ANIMAL CARE AND USE STANDARD

The Animal Care & Use Standards are designed to provide guidance regarding good practice to institutional animal users and carers, as well as Animal Ethics Committees (AECs), on the care and use of animals for scientific purposes such as research and teaching. The Standards are evidence-based, reflecting current or accepted good practice and allow for the flexibility that is required in research and teaching activities using animals.

MONITORING OF ANIMALS - POST ISSUE TO THE INVESTIGATOR

This standard has been developed by the University of Melbourne Animal Care & Use Standards Committee, and endorsed by the University of Melbourne Animal Welfare & Ethics Committee.

V1 Date of Approval:	4 April 2016	**Date of Review:**	4 April 2019

1. ASSOCIATED STANDARDS

This standard should be read in conjunction with the following University of Melbourne Animal Care & Use Standards:

- Handling and restraining mice and rats
- Training in non-surgical procedures

2. SUMMARY

Animal welfare monitoring is paramount in experimentation with animals. Monitoring measures undertaken to assess, or to ensure the assessment of, the wellbeing of animals must be in accordance with the Australian code for the care and use of animals for scientific purposes 8th Edition 2013 (The Code). Monitoring animals for scientific purposes once they have been issued to the named investigator by the animal facility occurs at different levels (including those of investigators, animal facility staff and AECs).

3. BENEFITS & RISKS

3.1 Monitoring by the investigator/s named in the approved ethics application allows for accurate assessment of the effect of the procedure being conducted or the procedure that was conducted on the welfare of the animal. This monitoring has benefits in determining the procedural effects compared to the controls. This allows the experiment to be terminated at the appropriate time to minimise the impact on animals. Pain and distress can adversely affect many biological parameters so ensuring humane endpoints are followed also allows for reliable data collection.

3.2 Monitoring by animal facility staff can be as; 1, a named investigator using the approved monitoring and intervention criteria sheets for those animals or, 2, routine monitoring which is carried out as part of the animal facility's standard practice. This has the benefits that animal facility staff are engaged with the investigators as in point 1, but also that a secondary welfare check, point 2, is conducted on the experimental animals. This has the extra benefit that additional checks are in place for monitoring animal welfare.

3.3 Risks in animal experimentation include unexpected adverse events. These are unintended impacts on the animal's welfare, i.e. signs not specified in the monitoring sheets, welfare impacts that are more severe, or welfare impacts that present more rapidly. The monitoring and intervention criteria sheets are designed and approved to capture the known welfare impacts as well as the unintended ones, and thus the risk of an unintended impact is reduced.

3.4 A potential risk of monitoring is that the time periods and frequency allotted for monitoring are not sufficient to detect animal welfare impacts.

3.5 Unforeseen complications due to a procedure or genetic influence on animals can result in animal welfare being comprised leading to an unexpected adverse event. By reporting the unexpected adverse event in detail, new monitoring and intervention criteria protocols can be established which can improve animal welfare. This then reduces the risk of future unexpected adverse events and is informative of how a procedure may affect an animal.

4. PROCEDURE/PROTOCOL

4.1 Monitoring and intervention overview

4.1.1 Monitoring of an animal can include assessment of unprovoked behaviour, physiological parameters, behavioural response to stimuli, clinical signs based on appearance or physical examination, pathology tests, and imaging.

4.1.2 Monitoring of an environment can include assessment of faeces/urine, blood/fluid discharge, nesting/bedding quality and manipulation, enclosure hazards (eg. sharp objects, toxins), ventilation, temperature, humidity, water, food, odours, noise, lighting, air pressure and vibration.

4.1.3 Monitoring must be more frequent in periods where risks to animal welfare are higher.

4.1.4 Interventions can include removal of hazards, termination of the study, adjustment of environment, seeking veterinary assistance, treatment of animals, and humane killing.

4.1.5 Where abnormal clinical or behavioural signs are noticed in animals that are not specifically listed on a monitoring sheet, the Animal Facility Manager (AFM) or Animal Welfare Officer (AWO) must be contacted.

4.2 Monitoring by named investigators.

4.2.1 The point of issue of animals is the time when investigators and animal facility staff agree to transfer welfare responsibilities of animals. Under the Code the investigator is responsible for animals from the point of issue until the end of the project.

4.2.2 The monitoring and intervention sheets are specific for each application and are designed and developed by the investigator with possible aid/consultation from the AEC secretariat, committee and/or AWO.

4.2.3 An animal may be at significantly increased risk of welfare compromise immediately after high impact procedures such as surgery or during stages of moderate to severe clinical disease. A uniquely coloured cage or record card must be used for animals at significantly increased risk to facilitate close monitoring.

4.2.4 Monitoring and intervention sheets are required to be in the room or on the rack where the animals are located. Where this is not possible they should be located in close proximity to the animals. Animal facility staff, the AWO, AECs or external auditors must be able to promptly access investigator monitoring records at all times. Where monitoring records are in a digital format, access to facility staff and others may be provided through a shared server that can be viewed within the animal room or in close proximity. Records of animals should be removed from monitoring folders at the end of each study batch and stored in an archive for the time required by legislation and University procedures.

4.2.5 All health issues that are not specific to the research (eg. fight wounds, non-experimental tumours) must be reported to the AFM for maintaining on a database. The facility database of health issues must be provided to the AWO at least every three months to ensure appropriate disease management.

4.2.6 Animals that die or are humanely killed due to an unexpected adverse event must have a necropsy. All animals that die from a cause other than due to humane killing must also have a necropsy. Necropsy results must be provided to the AFM and maintained on a database. Animals that are humanely killed as part of a study or for colony management purposes may sometimes have a necropsy performed at the determination of investigators, AFM and/or the AWO.

4.3 Monitoring by animal facility staff.

- Unless specifically listed as an investigator, animal facility staff are not responsible for the care and use of animals under a given application. Animal facility staff are responsible prior to issue of animals to a given

project; after issue the named investigator becomes the responsible person. Animal facility staff are still part of animal care, post issue, and perform 'routine' monitoring of the issued animals under the normal running practices of the facility.

Routine daily visual monitoring:

4.3.1 This is a qualitative inspection of the animals. Essentially a visual inspection of the health and wellbeing of the animals and the condition of the animal cage.

4.3.2 Visual inspection can pick up signs of distress shown in the animals such as; poor body condition, ruffled fur/feathers, hunching, size differences in animals, hair loss, fighting, bite marks, lumps, unexpected discharge from eyes and orifices, hydrocephalus, cataracts, skin colour changes, abnormal gait and mobility, malocclusion, tail deformities and dehydration.

4.3.3 The visual inspection is recorded on the routine monitoring sheet (Refer Appendix 1 for a mouse monitoring sheet) and will record that the animals were inspected in that room, the date and if any reportable issues were noted.

4.3.4 Reportable issues – these are instances when the animals are not looking well or are deemed distressed. In these instances the animals in question are recorded in the routine monitoring sheet along with the welfare issue. The investigator, AFM, AWO or veterinarian where appropriate is marked as contacted. The course of action taken to manage the welfare is the responsibility of the investigator with aid from the animal facility staff and animal welfare officer or veterinarian where appropriate.

4.3.5 Where an unexpected adverse event is observed (eg death or morbidity), this is recorded on the monitoring sheet and the investigator, AFM and AWO notified.

4.4 Monitoring specific to rodents

- Frequency of physical monitoring – within 7-10 days, all rodents will have a 'lids off' examination or cage change. In both events, all animals are visually inspected by looking into the cage and/or being picked up.

5. MONITORING & INTERVENTION

5.1 Monitoring and intervention of animals issued to a particular ethics number is the responsibility of the named investigators on the approved ethics application.

5.2 Routine daily and physical monitoring is conducted by animal facility staff as described above on weekdays, weekends and public holidays.

5.3 Monitoring and intervention sheets and criteria are designed and developed by the investigator for each project that impacts on animal welfare. Investigators should use the templates from the OREI website and add clinical signs that are specific to their project. Where uncertainty exists on appropriate criteria, advice should be sought from the AWO. In some situations a pilot study to assess animal clinical signs during the study may assist in defining criteria.

5.4 Monitoring and intervention sheets and criteria used need to be approved by the AEC.

5.5 The monitoring and intervention sheets should be reviewed where unexpected adverse events occur.

6. ADDITIONAL INFORMATION

- Australian code for the care and use of animals for scientific purposes 8th Edition 2013 (download; https://www.nhmrc.gov.au/guidelines-publications/ea28).
- Animal ethics links are on the Office for Research Ethics and Integrity web page - http://orei.unimelb.edu.au/
- Managing Approved Projects - http://orei.unimelb.edu.au/content/managing-approved-projects-animals
- OREI templates: sample monitoring and intervention sheets - http://orei.unimelb.edu.au/content/forms-templates-guidance-documents
- Guidance for investigators in designing monitoring and intervention criteria sheets http://orei.unimelb.edu.au/content/monitoring-your-animals
- Adverse incident information and form http://orei.unimelb.edu.au/content/unexpected-adverse-events-involving-animals

7. ENFORCEABLE REQUIREMENTS

7.1 Necropsy performed for all unexpected adverse events and any animal that dies of a cause other than humane killing. Necropsy records kept as above.

7.2 Investigator monitoring:

- Use of a monitoring and intervention sheet for experimental projects as documented in the approved ethics application.
- Frequency of monitoring to be adhered to as approved.
- Monitoring is completed by trained personnel as listed in the approved ethics document.
- Monitoring records located as above.

7.3 Animal facility monitoring:

- Frequency of monitoring is daily for food, water, temperature, pressure and air intake.
- 'Lids off' examination for rodents at least every 7-10 days.
- Any welfare and behavioural issues are escalated by reporting to the appropriate personnel (see Section 4.3) and recorded on the daily/routine monitoring sheet.

8. EXEMPTIONS

Where adherence to this Standard conflicts with proposed work, the University's AECs may grant exemptions to all or part of the Standard. To seek exemption, applications should clearly outline how the proposed work deviates from the Standard, and justify the need for this. Before seeking exemption, it is recommended that you consult with the University's AWO.

9. UNEXPECTED ADVERSE EVENTS

An unexpected adverse event is any event, which impacts negatively on the wellbeing of animals, and which was not anticipated, or has occurred at a frequency or severity in excess of what was anticipated in line with the AEC approval. This can be a single or cumulative event, and will normally involve unexpected mortality, morbidity or injury. Anyone identifying an unexpected adverse event must act to remove and/or minimise any immediate risk to animals. Immediately thereafter, the University's AWO and relevant AFM must be notified of the event. The AWO will advise researchers of the appropriate response.

10. GLOSSARY

Scientific Term	Lay Description
Investigator	Refer to The Code (see references)

11. REFERENCES & RESOURCES

The following source material contributed to the development of this Standard:

- NHMRC. 2013. Australian Code for the Care and Use of Animals for Scientific Purposes (The Code)
- NHMRC. 2008. Guidelines to promote the wellbeing of animals used for scientific purposes.

Appendix 1. Example Mouse Monitoring sheet

Daily/Routine Monitoring							
Room/Rack #							
Name: Initials:							
Date and time							
Temp							
Humidity							
Pressure							
ALL Air handling hoses connected correctly (Yes = ✓)							
Food checked and available (Yes = ✓)							
Water checked and available (Yes = ✓)							
Health/well-being – visual monitoring							
Health issue (Yes = ✓, No - X)							
Actions							
For health issues, list ethics numbers where an investigator was contacted.							
AFM contacted (Yes = ✓)							
AWO contacted (Yes = ✓)							

Observation	**Action**
Abnormal temperature, pressure, air handling hoses	Attempt to rectify if competent to do so. Contact Animal Facility Manager (AFM) immediately. Contact Infrastructure Services if necessary. Contact Animal Welfare Officer (AWO) if issue unlikely to be resolved promptly without impacting animals.
Low or no food/water	Add food or water. Contact responsible investigator and/or AFM to determine cause.
Health/well-being issue	Contact responsible investigator immediately. Place a uniquely coloured sick mouse card on the enclosure. Contact AFM and AWO if unexpected health issue. All animal deaths from a cause other than humane killing must be reported to the AFM and maintained on a database. Humanely kill the animal if unable to contact anyone and animal is in severe pain/distress.

AFM phone number:
AWO phone number: