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Animal Research Ethics Committee
SOP for Monitoring

1. PURPOSE OF THE SOP

The purpose of this SOP is to provide researchers and the Animal Research Ethics Committee (AREC) with guidelines on the monitoring of approved studies and amendments.

2. SCOPE

The Animal Welfare Act 1999 requires animal ethics committees (ARECs) to monitor:

- i) compliance with the conditions of project approvals
- ii) animal management practices and facilities to ensure compliance with the terms of the code of ethical conduct (section 99(1)(e)).

3. Monitoring

To meet the statutory requirements, monitoring activities can be categorised as ways of assessing whether:

- (i) the welfare of animals used (i.e. research, testing and teaching) meets the standards required by the committee
- (ii) the standards of animal care are acceptable (when assessed against statutes and codes).
- (iii) inform the research community about the use of animals



3.1 Passive monitoring of protocols

Passive monitoring specifically refers to the passive monitoring of projects and their associated activities that have received ethical clearance from the AREC. Ethical approval for a project is for one year, with an option to renew the approval for up to two times, i.e., a particular project can only be approved for up to a maximum of three years.

An Annual Report must be submitted for each approved project, during which a renewal can be requested. The Annual Report will consist of sections where amendments to the original approved protocols can be requested or it can be stated that the project is ending (i.e., Closure of Project is stated). The Annual Report will also provide sections where adverse events and unexpected injuries or mortalities have occurred during the project activities.

3.2 Active monitoring

Active monitoring specifically refers to the active monitoring of projects and their associated activities that have received ethical clearance from the AREC. Applicants will indicate on the animal ethics application form whether animals will be housed onsite for the project work. Should there be animals housed onsite, inspection of the facilities may be undertaken by the AREC or the EXCO. Inspections could include inspecting the animal housing setup (prior and/or during the project activities) and observing the project procedures to ensure competence of the researcher in the approved procedures.

If procedures are being done that were not in the approved ethical clearance application, the project will be instructed to cease any and all activities until an investigation can be carried out into the project activities up to that date and a determination will be made as to whether the project will be shut down entirely or whether the project may continue. If the housing setup is deemed inadequate or not in accordance with the standards outlined in the SANS 10386:2008, the project will be instructed to cease any and all activities until an investigation can be carried out into the project activities up to that date and a determination will be made as to whether the project will be shut down entirely or whether the project may continue.

2.3 Monitoring methods

In line with the SANS and NHREC requirements, AREC will monitor the research they approve, to ensure that adequate records are kept on the acquisition, breeding, health, care, housing, use, and disposal of animals. The frequency and type of monitoring should reflect the degree and the extent of risk of harm to participants or animals. Researchers should provide comprehensive and appropriate

information to the AREC to facilitate the monitoring process.



AREC may recommend and adopt a variety of monitoring approaches which may include:

- i. random (announced and unannounced) inspection of research sites;
 - ii. monitoring of data and signed informed consent documentation;
 - iii. monitoring of recorded individual interviews/focus groups;
 - iv. inspection to verify that experimenters adhere to SOPs and other approved experimental procedures;
- inspection of the scoring of welfare monitoring sheets (animals);

3.3.1 Scheduled and unscheduled site visits

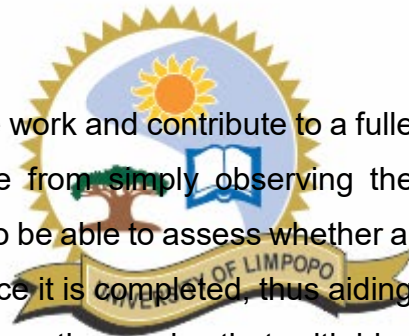
To assess whether animal use meets the protocol and conditions approved by an AREC, the committee will arrange visits to coincide with scheduled manipulations. AREC will appoint a sub-committee of two or three committee members whose attendance is easier to coordinate than that of the entire committee. The sub-committees will always include a veterinary member and one other “external” member.

A report on the visit should be prepared on completion of the visit; this is necessary to inform other AREC members (where sub-committees conducted visits) of the findings, to support any recommendations that the AREC may make to the project leader or host institution, and to provide, for future statutory reviews, evidence of the monitoring that was undertaken. Apart from providing AREC members with first-hand experience of manipulations, and hence a better basis for evaluating ethical cost-benefit in the future, observation of manipulations alongside project leaders facilitates the development of a relationship based on a common concern for animal welfare and may lead to suggested improvements in technique.

When deemed necessary AREC may carry out unscheduled visit to ...

3.3.2. Review of completed projects

Reviews by the AREC of completed projects should be retrospective, detailed assessments of the conduct of a piece of work, from beginning to end, against the specifications of the AREC-approved protocol. There are a number of potential benefits to be gained by ARECs periodically selecting a range of completed projects for review.



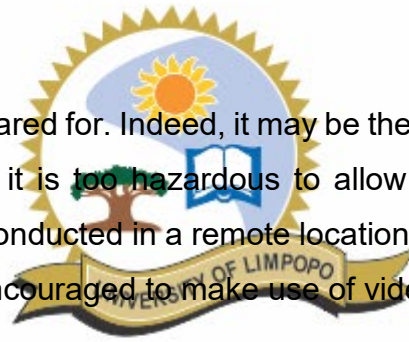
Firstly, reviews provide an overview of the work and contribute to a fuller assessment of whether it was conducted as approved than is possible from simply observing the actual animal manipulations. Importantly, the committee is more likely to be able to assess whether animal suffering was outweighed by the benefits accruing from the work once it is completed, thus aiding evaluation of future proposals. Secondly, unanticipated difficulties may sometimes arise that, with hindsight, may change the balance of costs and benefits; knowledge of this can be helpful to both project leaders and ARECs in refining methods in future proposals to use animals for similar purposes. Thirdly, project reviews are useful in assessing the adequacy of the processes used by the AREC itself in regulating research. This is a particularly valuable benefit as it can form a regular, systematic means by which the appropriateness of ARECs' codes and processes are assessed and gradually improved. Fourthly, the five-yearly code-compliance reviews carried out by independent reviewers will be helped by such "internal" project reviews; they provide concise but comprehensive "case-studies", and enable reviewers to assess how well ARECs both regulate and monitor RESEARCH. Where the scope of work by a code holder is limited (e.g. training courses using animals), it is advisable to conduct a complete review annually. Where a wide range of animal use is undertaken, the criteria listed above (1) should be used to identify where project reviews will be most useful.

4. Reports to the AREC

ARECs will require project leaders to submit interim reports at least annually, and a final report on completion. The report should be gather information on the achievements of the work in relation to the objectives, and whether any animal welfare issues (positive and negative) have arisen. As well as enabling the committees to "keep in touch" with approved work, the reports may provoke an AREC to take a closer look at how a project is progressing, or to re-evaluate some aspect of its own performance in relation to the project

5. Presentations to the AREC

Another way in which an AREC may maintain familiarity with a project, or a more general area of work, is to invite project leaders to AREC meetings to give presentations on their work. This could form a regular part of the agenda of committee meetings, and provides an opportunity for presentation and discussion of proposed new work, work in progress, or completed work. As with written reporting, the emphasis of the presentation should be on the ethical costs and benefits of the work, and the animal welfare issues it entails. AREC aim to help project leaders carry out their work in an ethically defensible manner, and useful advice, particularly from AREC veterinarians, can often be gained by researchers during the proposal stage where work entails invasive manipulation. Once studies are underway, a presentation constitutes a form of monitoring that enables the committee to observe, albeit indirectly,



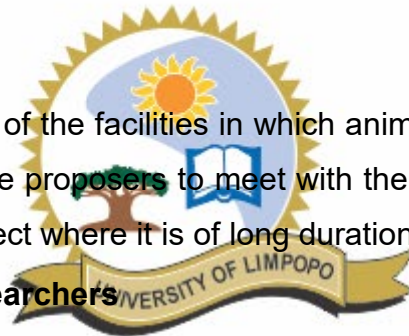
how animals are being manipulated and cared for. Indeed, it may be the only practicable way of gaining first-hand experience of the work where it is too hazardous to allow site visits (e.g. work involving infectious diseases) or where it is being conducted in a remote location (e.g. Antarctic wildlife work). In these cases, project leaders should be encouraged to make use of video to demonstrate to the AREC the manipulations carried out.

6. Compliance reporting

AREC should make provision for any staff members within the host institution to raise a concern over the conduct of work. This provides a structured means of informing the AREC and key staff when things do not go to plan. Sometimes the non-compliance may be considered justifiable in hindsight; on other occasions there may be a need to make changes to how work is conducted. The aim should be to firstly consider the action that may be needed to address any animal welfare concerns, and secondly to address procedural and personnel matters based on a clear understanding of the nature of and reasons for non-compliance. Serious cases of non-compliance should be addressed by disciplinary procedures, as determined by management of the host institution in conjunction with the AREC. In large, structurally complex institutions, statutory compliance has to be managed in a well-organised fashion; it is generally regarded as a “high-risk” area for such institutions as failure can be disastrous. AREC can assist the institution in managing this risk by supplying reports of AREC activity on an appropriately regular basis. The emphasis here should be to alert institutional management to any instances of non-compliance and the measures that have been taken to address the causes and consequences of incidents, although in serious cases, some other reporting mechanism should be used to achieve this immediately (see “Adverse incident reporting” below). While this form of monitoring is not directly aimed at meeting the statutory requirement, it may help maintain the robustness of the regulatory system by regularly reminding institutions’ management of the need to support the work of its AREC.

7. Monitoring of contracted or parented work

In some cases, an AREC may approve work that will be carried out for the host institution by a third-party animal facility under separate management. Similarly, there may be instances where an AREC is asked by another institution to “parent” work where the institution does not maintain its own AREC. Where such arrangements are made, the AREC will have the same statutory responsibilities that apply to work carried out within the host institution, and it is therefore important in both cases that high standards of monitoring are applied. Difficulty may arise where the work is to be conducted at a distance that makes normal site visits impractical, and in such cases the AREC should consider contracting the services of consultant veterinarians or auditors to carry out monitoring. It is essential, however, that the AREC defines the monitoring programme in relation to the key areas of animal welfare identified in the



proposal and with regard to the standard of the facilities in which animals will be kept. Where work is being parented, it is also advisable for the proposers to meet with the AREC when the work is being considered, and at key stages of the project where it is of long duration.

8. Monitoring of animal welfare by researchers

Where applications to the AREC anticipate a significant impact on animal welfare, the AREC should ensure that

this is monitored through the use of a purpose-designed monitoring schedule and appropriate monitoring sheets (examples given in National Research Council 2008). In certain cases, the AREC may have a particular interest in evaluating such monitoring data, and could therefore require that the information should be provided as a condition of approval. For practical purposes, it may be adequate for the AREC to receive a summary of such data.

9. AREC monitoring of animal management practices and facilities

9.1. Scheduled visits

The purpose and scope of AREC inspections of animal facilities needs to be defined clearly and may vary from, for example, inspection of a specific aspect of animal husbandry practice or the adequacy of a particular building, to a complete assessment of all practices and facilities. Complete assessments are probably most beneficial at a point midway between scheduled statutory reviews, and ARECs are encouraged to use the comprehensive checklists used by accredited reviews during statutory reviews (appendix 6). AREC inspections of animal facilities should be preceded by familiarisation with the relevant documents (e.g. livestock codes, standard operating procedures (SOPs)) that describe the physical conditions under which animals are kept, and the routine husbandry practices and experimental techniques that are used. Reference to these documents enables AREC members to judge the adequacy of facilities and practices, and may result in suggested improvements or, alternatively, modifications to SOPs.

9.2. Non-scheduled visits

As in the case of surprise visits to monitor approved work, there is the possibility that non-scheduled visits to monitor animal facilities and routine practices may have negative consequences. ARECs often include in their membership an animal carer from the host institution. This has often proved useful in forming a close linkage between the AREC and the operation of animal facilities, such that high standards are reinforced and incremental improvement is encouraged. Non-scheduled monitoring visits are likely to erode this collaborative approach, with the relationship becoming increasingly adversarial the more visits occur. However, the AREC and institutional managers need to consider whether these disadvantages are outweighed by, for example, a greater degree of public accountability in the use of

animals.



9.3. Routine monitoring of animal health

All animal facilities should routinely monitor animal health. This is essential to prevent unnecessary impact on animal welfare, to ensure that the quality of scientific data is not compromised by animals behaving or functioning abnormally, and to avoid costly and disruptive disease outbreaks. It is expected that animal carers will have been appropriately trained and capable of designing and implementing such a health monitoring programme. There is a large body of literature to assist this process.

ARECs should utilise the expertise of their veterinary representatives in periodically reviewing the monitoring programme (perhaps in conjunction with visits or as part of reviews of SOPs – see below). Committees could also request regular summaries of animal health data from facility staff as a means of overseeing the effectiveness of the husbandry practices used.

9.4. Adverse incident reporting

Adverse incidents are unanticipated or atypical events that occur to an animal as a result of routine husbandry, experimental manipulation, or diseases. Where unexpected adverse incidents or outcomes occur during research, rapid reporting is essential, primarily from the point of view of animal welfare. Understanding of incidents and how to respond to them may require specialised knowledge, so it is important that key information is recorded and reported promptly to those responsible for the work and the AREC, and a collective response made. This may be, for example, isolation of affected or potentially affected animals, closer monitoring, changes to routine husbandry or experimental procedures, or suspension or termination of the work.

10. Animal carer on the AREC

The most direct means for the AREC to monitor the day-to-day operation of an animal facility is through the membership of an animal carer of the host institution on the committee. This enables the AREC to gain insight into the culture, commitment, capability and effectiveness of the staff responsible for animal welfare.