.

12. Decision-making

Guidelines are provided in the Standard Operating Procedure SOP-LRC-004.

12.1. Decision-making by the LAREC should be in compliance with the requirements of the SANS 10386:2021 and the South African Department of Health, Ethics in Health Research Guidelines, 2015 or latest version.

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 (SOP-LRC-009).

12.3. Decisions should be made as promptly as possible.

12.4. The LAREC 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 LAREC-approved projects or activities: Approval is continued, suspended, modified or discontinued, following review by the LAREC of the annual report for the project/activity or review by the LAREC of other relevant reports or evidence pertaining to the project/activity,

12.4.3. Any LAREC 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. LAREC decisions should be based on a thorough, fair and inclusive process of discussion and deliberation by the LAREC 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 LAREC should explore with the applicant ways of modifying the project or activity that may lead to consensus. Should consensus still not be achieved, the AREC 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, i.e. does not count.

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 LAREC 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 the PI and funding bodies.

12.8.2. In all cases where LAREC-approval is granted for multiple years, such approval should be conditional on the LAREC formally granting reapproval for the project or activity annually, based on receipt and review by the LAREC of a satisfactory annual status report.

12.8.3. The LAREC should remain mindful of the evolving nature of science, animal welfare science, ethical standards and legislation. Therefore, a relevant maximum duration of LAREC approval will be three years,

wherafter a new application will need to be submitted well in time before the three years are up.

13. Monitoring

Guidelines are provided in the Standard Operating Procedure SOP-LRC-001 and SOP-LRC-007.

13.1. The LAREC 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 LAREC. This should include the acquisition, transport, breeding, housing and husbandry of animals.

13.1.1. In cases where there are animal facilities used, the LAREC 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 used, regular inspections by appropriate independent animal welfare organisations should be conducted, with reported concerns addressed appropriately and timeously.

13.2. The LAREC (or appointed LAREC 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. LAREC 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 LAREC 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 LAREC 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 LAREC, including using e.g., audio-visual footage.

13.6. Inspections may be announced or unannounced.

13.7. The LAREC 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

Guidelines are provided in the Standard Operating Procedure SOP-LRC-001 and SOP-LRC-010.

14.1. Administrative responsibility

14.1.1. The LAREC shall develop policies and procedures for the submission, receipt and processing of applications and reports to the LAREC and make the policies/procedures readily available (SOP-LRC-005).

14.1.2. The LAREC should ensure that forms for reporting of concerns, alleged non-compliance, severe adverse events and whistle-blowing are publicly accessible on the Liselo Labs website.

14.2. The LAREC shall develop documentation for the following:

14.2.1. Application form for review, in order to commence a project or activity using animals (FRM-LRC-001).
Note: All research projects should be submitted to the LAREC using the relevant application form.

14.2.2. Follow-up relating to a LAREC-approved project or activity, including:

14.2.2.1. Application form for an amendment to an approved project or activity (FRM-LRC-002).

14.2.2.2. Annual progress report form: for all on-going projects and activities (FRM-LRC-012).

14.2.2.3. Final report form: for projects and activities that have been completed or discontinued (FRM-LRC-005).

14.2.2.4. Reporting form for serious adverse events in a project or activity (FRM-LRC-010).

14.2.2.5. Reporting form for potential non-compliance for approved projects or activities (FRM-LRC-010).

14.2.3. Template letter for the appointment of LAREC members.

14.2.4. Confidentiality agreement for LAREC members and reviewers.

14.2.5. Conflict of interest declaration for LAREC members and reviewers.

14.2.6. Form for recording post-approval monitoring of a project or activity (i.e., onsite inspection) (FRM-LRC-008a/b).

14.2.7. Form for recording inspections of animal facilities by LAREC members (FRM-LRC-009).

14.3. The LAREC shall further develop Standard Operating Procedures (SOPs) which enable it to meet its responsibilities and functions as outlined in this document. Guidelines are provided in the Standard Operating Procedure SOP-LRC-001 and SOP-LRC-008.

14.3.1. SOPs should be formally reviewed and approved by the LAREC, for adoption by the Liselo Labs IO.

14.3.2. Approved SOPs should be re-evaluated annually, or more frequently as required.

14.3.3. The following minimum SOPs should be established:

14.3.3.1. SOP for preparation of agendas and minutes and distribution of documents prior to meetings (SOP-LRC-001).

14.3.3.2. SOP that describes the process for making an application to the LAREC (SOP-LRC-005), the LAREC review and approval process for proposals or amendments (SOP-LRC-005), including how prompt notification of decisions are made to applicants (SOP-LRC-004).

14.3.3.2.1. The SOP may specify that different types of applications are handled differently by the LAREC, including but not limited to different application forms, requirements for requisite documentation, review and approval processes, as applicable (SOP-LRC-005).

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 LAREC (SOP-LRC-003).

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 LAREC (SOP-LRC-003).

14.3.3.5. SOP prescribing mechanisms for “whistle-blower” protection (SOP-LRC-002).

14.3.3.6. SOP detailing the LAREC 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 LAREC; and how this will be acted upon by the LAREC. (SOP-LRC-003/7).

15. Record-keeping

Guidelines are provided in the Standard Operating Procedure SOP-LRC-001.

15.1. Accurate records relating to the LAREC'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 LAREC, 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 LAREC'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 (e.g. problems).

15.1.2.5. Record relevant Exco decisions that were taken between LAREC meetings.

15.1.2.6. Final approved minutes should be signed by the LAREC chairperson.

15.1.3. Written communication between the LAREC and Principal Investigators (PI), which document the review process from time of initial submission of the application/amendment, the LAREC'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 LAREC to the PI (SOP-LRC-004).

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 LAREC's formal decision. The letter must be signed by the LAREC chairperson.

15.1.4. Copies of the final LAREC-approved versions of all applications and amendments.

15.1.5. Records of all inspections and post-approval monitoring conducted by the LAREC.

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 LAREC and from independent external reviews of the LAREC's functioning.

16. Complaints and Non-Compliance

Guidelines are provided in the Standard Operating Procedure SOP-LRC-003.

16.1. Procedures shall be established to investigate and address the following:

16.1.1. Complaints related to LAREC processes, irreconcilable differences between the LAREC and investigators and conflict management between LAREC members.

16.1.1.1. The IO acts as chief arbitrator in the case of disputes or disagreements between scientists (or other persons) and the LAREC. In cases where the IO 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. Liselo Labs institutional policies or procedures, including LAREC requirements.

16.1.2.2. The conditions or details as specified in LAREC-approved protocols.

16.1.2.3. The SANS 10386:2021, relevant national laws and regulations.

16.2. A whistle blower policy is required to protect whistleblowers. The Liselo Labs Whistle Blowing Policy applies. Guidelines are provided in the Standard Operating Procedure SOP-LRC-002.

16.3. In cases where projects or activities are detected that are in breach of the required standards or the LAREC's requirements, the LAREC 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. Actions may also include a report to animal welfare organizations.

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 the Liselo Labs Institutional Official (as defined in the LAREC Policy) for action.

16.3.4. Non-compliance receives appropriate follow-up.

17. Review of LAREC functioning

Guidelines are provided in the Standard Operating Procedure SOP-LRC-006.

17.1. An annual review of the operation of the LAREC should be conducted, to ensure that it is effective and consistent with the SANS 10386:2021 and institutional policies.

17.1.1. This shall include but not be limited to, an assessment of the LAREC's annual report and relevant LAREC records, as well as a meeting with the LAREC 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 LAREC chairperson, the Liselo Labs Managing Director (or their senior delegate) and one external reviewer, as a minimum composition.

17.2. An independent external review of the LAREC should be conducted at least every four years, in order to assess institutional compliance with the SANS 10386:2021 and to ensure the continued suitability, adequacy and effectiveness of the LAREC's procedures (including LAREC functioning and adherence to its Terms of Reference) in order to meet its responsibilities under the SANS 10386:2021.

18. Reporting

The LAREC should submit a written report on its operations to the Liselo Labs IO, 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 LAREC 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 LAREC 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, complaints and investigations.

18.6. Any education or training that was performed or is required for LAREC 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 LAREC.

18.8. Any matters that may affect LAREC ability to maintain compliance with required standards.

18.9. Recommendations regarding the oversight of LAREC animal care and use programme.

19. Relationship to other Entities

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

19.1.1. The Liselo Labs Managing Director shall be a signatory to all such MoUs.

20. Monitoring and Evaluation

The IO 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 LAREC strategic objectives.

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