



AnimCare Ethics Committee on Animal Care, Health and Safety in Research (AREC-130913-015)

Instructions for Adverse Event Containment & Reporting

AnimCare 07-02a, Version 4.10 (Nov 2016)

What constitutes an adverse event relating to animals?

These instructions relate to *project procedure-related adverse events* that threatened or affected human safety (*i.e. of the researcher, student or NWU Vivarium staff*), animal wellbeing, and/or the integrity or safety of the environment (*e.g. animal holding facility or university premises*).

- An **adverse event** relates to an untoward occurrence (*i.e. something that went wrong*) during the course of and/or as a result of the experimentation using animals, to negatively affect (*harm*) the safety/health of the researcher, the wellbeing of the animal and/or the integrity of the environment (*for example a scientist being bitten by an animal, an anecdotal adverse effect of an intervention or drug, an animal unexpectedly getting hurt, diseased, reaching humane endpoint or dying, or any other negative effect not projected or desired by the experiment*).
- An animal-related **incident** is reported by writing an informative e-mail to AnimCare Ethics-AnimCareIncident-SAE@nwu.ac.za (*i.e. NOT by completing the Adverse Event Report form*), and relates to something unrelated to experimentation, and that negatively threatened or affected the safety/health of the researcher, the wellbeing of the animal and/or the integrity of the environment (*for example infrastructural failure or use error in an animal holding facility (or other University facility) that threatens animal wellbeing or hurt animals or compromise the environment, or any emergency, event, negligence or challenge that impacts on animal wellbeing, within the jurisdiction of AnimCare, particularly at the University and any of its facilities*).

Emergency contact: ☎ 018-299-2211 📧 Ethics-AnimCareIncident-SAE@nwu.ac.za

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General instructions for the containment and reporting

Upon identification of an adverse event involving animals, the following general procedure should be adhered to the steps 1 to 4 outlined and described below.

STEP 1: Immediate intervention

1. Stop the procedure/intervention immediately and, where applicable, take all reasonable and appropriate steps to avoid any further injury or harm to any animal or human and to ensure a safe and contained environment for all animals.
2. If there is any serious **emergency** (e.g. a researcher, student or NWU-appointed field worker is seriously injured, or University property or environmental safety is seriously compromised) on campus, call the **NWU emergency number 018 299 2211**, who will facilitate appropriate handling of the emergency. Outside of the campus, however, appropriate local services must be contacted.
3. Observe closely how the disturbance has affected animal wellbeing and make the necessary notes on the appropriate monitoring sheets in this regard.
4. Follow any steps authorised by the approved protocol and notify another witness where possible:
 - 4.1. If no continued / sustained injury, pain or distress is suspected or observed, or if the environmental integrity or safety is not compromised, you may continue.
 - 4.2. ... **otherwise** continue with the steps below.
5. If any continued / sustained injury, pain or distress is suspected or observed, or if the environmental integrity or safety may be compromised, immediately notify the delegated supervisor of the animal facility (onsite or via telephone).
6. In severe cases requiring professional intervention, immediately seek the advice from the Veterinarian (onsite or via telephone).
7. Act immediately to alleviate pain or distress to the animal(s) as soon as possible, either by the veterinarian, according to the advice of the veterinarian, or if not available, as assisted by the delegated professional supervisor of the animal facility (e.g. NWU Vivarium's registered Laboratory Animal Technician), or if not available according to the approved protocol guidelines.

Importantly:

 - 7.1. Ensure at all times that all individuals perform ONLY those interventions they are competent and authorised to do.
 - 7.2. Alleviation of pain and distress always takes precedence over continuing / finishing the project.

STEP 2: Urgent intervention

8. After immediate action has been taken, ensure that the situation is fully contained:
 - 8.1. Take all precautionary measures to prevent any further adverse events or further complications following from the adverse event.
 - 8.2. Do a post-mortem investigation and report (by veterinarian or authorised person) if an animal were euthanized or died (**mandatory**).
9. Now, without delay, notify the following persons in writing of the adverse event (preferably via **e-mail**, as soon as reasonably possible – **same day or at least within 24 hours**):
 - 9.1. Project head (e.g. the principle investigator, study leader)
 - 9.2. Central notification to **Ethics-AnimCareIncident-SAE@nwu.ac.za**, which will automatically forward the e-mail to the:
 - 9.2.1. AnimCare Chairperson and adverse event committee members
 - 9.2.2. Head of the NWU Health Sciences Ethics Office
 - 9.2.3. Head of the NWU Vivarium
 - 9.3. Carbon copy (cc) to all witnesses
 - 9.4. Only if applicable, also carbon copy (cc) the following:
 - 9.4.1. If not at the NWU Vivarium, the head of the animal facility
 - 9.4.2. If on a private or state-owned property, the owner or overseeing authority

Important! In this e-mail, provide the *ethics number* and concisely describe *what happened, where & when? ... how many and which animals and/or humans were involved? ... was the matter managed and contained? ... any continued risk/uncertainty? ... anything that flags specific safety, ethical or public concern? ... any need for urgent follow-up? ... contact name & number.* The information should be clear and sufficient to enable those receiving the e-mail (*in particular*

the AnimCare chairperson) to determine whether immediate additional emergency intervention is required, or an emergency meeting is necessary to enable any further corrective and responsible action via collective consideration.

STEP 3: Timely intervention

10. Upon notification and within *one working day* the Project Head (or delegated supervisor if not available in time) should now:
 - 10.1. Follow up with a telephone call to the AnimCare chair, Prof Tiaan Brink, at **082 920 9698** (*mobile*) or **018 299 2234** (*office*), ensuring that the e-mail notification was received.
 - 10.2. Complete this Adverse Event Report Form. **Important!** Always ensure that you have the latest version of the report form (download from <http://health-sciences.nwu.ac.za/healthethics> under [AnimCare] / [Report Forms]). Previous versions will not be accepted. Also attach:
 - 10.2.1. Declaration Form for Adverse Event Reports (*separate, signed document*)
 - 10.2.2. Monitoring Sheet(s) (*as completed with observations during the adverse event*)
 - 10.2.3. Additional Statements (*where applicable*)
 - 10.2.4. Post-Mortem Report (*where applicable*)
 - 10.3. Complete the checklist (*end of document*) to ensure your application contains all required documents.
 - 10.4. Submit via e-mail the completed Adverse Event Report plus attached associated declaration form (*separate document*) and any supporting documentation to the chair: AnimCare (currently Prof Tiaan Brink at Tiaan.Brink@nwu.ac.za), and address any further correspondence directly with the chair.
 - 10.5. Receive feedback from AnimCare as applicable. **Please note!** On basis of the report (or for other relevant reasons), AnimCare may request or order further consultation with the project head.
11. In addition, the Project Head should notify the relevant Regulatory Authority where appropriate (*e.g. Department of Agriculture, Forestry and Fisheries (DAFF) as applicable*).

STEP 4: Resolving the matter

12. The AnimCare chair now:
 - 12.1. will verify all documents, procedures and measures
 - 12.2. may call an emergency meeting with the project manager
 - 12.3. may intervene (*and has the power to suspend or terminate a study, as deemed necessary in extreme cases*)
 - 12.4. may discuss this with the executive committee
 - 12.5. will report the incidence or adverse event for notice at the next AnimCare meeting (*and/or discuss and decide to accept the report, request more information or an interview with the project manager, follow-up or intervene, or even suspend or terminate the project as deemed necessary*)