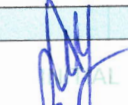



STANDARD OPERATING PROCEDURE

Title:	Terms of Reference for the MRU AEC	Page No.	Page 1 of 15
		SOP No.	MRU-SOP-ETH-001
Scope:	Malelane Research Unit ETHICS	Version No.	02
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Purpose and scope

To consolidate in one document the Terms of Reference that guide the MRU AEC. Malelane Research Unit has an Animal Research Ethics Committee (MRU AEC) constituted under the guidelines and standards set out in the SANS 10386:2021, EDITION 2. STANDARDS SOUTH AFRICA, PRETORIA, 2002.

The Terms of Reference ("ToR") are designed to ensure that MRU AEC is compliant with the requirements of the above-mentioned standard and other guidelines as referenced. This document describes the formal character of the committee, how it complies with organizational and statutory requirements, affiliation of members to the organization (MRU), and how the members, chairperson, deputy chairperson, administrator/s of the MRU AEC are appointed. Sets out the responsibilities of the AEC and the quorum rules required for approvals. The Terms of Reference aim to outline the responsibilities of MRU AEC to ensure that animal care and use comply with the current SANS 10386 document, incorporating the core ethical principles of

1. **Replacement** of the use of animals with alternative models where feasible
2. **Reduction** of the number of individual animals used
3. **Refinement** of experimental design, procedures, care, and husbandry, to minimise or eliminate the impact on individual animals in terms of actual or potential pain, suffering, stress, and lasting harm.
4. The knowledge and acceptance of one's **Responsibilities**.

This document must be read in conjunctions with all the related documents listed in section 12.1.

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1 Abbreviations/Definitions

1.1 Abbreviations

1.1.1	AEC	The Animal Ethics Committee of the Malelane Research Unit
1.1.2	Malelane Research Unit (The Facility)	Malelane Research Unit (The Facility)
1.1.3	SOP	Standard Operating Procedure of the MRU
1.1.4	PDA	Public Disclosure Act No. 26 of 2000
1.1.5	CV	<i>Curriculum Vitae</i>
1.1.6	PSP	Protocol/Study Plan
1.1.7	AA	Automobile Association of South Africa
1.1.8	GCP	Good Clinical Practice
1.1.9	GLP	Good Laboratory Practice
1.1.10	VMP	Veterinary Medical Product

1.2 Definitions

1.2.1	Chairperson	Refers to Chairperson of MRUAEC
1.2.2	Management	The Test Facility Manager as it pertains to GLP and the Site Manager as it pertains to GCP
1.2.3	Committee	Malelane Research Unit Animal Ethics Committee
1.2.4	AEC Liaison	The person that will assist with all communication between the Facility and the AEC as needed. This person is a member of the AEC and in the employ of the Facility.
1.2.5	The Facility	Malelane Research Unit
1.2.6	<i>Ex officio</i>	As a result of one's position held at the Facility
1.2.7	Serious Adverse Event	Relates to an unforeseen harmful event related to all animals (e.g. injury/death due to an experimental / VMP intervention).
1.2.8	Serious Incident	Relates to an unforeseen harmful event unrelated to a study/project itself (e.g. facility failure/pathogen outbreak), taking into account the effect on the animals (including resident animals)
1.2.9	Active Monitoring	A documented visit of an AEC member/person nominated by the AEC, to the Facility or off-site location, with the intention to monitor approved proposal procedures. May include visual material for example photographs or videos.
1.2.10	Oversight	A documented visit of an AEC member/person nominated by the AEC, to the Facility or off-site location, with the intention to inspect animal facilities and animal husbandry. May include visual material for example photographs or videos.
1.2.11	Lay person	Person that is not an expert in or does not have a detailed knowledge of a particular subject.
1.2.12	Expedited meeting	Meeting other than the routine scheduled AEC meeting, to review an urgent matter.
1.2.13	The Committee	Refers to the Animal Ethics Committee at Malelane Research Unit
1.2.14	<i>Ad hoc</i> member	Member invited to AEC meetings to provide specific feedback/insight, but are not eligible to cast votes regarding AEC matters or applications
1.2.15	Off-site	Research site not at Malelane Research Unit
1.2.16	Research	Refers to all activities that involve the experimental use of animals, including studies/projects.
1.2.17	Applicant	Person submitting a proposal application to the AEC (eg Researcher)

1.2.18	Projects	Refers to all activities that involve the use of animals for other purposes than studies, such as teaching, parasite breeding etc.
1.2.19	Researcher	Person recognized by the AEC as competent (including qualification, training, experience and practical skills) to conduct research involving animals (including studies and projects).
1.2.20	Non-affiliated Researcher	Researcher not in the employ of Malelane Research Unit but complies to all the requirements of a Researcher.
1.2.21	Major Study/Project Amendments	Changes to the final approved proposal, that will have any influence on the animals or change the objectives of the research (i.e. changes that will involve any of the information of the proposal application submitted to the AEC)
1.2.22	Minor Study/Project Amendments	Changes to the final approved proposal that does not have any influence on the animals nor change the objectives of the research (i.e. no changes to any information of the proposal application submitted to the AEC)
1.2.23	Corrective Modification	Changes made to a proposal application as per recommendation of the AEC after review, by not requiring an Amendment. Will be submitted as an Appendix to the proposal application, addressing the recommendations.
1.2.24	Proposal Application	Study/project/major amendment that requires ethical approval before commencement of any activities and is done via formal written application to the AEC.
1.2.25	Routine Parasite Breeding Projects - ongoing	Parasite breeding projects established at the Facility, utilizing resident animals on a permanent basis. Following standard procedures at the Facility. Proposal applications are submitted annually by the Researcher to the AEC.
1.2.26	Routine Parasite Breeding Projects - intermittent	Parasite breeding projects following standard procedures at the Facility, with irregular frequency and often involving the acquisition of animals for the specific project. Proposal applications are submitted annually by the Researcher to the AEC, but informs and reports to the AEC during each project.
1.2.27	Non-routine Projects	Infrequent projects for which potentially no standard procedure is available at the Facility. Proposal application submitted for each project to the AEC by the Responsible person and reports to the AEC regarding the project.
1.2.28	Routine Study	Study that has been approved by the AEC in the last 12 months, that follows the same basic methodology, and is conducted in the same species.
1.2.29	Teaching activity	Activity that involves animals and is performed to acquire, develop, or demonstrate knowledge or techniques in any scientific discipline, including studies for the purposes of teaching and training in primary, secondary and tertiary institutions
1.2.30	Member	Person appointed in the appropriate category to the AEC
1.2.31	Non-affiliated member	An AEC member with no employment association with the Facility
1.2.32	Affiliated member	An AEC member employed at the Facility
1.2.33	Site Veterinarian	Permanent employee of MRU, responsible for the health and welfare of all animals at the facility.

2 Responsibilities of the AEC

2.1 General

- 2.1.1 The AEC shall, on behalf of the Facility, ensure that all activities relating to the care and use of animals, are conducted in compliance with current standards and guidelines. The primary role of the AEC is to protect the welfare interests of animals used or to be used in research.
- 2.1.2 Comply to the Code of Conduct for Ethics set out in MRU-SOP-ETH-004 and other standard procedures developed by the Facility to guide the AEC relating to all ethics matters. (Refer to related documents in section 12.1.)
- 2.1.3 Regularly consult and engage with recognized authorities and reputable sources of information to ensure that they are abreast of developments in the field of ethical review and analysis.
- 2.1.4 The Committee meets at least quarterly to examine proposal applications for studies/projects, discuss endorsement of SOPs, review reports received, and deliberate other matters pertaining to the AEC or relevant Facility matters, which falls within the Terms of Reference for the AEC.
- 2.1.5 Uphold required registration compliance with NHREC, including annual completion of report to NHREC.
- 2.1.6 Further details regarding the Role of the AEC are provided in MRU-SOP-ETH-003. This procedure gives a detailed lay out of all the functions performed by the AEC.

2.2 Review of proposal applications

- 2.2.1 The AEC only considers proposal applications for research conducted on behalf of the Facility. All activities, including projects/studies that involve the care and use of animals for scientific purposes shall
 - be subject to ethical review, approval, and monitoring by the AEC,
 - commence only after final approval has been granted by the AEC,
 - be conducted in accordance with the AEC approval, and
 - cease if approval from the AEC elapses, is suspended or withdrawn, or period of said approval ends
- 2.2.2 The AEC shall be satisfied that there is sufficient evidence to support a case that the proposed use of animals is justified.
- 2.2.3 The AEC endeavors to provide independent ethics review of all proposal applications and encourages all members to be objective, informed and to act without fear or favor in their individual scientific and ethical views. Any concerns raised by members should be deliberated and decisions to impose additional conditions to protect the human and environmental food chain, animals and Researchers should be taken where necessary.
- 2.2.4 Provide ethical guidance to Researchers regarding standards of animal care and welfare, as well as potential ethical issues arising from proposed/ongoing research.
- 2.2.5 Promote the increased awareness of animal welfare issues and the implementation of the 4Rs in animal use.
- 2.2.6 Examine proposal applications with reference to the likely harm that may be caused to the animals and the likely benefits that may arise from such work.
- 2.2.7 Examine the hypotheses/objectives/design, to ensure it is well considered, plausible and have a reasonable prospect of yielding good results.
- 2.2.8 Establish that the Researcher and other people involved in the research, have the competence, training, and skills to ensure the welfare, health, and humane treatment of animals
- 2.2.9 Evaluate and approve, subject to modification, or reject proposal applications for the use of animals. Approve proposal applications that comply with ethical principles for humane animal use.
- 2.2.10 Propose amendments and modifications, seek clarification, and request revised submissions in the case that applications are not approved.
- 2.2.11 Carefully consider the re-use of animals, considering the cumulative effects of previous activities and conditions and shall consider the lifetime experience of the animal. Consideration must also include the time allowed for recovery of the animals between

activities and whether an animal has fully recovered. Consider the harm, pain, and distress the following research will cause and the time length of the research.

2.3 Monitoring

- 2.3.1 Conduct follow-up review of approved proposal applications by active monitoring, Facility oversight, and reviewing records and reports (including off-site research).
- 2.3.2 Monitor activities that are likely to cause pain, suffering, distress, or lasting harm at an early phase of conducting the activity.
- 2.3.3 Take appropriate actions regarding Serious Adverse Events, Serious Incidents, and cases of non-compliance, to ensure that animal wellbeing is not compromised. These issues are addressed promptly and activities that have potential to adversely affect the wellbeing of the animal cease immediately. The Chairperson will take responsibility of initiating the required actions to address these cases as well as the appropriate follow up requirements. The Facility will provide full support to the AEC. Actions may include consulting with the relevant people, and where necessary, suspending or withdrawing approval for the research, and/or order authorize the removal/humane termination of any animal which is being subjected to unnecessary deprivation, fear, distress and pain. All actions will be documented and reported to all relevant parties.
- 2.3.4 Monitor, inspect and assess the acquisition, transport, production, housing, care, use, termination, and disposal of animals.
- 2.3.5 Monitoring requirements may be established as conditions of approval for the proposal application or further monitoring requested by the Facility or Chairperson of the AEC, during the research, depending on the requirements identified. Due to the remote location of the Facility, member availability must be considered for expected frequency of monitoring.
- 2.3.6 Determine the frequency of Facility oversight. Influencing factors include the number and types of activities, and whether it could be combined with scheduled AEC meetings. All AEC oversight/monitoring visits may be announced/unannounced.
- 2.3.7 In addition, the AEC should decide if certain studies/projects may require more frequent monitoring. Records must be maintained of all oversight and monitoring visits. When specific active monitoring requirements are set during deliberations of the application consideration, the Chairperson will ensure that these requirements are met by the AEC.
- 2.3.8 Monitor the conditions/recommendations set out in a corrective modification to an approved proposal application. This will be delegated by the Chairperson to a nominated person that will provide feedback to the committee.
- 2.3.9 Delegate authority to suitably qualified person to monitor animals care and use off-site (for example fieldwork). Predetermine the activities/aspects to be included in the report and format of feedback required (photos, videos etc)
- 2.3.10 Review reports submitted by the Site Veterinarian and the Researchers, concerning regular monitoring, inspections and assessment of the acquisition, transport, husbandry, care, use and disposal of animals used in research, parasite breeding or teaching. All these aspects must be in accordance with current standards and legislation relating to the ethics, welfare, and use of animals. The Committee is expected to act on the reports as necessary.

2.4 Facility matters

- 2.4.1 Regular review of standard operating procedures of the Facility where these relate to the use of animals.
- 2.4.2 Recommend to the Facility any measures needed to ensure that national standards and guidelines are met.
- 2.4.3 Report at least annually to Management of the Facility regarding number approved proposals or applications rejected, Facility oversight and monitoring reports, and any difficulties experienced in the ability to maintain compliance with set standards.

3 Composition of the AEC

3.1 General

- 3.1.1 Collectively, the committee will include sufficient members with the necessary qualifications and experience, including research ethics training, to be able to review and evaluate the science, the health aspects, the ethics of the proposed research, as well as to assess the anticipated layperson's perspective.
- 3.1.2 Membership should be managed to ensure an optimal mix of experienced and new members to promote good succession planning.
- 3.1.3 Four categories of members are dictated by international and national standards. In keeping with these requirements, the MRU AEC should consist of at least 8 members (representative of the 4 categories), including specific position members referred to in section 3.6. When members resign from the AEC, the committee will endeavor to find suitable new members as soon as possible, to maintain quorum requirements.

3.2 Four categories of member are required:

- A:** Person with qualifications in veterinary science (Veterinarian). Experience in relevant activities at MRU would be advantageous.
- B:** Scientists with substantial and recent experience in the use of experimental animals. Preferably such experience should be similar in nature to the research conducted at MRU.
- C:** A person with demonstrable commitment to, and established experience in, furthering the welfare of animals, who is not employed by or otherwise associated with MRU, and who is not involved in the care and use of animals for scientific purposes.
- D:** An independent person who does not currently, and has not previously conducted scientific or teaching activities using animals, and who is not an employee of MRU

3.3 Composition of MRU AEC

- 3.3.1 **Facility affiliated members of the AEC (non-remunerated)**
- Management (*ex officio*)
 - The Site Veterinarian (*ex officio*) – responsible for the routine care of animals within the Facility, ensuring that the AEC have up-to-date information of all the various facilities/activities at the Facility.
 - Researcher/s or other personnel (may be appointed as members of the AEC in applicable categories)
- 3.3.2 Depending on the existing members of the AEC, the *ex officio* members mentioned above, may be appointed in either Category A or Category B (provided they meet the requirements of that category), or as *ad hoc* members to provide feedback/insight during meetings. *Ad hoc* members will not hold a category position on the committee and are not eligible to vote on AEC matters.
- 3.3.3 **Non-affiliated members**
- At least one person representing veterinary science – Category A
 - At least one person representing animal welfare organisations – Category C
 - At least one lay person – Category D
 - Additional members as required regardless of category.
 - Where appropriate, specialists and other advisers may be appointed *ad hoc* to attend meeting and/or give input. Such members are not eligible to vote.
 - Observer members and applicants may be invited to the meetings. Such members are not eligible to vote.
- 3.3.4 Balance of members: Category C and D shall, together, represent at least one-third of the AEC membership. In cases where category D member is affiliated with the Facility, at least

one Category D member must be non-affiliated. The AEC must have at least 8 members which includes the chairperson.

3.4 Renumeration of members

- 3.4.1 Non-affiliated members may or may not be remunerated for their professional time lost. The amount agreed for remuneration is agreed to at appointment and shall not exceed 2/3's of the expected income lost per hour. In addition, there may be compensation for distance travelled (based on AA rates)
- 3.4.2 All remunerations will be documented on appointment letters for each member.
- 3.4.3 Members shall generally not receive gifts. Should any branded stationary or other gifts, be handed to AEC members, this shall be recorded on the meeting minutes.

3.5 Recruitment/nomination of new members

- 3.5.1 The recruitment and appointment of AEC members will be transparent.
- 3.5.2 Any committee member may nominate a new member for recruitment to the AEC to fill a vacant position on the committee, or to expand the committee. These nominations will be heard by MRU AEC at a routine quarterly meeting and opened for discussion. Due to the remote location of the Facility, it is advantageous to recruit members from the local community, whenever possible.
- 3.5.3 New members for the AEC are appointed by the Chairperson in consultation with the committee. Factors to consider for appointment to the AEC include but are not limited to experience, expertise (knowledge), and availability to serve on the committee. At a minimum, the CV of applicants will be reviewed. When a new member is considered for a category that requires qualifications, these certificates of qualifications must be made available to the committee. Declaration of any possible conflict of interests. All documentation pertaining to each committee member will be kept with each member's personal file at MRU and handled as confidential.
- 3.5.4 All AEC members are provided with a formal appointment letter that sets out, at a minimum, the term of office; where to find the necessary information for new members; and the assurance that members are indemnified from personal liability against claims that may arise during ordinary business of the AEC.
- 3.5.5 Recruitment of additional members over and above the required minimum of 8 described above, should be approved by the Facility.
- 3.5.6 Before appointment, all members of the AEC should acknowledge their acceptance of the Terms of Reference and Code of Conduct of the committee, as well as requirements for the confidentiality required by the Facility. All potential conflicts of interest must be declared by members at appointment.

3.6 Specific positions within the AEC

- 3.6.1 Chairperson of the AEC
 - 3.6.1.1 The Chairperson of the AEC is appointed by Management.
 - 3.6.1.2 If affiliated, the Chairperson should hold a senior position at the Facility. When the Chairperson is non-affiliated, the Facility shall provide the necessary support and authority to the Chairperson to carry out the role. The Chairperson should be appointed outside of Categories A to D.
 - 3.6.1.3 The Chairperson should have experience in research methodology and training in animal ethics (or should have served on the AEC for a period of at least a year)
 - 3.6.1.4 Management itself may assume the role of the Chairperson (as prescribed by the SANS 10386 guideline), to facilitate easy compliance by the Facility. Otherwise, a non-affiliated member of the AEC may be elected to promote independence.
 - 3.6.1.5 The Chairperson is elected for a period of 3 years (with the option to renew once).
 - 3.6.1.6 The Chairperson should be assisted by the Deputy Chairperson, The Deputy Chairperson is expected to assist the Chairperson with responsibilities and inter-meeting matters, as well as to step into the role of Chairperson when necessary.

- 3.6.1.7 The Chairperson may deal with minor matters with or without consulting other members. Progress reports and the outcomes of completed studies/projects, however, shall be reported to all the members.
- 3.6.2 Deputy Chairperson of the AEC
- 3.6.2.1 Any member of the AEC may be elected as the Deputy Chairperson. However, it is recommended that should the Chairperson be a non-affiliated member, the Deputy Chairperson should be Facility affiliated (and vice versa). This is to facilitate optimal cooperation between the Facility and the AEC at the highest levels of the AEC and the Facility.
- 3.6.2.2 The Deputy Chairperson is elected democratically by the members of the AEC for a term of 3 years (with the option to renew once). The voting process will be conducted at a routine meeting, and the proceedings will be at the discretion of the Chairperson.
- 3.6.3 Administrator/s
- 3.6.3.1 The administrator/s shall be appointed by Management to perform the AEC's administrative duties, provide administrative assistance to the Chairperson of the AEC and the Facility regarding all AEC matters, and maintain records of all documents and correspondence as required.
- 3.6.3.2 Detailed description of the duties of the Administrator is available in MRU-SOP-ETH-003, The Role of the AEC in the ethics process.
- 3.6.4 AEC Liaison
- 3.6.4.1 Facilitates communication between the AEC, Researchers/Applicants, and the Facility.
- 3.6.4.2 Ensures timeous reporting of active reports of Major Deviations, Adverse Events, Non-routine concomitant treatments, and Serious Incidents to the AEC that is received from Researchers, as well as feedback received from the AEC to the Researcher.

3.7 Minimum training requirements of AEC members

- 3.7.1 The Facility shall ensure that AEC members undergo appropriate induction and have access to appropriate continuing education programs and resources.
- 3.7.2 AEC members are expected to familiarize themselves with the Facility documentation (SOPs), as well as national and international research ethics guidelines, and should have documented proof of such familiarity.
- 3.7.3 It is the responsibility of the Facility to make the training documents and opportunities available to AEC members.
- 3.7.4 Training internally provided should be accompanied by short assessments where possible.
- 3.7.5 The AEC Administrator shall keep record of the training of the AEC members.
- 3.7.6 Any member that is not up to date with their training shall not be eligible to actively participate in a meeting. This includes the minimum required training as induction following appointment.

Terms of Reference for the MRU AEC

3.8 Table 1: The minimum training requirements for AEC members

Training topic	Induction training (required before active participation if AEC meeting)	Required within 9 months of appointment to AEC	Method/Format of training	Minimum Refresher cycle
MRU-SOP-ETH-001 Terms of reference of the MRU AEC	✓		Read and understood confirmation by member	2 years
MRU-SOP-ETH-003 The Code of Conduct of the AEC in the ethics process	✓		Read and understood confirmation by member	2 years
Basic GLP/GCP understanding	✓		Training provided to AEC	2 years
The 3 Rs of animals in research	✓		Training provided to AEC	2 years
The 5 freedoms of animal welfare	✓		Training provided to AEC	2 years
SANS 1048 – Transportation of livestock (latest edition)		✓	Read and understood confirmation by member	3 years
MRU-SOP-ETH-002 The role of MRU in the ethics process		✓	Read and understood confirmation by member	3 years
MRU-SOP-ETH-005 Complaints		✓	Read and understood confirmation by member	3 years
MRU-SOP-ETH-006 Whistleblowing		✓	Read and understood confirmation by member	3 years
SANS 10386 – The care and use of animals for scientific purposes (latest edition)		✓	Resource provided to member by the Facility	3 years
DoH 2015, Ethics in Health Research (or later edition)		✓	Resource provided to member by the Facility	3 years
Resource booklet for lay members of ethical review		✓	Resource provided to member by the Facility	3 years
Site specific research procedures; technical aspects of the research, etc			Training provided by the Facility	<i>Ad hoc</i> and continuous

4 Quorum rules

4.1 General

- 4.1.1 The quorum rules for each available approving authority are described below. At least one member from each of the membership categories shall be present throughout the meeting to establish a quorum. Category C and D together shall represent one-third of the members present.
- 4.1.2 There is one vote per category (A, B, C and D) and there may be no conflict of interest in any of the categories voting. In the case of a split vote within a category, the majority vote within the categories becomes the category's vote. If there is a tie within the category, the category's vote is nullified. The Chairperson does not usually have a vote, but in cases of a tie across categories, the Chairperson has the deciding vote, provided there is no conflict of interest.
- 4.1.3 For decision making, members with conflict of interest shall withdraw from the meeting. The remaining members shall constitute a quorum as defined. Refer to section 6.

4.2 Table 2: The quorum requirements of the different review processes.

Approving authority	Quorum requirements
AEC approvals via e-mail	<ul style="list-style-type: none"> >75% of all AEC members have responded. At least one member from each Member Category has responded of which none have a conflict of interest pertaining to the approval. When a category is not represented by a member, final approvals may not be granted until a member of the absent category has provided approval in the timeline agreed upon.
Expedited meeting	<ul style="list-style-type: none"> Chairperson or Deputy Chairperson present At least one member from each category with no conflict of interest pertaining to topic of meeting
Routine meeting	<ul style="list-style-type: none"> Chairperson or Deputy Chairperson present >75% of all AEC members present At least one member from each category. Voting for approvals as per quorum rules

5 Absenteeism

5.1 AEC members

- 5.1.1 Where committee members are not able to attend a committee meeting/commitment, they should notify the Chairperson of their expected absence in advance. Members that are unable to attend the meeting may submit their reviews of the proposals in writing to the Chairperson to be considered at the meeting.
- 5.1.2 If a committee member is absent for two consecutive meetings without first notifying the Chairperson of their absence, or if a committee member is absent for three consecutive meetings having notified the Chair of their absence, that committee member is in breach of their obligations and is liable for removal from the committee, subject to the decision and endorsement by the Chairperson. (For this purpose, the submission of reviews to the Chairperson does not equate to attending the meeting).

- 5.1.3 Members are expected to attend meetings in person as far as possible. Due to the remote location of the Facility, it is acceptable for members in outlying areas to attend virtually. Provided these members attend at least one meeting at the Facility annually. Members from the local community will be expected to attend meetings in person as far as possible and must communicate to the Chairperson in advance when this will not be possible due to unforeseen circumstances.

6 Conflict of Interest of AEC members

6.1 AEC members

- 6.1.1 AEC members should disclose information that may lead to perceptions of conflict of interest.
- 6.1.2 AEC members should not review or make decisions about proposal applications in which they are involved personally or financially. When such a proposal is to be discussed, the member concerned should declare the potential conflict and offer to recuse herself from the meeting for that time. Should the member be permitted to remain for the discussion at the discretion of the Chairperson, the member may not participate in the final decision-making on the application in question.
- 6.1.3 Where a member has conflict of interest regarding a matter/decision, the member may not provide email or expedited meeting approvals.
- 6.1.4 Where a category is fulfilled by an *ex officio* member, this person will not be allowed to vote where they are the researcher or the project manager. This person will however fulfill all other responsibilities required as a member.
- 6.1.5 When the Chairperson has conflict of interest, the Deputy Chairperson will fulfil the role of Chairperson.

7 Terms of office

7.1 AEC members

- 7.1.1 All Animal Ethics Committee members are generally appointed for a term of up to three years (with the option to renew). It must be appreciated that members need time to absorb the ethos and develop the skills of ethical review.
- 7.1.2 No AEC member (except *ex officio* members) should serve for longer than 12 years without taking a 2-year absence from the AEC. (This is to ensure rotation of members). This ensures that both expertise and responsibilities are fairly distributed and encouraged in a range of members, and that institutional memory is accumulated.
- 7.1.3 The membership of members that attend 50% or fewer of the scheduled meetings per annum shall be reviewed annually by the AEC. The review shall consider the member's conflict of commitment and the probability for the member to continue to be absent from meetings. The review shall also consider the member's contributions to the discussions of the AEC.

7.2 Resignations

- 7.2.1 Members can resign from the AEC (or any position within the AEC) by communicating their resignation on any format to the Chairperson or Management (where appropriate). To ensure continuity, members are requested (where possible) to provide the AEC with at least 60-day notice.

8 Fees charged for reviews of proposal applications

8.1 Internal applications

- 8.1.1 As the MRU AEC is affiliated with MSD and only reviews MSD projects, no fees shall be charged for any reviews. The MRU AEC may occasionally review local MSD proposals, that are conducted off-site by non-affiliated Researchers.
- 8.1.2 No external applications will be reviewed.

9 Proposal Application Review Procedures

9.1 Overview

- 9.1.1 The basic approval processes of the AEC are described below in Table 3.
- 9.1.2 As noted in Table 3 below, the four different approval authorities follow a hierarchy of increasing authority from email approval to the Routine Meeting (highest authority). Each approving authority may choose to reserve judgement, instead referring the review to a higher authority of their choice.

9.2 Table 3: Summary of the different application and approval processes

	Format of application		Responsible person		Frequency of application	Approval authority (direction of increasing authority →)		
	Facility SOPs in place	Application form including documentation required	Shared by	Firstly Directed to, before sharing with AEC		AEC via e-mail	Expedited meeting [#]	Routine meeting
SOP with animal involvement	✓		Administrator	AEC	Per AEC request/Facility review cycle/Endorsement required	✓	✓	✓
SOP with <u>no</u> animal involvement	✓		Administrator	AEC	Per AEC request/Facility review cycle/Endorsement required	✓	✓	✓
Routine Parasite Breeding Projects (ongoing/intermittent)	✓	✓	Researcher	Administrator	Annually			✓
Non-Routine Projects (eg. resident animal expansions).		✓	Applicant	Administrator	Before the commencement of Project	✓ [#]	✓ [#]	✓
Animals used for training purposes		✓	Applicant	Administrator	Before the commencement of Project	✓ [#]	✓ [#]	✓
Routine study	✓	✓	Researcher	Administrator	Before the commencement of Study	✓ [#]	✓ [#]	✓
Non-routine study		✓	Researcher	Administrator	Before the commencement of Study		✓ [#]	✓
Major Amendment to study/project		✓	Original Applicant	Administrator	Before the implementation of the Amendment	✓ [#]	✓ [#]	✓
Corrective Modifications to applications following conditional approvals from AEC		✓	Original Applicant	Administrator	Before the commencement of Study/Project	✓	✓	✓

[#] E-mail approvals and Expedited meetings should only consider proposals with no or minimal risk of harm and impact on animal welfare

9.3 In addition to the Terms of Reference, the following procedures are in place:

- MRU-SOP-ETH-002, The role of MRU in the ethics process. To describe in detail the responsibilities of MRU management and researchers.
- MRU-SOP-ETH-003, The role of the AEC in the ethics process. To describe in detail the expectations of the AEC members. To describe in detail the procedures involved in ethical review.
- MRU-SOP-ETH-004, Code of Conduct for MRU Animal Ethics Committee Members. To describe the code of conduct for all members of the AEC regarding all AEC matters
- MRU-SOP-ETH-005 Complaints involving the AEC and animal research. To describe the appropriate avenues to address complaints by committee members and researchers
- MRU-SOP-ETH-006 Whistleblowing. To allow for avenues to address allegations of non-compliance and allegations of research misconduct, and to hear appeals where complaints are not sufficient (or have not been effective).
- MRU-SOP-ORG-002, Organizational structure and authorization procedure. MRU lines of authority and organizational structure.
- MRU-SOP-ADM-005, Animal ethics. General research/ethics policy.

10 Confidentiality

10.1 General

- 10.1.1 Committee business is confidential, to protect the intellectual property, Researchers' interests, and to permit the committee members to speak freely and frankly, as well as to protect the public image of the Facility. This policy is affirmed by signing of the confidentiality document during appointment to the committee. Breaches in confidentiality should be raised in the first instance with the Chairperson, and if not addressed to the satisfaction of the complainant, thereafter with Management.
- 10.1.2 Personal information of all AEC members will be kept confidential and filed securely at the Facility.

11 Mechanisms for Reporting

11.1 AEC members

- 11.1.1 All members have direct communication lines to the Chairperson and Management. Depending on the nature of the complaint/report, the AEC member can use one of several avenues:
- The Chairperson of the AEC
 - The global ethics office of MSD: officeofethics@merck.com
 - Management of MRU.
- 11.1.2 Should the AEC member feel that the complaint was not handled appropriately, a complaint can be lodged The National Health Research Ethics Committee: nhrec@health.gov.za
- 11.1.3 For further reference, MRU- SOP-ETH-005, Complaints involving the AEC and animal research

12 Related documents

12.1 Internal

- 12.1.1.1 MRU-SOP-AEC-002 The Role of MRU in the Ethics Process
- 12.1.1.2 MRU-SOP-AEC-003 The Role of the AEC in the Ethics Process
- 12.1.1.3 MRU-SOP-ETH-004 Code of Conduct for MRU Animal Ethics Committee Members
- 12.1.1.4 MRU-SOP-ETH-005 Complaints involving the AEC and animal research
- 12.1.1.5 MRU-SOP-ETH-006, Whistleblowing
- 12.1.1.6 MRU-SOP-ORG-002, Organizational structure and authorization procedure

12.1.1.7 MRU-SOP-ADM-005. Animal Ethics

12.2 References

- 12.2.1 SANS 10386:2021, EDITION 2. STANDARDS SOUTH AFRICA, PRETORIA, 2002 (or the latest edition).
- 12.2.2 ETHICS IN HEALTH RESEARCH: PRINCIPLES, PROCESSES AND STRUCTURES, DEPARTMENT OF HEALTH, 2ND ed. 2015 (or the latest edition).
- 12.2.3 MRC GUIDELINES ON ETHICS FOR MEDICAL RESEARCH Book 3: Use of animals in research and training (2004).

13 Appendices

None

14 Distribution

Refer to MRU-SOP-QA-02-F01 for distribution details of SOPs. This SOP is available on the public platform for MRUAEC marked as an uncontrolled copy. (<https://www.msd-animal-health.co.za/malelane-research-unit-ethics-documentation>)

15 Version History

Version	Effective date	Short description of changes
1.0	01APR2022	NEW. Collates information previously contained in MRU-SOP-ADM-005.
		Define recruitment and appointment for new members. Outline of basic training and induction given to members. Remuneration of members outlined. Tables added to summarize the review process. Define the quorum rules. Add the MRC GUIDELINES ON ETHICS FOR MEDICAL RESEARCH Book 3: Use of animals in research and training (2004) as a reference for this document. Added the responsibilities of the AEC in section 2 based on References in section 6. Outline the required composition of the AEC membership. Clearly define the rôlls of Chairperson, Deputy-chairperson, and Administrator Added several definitions to provide clarity on new included information.
2.0	24AUG2023	Requirements for non-affiliated Researchers