
	Title: LLAREC SOP for Instructions for PI	Effective Date: 10/01/2024 Review Date: 09/01/2025
	Document Number: SOP-LLRC-010 Version #1.0	Approved by: David Jarvis Date: 10/01/2024 Signature 

# Liselo Lesotho Animal Research Ethics Committee (LLAREC)

## Standard Operating Procedure (SOP) for Instructions for PI



### 1. Purpose

This document sets out the process of submitting an animal ethics application to the Liselo Lesotho Animal Research Ethics Committee (LLAREC) for the Principal Investigator (PI) and their responsibilities post-approval.

- 1.1. Steps to be taken before submitting a new protocol
- 1.2. Submission of applications
- 1.3. Responding to comments
- 1.4. Amendments to approved protocols
- 1.5. Annual progress reports
- 1.6. Final Reports

### 2. Scope

This information is relevant for all PIs who intend to submit applications, amendments and expedited reviews for research and lecturing purposes involving the use of animals in Lesotho at Liselo Labs or for external applicants. Information is provided on the process of submission and post-approval responsibilities.

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### 3. Pre-requisites



Applicants should consult the World Organisation for Animal Health (WOAH)'s Terrestrial Animal Health Code of 2023, the South African Department of Health's Guidelines for Ethics in Health Research (2015 or newer) and ideally, the South African National Standard: The care and use of animals for scientific purposes (SANS 10386:2021 or newer) - or if the SANS 10386:2021 is not available, then the Australian Standard of Practice for the care and use of animals for scientific purposes on which SANS 10386:2021 is based.

### 4. Definitions

- 4.1. SOP - Standard Operating Procedure
- 4.2. LLAREC - Liselo Lesotho Animal Research Ethics Committee
- 4.3. AREC - Animal Research Ethics Committee
- 4.4. IO - Institutional Official
- 4.5. EXCO - Executive Committee
- 4.6. PI - Principal Investigator

### 5. Responsibilities

The PI is a scientist who has a sole or joint responsibility for the design, conduct, delegation of trial responsibilities, analysis and reporting of the trial. The PI is accountable to the sponsor and regulatory authorities as required by these guidelines. The PI should be knowledgeable and have an understanding of the parameters of the study. In the case of a multi-centred trial there must be a local PI attached to each site. It is unacceptable to have an "absentee" PI who is based in a country unrelated to where research is being carried out.

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## 6. Procedure



### 6.1. Steps to be taken before submitting a new protocol

- 6.1.1. PIs submitting a new application to conduct animal research and/or teaching must consult the World Organisation for Animal Health (WOAH)'s Terrestrial Animal Health Code of 2023, the South African National Standard: The care and use of animals for scientific purposes (SANS 10386:2021 or newer) or the Australian Standard of Practice for the care and use of animals for scientific purposes on which SANS 10386:2021 is based, Veterinary Scientific Services (VSS), or relevant bodies for guidelines on their research study.
- 6.1.2. The objectives of these consultations are to ensure that veterinary, clinical, husbandry and welfare aspects are appropriately considered so as to improve the efficiency of the processing of the application by the LLAREC.

### 6.2. Submission of applications

- 6.2.1. The application form and supporting documents are to be emailed to [llarec@liselo.com](mailto:llarec@liselo.com). Applicants should consult the SOP for the Submission of applications and process of review and approval provided on the website (<https://liselo.com/animal-research-ethics/>).
- 6.2.2. The protocol will then be screened by members of the LLAREC.
- 6.2.3. Reviewers' queries, comments and suggestions will be forwarded to the PI, to allow the protocol to be amended.



### 6.3. PI responding to LLAREC comments

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- 6.3.1. On a cover letter, copy each question or concern and provide a detailed and thoughtful response. Incomplete responses are likely to trigger a repeat query from the reviewer, which may slow down the process.
- 6.3.2. Address all points and queries, using references where necessary.
- 6.3.3. If feedback is unclear or ambiguous, you may contact the LLAREC and request clarification.
- 6.3.4. If you disagree with a comment or recommended change, provide your rationale. Please note that the committee may not agree with your rationale and still require changes to be made to the protocol to ensure the welfare of the experimental animals.
- 6.3.5. If further changes to the protocol are required, they must be implemented and the protocol resubmitted to the LLAREC incorporating these additional changes.
- 6.3.6. The PI may commence with the research and/or teaching project, once they have received a formal approval letter from the LLAREC.

**6.4. Amendments to approved protocols**

- 6.4.1. Researchers must apply for approval of any amendment(s) to an approved protocol (e.g., number of animals, strain, compounds, adding of new organisms, research participants, etc.).
- 6.4.2. Amendments must be submitted via email to [llarec@liselo.com](mailto:llarec@liselo.com). Acknowledgement of receipt will be received.
- 6.4.3. Amendments to a protocol may only be implemented after obtaining approval from the EXCO. The EXCO reserves the right to escalate the amendment to the LLAREC for approval whenever it deems it appropriate. The outcome of the amendment application will be communicated to the PI.

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## 6.5. Annual progress reports

- 6.5.1. The PI is responsible for submitting an annual progress report to the LLAREC in a timely manner before the approval period for the study expires.
- 6.5.2. The LLAREC may conduct a post-approval monitoring inspection of the approved protocol.
- 6.5.3. The LLAREC has the authority to suspend or terminate research that does not comply with annual reporting requirements.
- 6.5.4. The Annual Progress Report form (FRM-LLRC-012) is available online (<https://liselo.com/animal-research-ethics/>).

## 6.6. Final Reports

- 6.6.1. The PI is responsible for submitting a final report to the LLAREC.
- 6.6.2. The Final Report form (FRM-LLRC-005) is available online (<https://liselo.com/animal-research-ethics/>).
- 6.6.3. The final report is for the closure of the study at its expiry date.

## 7. References

- 7.1. South African National Standard: The care and use of animals for scientific purposes (SANS 10386: 2021).
- 7.2. SOPs adopted from the University of Cape Town.
- 7.3. World Organisation for Animal Health (WOAH). 2023. Terrestrial Animal Health Code. Accessed on 10 January, 2024 at: <https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/>