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Animal Research Ethics Committee
SOP for Incidents/Adverse Effects

1. PURPOSE OF THE SOP

The purpose of this document is:

- To provide a clear description of the steps to follow when reporting an incident or adverse/serious adverse event promptly and confidentially.
- To give guidance to the AREC to manage the event with insight and sensitivity.

2. SCOPE

This document covers the process to be followed from the occurrence of the incident or adverse event to the successful management thereof.

3. RESPONSIBILITIES

It is the responsibility of the researcher to report any incidents/serious adverse events to AREC within 24 hours.

The AREC has to effectively manage the reported incident/adverse event within 24 hours upon receipt of the report.

4. PROCEDURE(S)

4.1 When an incident or adverse event happens the researcher must stop the study immediately and take all reasonable and appropriate steps to avoid further occurrences.

4.2 The researcher must within a reasonable time (within 24 hours) as soon as possible and complete the AREC prescribed incident report form electronically. Care should be taken to describe how the incident/adverse event was contained and how the matter will be resolved.

A detailed incident report should contain the following :

- Date
- Time
- Number of animal affected
- the description of the event
- how the event and welfare of the animals are monitored and addressed
- the actual and potential impacts of the event on animal welfare
- the actual and potential impacts of the event on the aims and outcomes of the activity
- what immediate and long-term steps are being taken or considered to investigate causes and develop future prevention strategies etc.

4.4The form should be sent via email to: arec@ul.ac.za (for research with animals)

4.5 The email is forwarded to the members of the AREC which includes the Chairperson of the AREC, and at least two other AREC members.

4.7The matter will be handled as confidential.

4.8 The researcher and supervisor/s are not included during the handling of the matter by AREC.

4.9 The secretariat of the AREC contacts the involved researcher and indicates to him/her that the study should be suspended until a full review of the situation can be instituted.

4.10 A meeting is scheduled as soon as possible with the AREC to decide how the incident/adverse event will be handled.

4.11 If additional assistance is required in the incident management strategy, other members could be co-opted.

4.12 Any further reports from the researcher are sent directly to the secretariat at arec@ul.ac.za. The secretariat then sends these to the AREC members.

4.13 Once the incident/adverse event has been satisfactorily dealt with (according to the mutual agreement of the committee members and other parties) and all outstanding documentation has been received, the incident/adverse event report is finalised and signed by the chairperson.

4.14 The Incident and Adverse Event Committee will report the incident to the executive dean of the concerned faculty.

4.15 Following completion of this process, the secretariat keep a copy of the incident/adverse event by receiving a hard and/or electronic copy of all the required documentation related to the reporting and management of the incident/adverse event.

4.16 The secretariat will place the incident/adverse event on the agenda of the next AREC meeting, during which the chairperson will give a very brief description of the incident/ adverse event and how it was dealt with.

4.17 The researcher will be informed about the outcomes of the AREC process in writing and a copy of the report will be shared with them.

4.18 If the researcher is not satisfied with the outcomes, he/she can appeal to SENATE.