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UNIVERSITY OF FORT HARE

UNIVERSITY OF FORT HARE ANIMAL RESEARCH ETHICS COMMITTEE (UFH-AREC)

STANDARD OPERATING PROCEDURE: Reporting of adverse events

Purpose

This document provides a mechanism whereby person(s), who have identified animal welfare incidents related to animal research procedures, treatments, and the care and wellbeing of research animals at the University of Fort Hare, can record important data. This data can be recorded, referenced and filed with the relevant protocol case history. This data may be used as evidence in any animal welfare investigation, allegations of research misconduct, disciplinary hearings or applications for research funding.

Scope

The process applies to all research institutions and persons conducting, and associated with, animal research. The implementation and management of this process shall be at the discretion of the UFH-AREC.

Prerequisites

All research and teaching activities have to be conducted under the auspices of an approved UFH-AREC project and as such all activities related to animals will be dictated by the approved protocol activities.

Responsibilities

1. It is the responsibility of all researchers and lecturers to ensure that they report any adverse or unexpected incidents to the UFH-AREC. Adverse or unexpected incidents are those events or incidents that are not planned or expected during experiments as laid out by the approved protocol.

Procedures

1. It is the responsibility of the researcher or lecturer to report any animals or person related adverse events or incidents that occur during the course of a research study or teaching activity (Including unexpected deaths) to the UFH-AREC and to the animal facility manager.
2. Animal welfare and mortality events should be reported within 24 hours. Other adverse events should be reported within three days. An incident report form, available from the UFH-AREC, GMRDC and on the GMRDC website, must be completed and submitted within the time frames indicated above. These time frames allow for immediate corrective action to be taken.
3. The manager of the animal research facility must co-sign the incident report or submit an independent incident report to UFH-AREC.
4. The member of the committee that received the report should forward the report to the rest of the committee immediately on receipt. This will then allow the committee to discuss the event (and potential corrective actions) via round-robin or through an emergency meeting (face to face or via skype).
5. The incident will be tabled for a full discussion at the next UFH-AREC meeting.
6. Should the committee deem it necessary, a root cause analysis should be carried out by an independent assessor to ensure that the incident will not recur.
7. The Chairperson (as a representative of the committee) has the authority to take immediate appropriate action (i.e. to suspend all further study-related activities) if circumstances indicate that such action is warranted.
8. Following corrective actions, the committee reserves the right to request frequent reports (at the committee's discretion) to monitor and evaluate the situation to assess the adequacy of the corrective action applied.

References

Forms have been adapted from the University of Kwa-Zulu Natal and University of Pretoria

SOP adopted from Stellenbosch University and University of Pretoria