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INCIDENTS REPORTABLE TO IACUC

1. Policy statement

The intent of this policy is to ensure that reportable incidents are reported timely to IACUC, IO, other NUS Officials, external agencies such as Animal and Veterinary Service (AVS), Ministry of Health (MOH) and institutions including AAALAC International.

2 Definitions

Adverse event and unexpected outcome	Any event that has a negative impact on the well-being of an animal used for scientific purposes.
Approved Protocol	Any project that involves the use of any animal for any scientific purpose and that is approved by an Institutional Animal Care and Use Committee (IACUC).
Attending Veterinarian (AV)	A veterinarian employed or contracted by an institution, on a full-time or part-time basis, with relevant training or experience in laboratory animal science and medicine to provide adequate veterinary care to the animals in the research facility of the licensee.
Genetically Modified (GM)	Genetically modified animals are animals that have had changes made to their DNA through molecular techniques. Changes in the DNA give these animals new characteristics.
Institutional Official (IO)	The person who is in the position to obtain resources for the institution's animal care and use programme and to enforce the recommendations of the IACUC.
Scientific Purposes	Any purpose for which activities (including breeding of animals integral to a research or teaching project) are performed for the acquisition, development or demonstration of knowledge or techniques in any scientific discipline, including the purpose of research, teaching, diagnosis, field trials, product testing, production of biological products and environmental studies.
Principal Investigator (PI)	A person who proposes and/or has IACUC approval to conduct a protocol involving the use of animals, and has overall responsibility of a protocol.

3 Scope

This policy applies to unexpected research outcomes, adverse events, and violation of regulatory requirements. Please refer to Annex B for details on the lists of incidents reportable to IACUC. Annex C provides a list of incidents that are not reportable to IACUC.

4 Guidelines

4.1 Principles in the monitoring and reporting of IACUC reportable incidents

4.1.1 Adverse events or unexpected outcomes negatively affect animal well-being and were not described in the approved IACUC protocol (for example, animals are not expected to die during an imaging procedure but do).

4.1.2 Adverse events and unexpected outcomes may be a result of deficiency in procedures, inadequate monitoring, faults in study design, or lack of training, etc. They may also be seen with novel procedures, new model development, or new GM animals.

4.1.3 The PI and research team members must monitor and report adverse events, unexpected outcomes or unpredicted phenotypes to the AV and the IACUC.

4.1.4 When there is adverse events or unexpected outcome, where applicable, the protocol should be amended, to establish additional monitoring parameters and criteria for humane endpoints.

5. Reporting of incidents reportable to IACUC

5.1 Guide for PIs and Researchers for reporting

The following reporting process should be followed for the reporting of phenotypes not described in IACUC approved protocol:

a. phenotypes with no welfare concerns should be reported during the Annual Protocol Review (APR) or Annual Breeding Protocol Review (ABPR); and

b. phenotypes affecting animal welfare should be reported as described in section 5.1.1 below.

Please refer to Annex B for more details on the lists of incidents reportable to IACUC and section 5.1.1 below for the reporting timeline to ensure prompt reporting.

5.1.1 PIs and Researchers should use the table below as a guide for reporting. Researchers must keep PIs informed throughout the reporting process.

If...	Report to:
Immediate care is needed (emergency). Reporting must be done immediately to Veterinary staff.	1. **Veterinary staff.** Refer to the specific contact information posted on the animal housing facilities. Reporting must be done immediately and be done by telephone. Reporting should be done following CM SOP 507 *Animal Health Reporting*.; **and**

	2. **IACUC Office.** A completed IACUC Self-Report Form (Annex D) is to be emailed to IACUC Office. Reporting should be completed within 5 working days.
Immediate care or intervention is **NOT** needed.	1. **Veterinary staff.** Refer to the specific contact information posted on the animal housing facilities. Reporting must be done within 4 hours or end of business day, whichever is sooner so that veterinary staff can assess the animal and provide care as needed. Reporting can be done following CM SOP 507 *Animal Health Reporting*. 2. **IACUC Office.** Email IACUC Office the completed IACUC Self-Report Form (Annex D). Reporting should be completed within 5 working days.
Anonymous reporting is necessary	**Option 1** Download Animal Care and Use Concerns Reporting Form, complete and submit it to IACUC Whistleblowing or call 65162644 to make an anonymous report. **Option 2** Contact the University Whistle-blowing Reporting Unit via the following channels: Email: whistleblow@nus.edu.sg Tel: 65166209 Postal address: Attn: Whistleblowing Unit, University Hall, Tan Chin Tuan Wing, UHT #03-01, 21 Lower Kent Ridge Rd, Singapore 11907 Please seal the envelope and mark "Confidential" on it. Please be assured that strict confidentiality will be maintained. More details can be found in the NUS Whistleblowing Policy.

5.2 Reporting by Comparative Medicine (CM)

The appropriate CM personnel, e.g. Clinical Veterinarian or Animal Facility Manager will either complete the CM Reportable Incident Form for the reporting of adverse events to IACUC or send an email to the IACUC Chair, Head of the IACUC office, and AV.

5.3 Reporting by NUS licensed satellite facilities and procedure rooms

5.3.1 Generally, the individual responsible for oversight of a facility (e.g., facility director or manager) should inform the IACUC of the incidents, including the corrective actions implemented to help prevent further events.

5.3.2 Reporting should be done as described in section 5.1.1.

5.4 Reporting by Office of Risk Management and Compliance (ORMC)

5.4.1 Adverse events that concern human safety must be reported promptly via the online reporting platform, Accident and Incident Management System (AIMS).

5.4.2 Upon investigation by ORMC, significant health issues, such as Level 3 incidents, that are of human health concern directly related to the animal care and use program should be reported to IACUC.

6 IACUC review and decisions

6.1 The IACUC Chair and AV will be notified of the incidents reported to determine if immediate review is needed.

6.2 All reports will be processed and any additional information required or follow-up questions will be collected as needed by IACUC Office. These reports will be presented by IACUC Office to the IACUC for review, deliberation and decision in accordance with IACUC internal SOP-007 "Reporting (Whistleblowing) and Investigating Animal Concerns" and SOP 008 "IACUC Action for Non-compliance".

6.3 IACUC will determine whether the incident is significant or serious enough to be reportable to the IO, other NUS Officials, external agencies and institutions including AAALAC International. Notification to the appropriate agencies will occur after a full discussion by the IACUC.

7 Confidentiality and protection of personnel involved

7.1 Confidentiality of the following must be protected:

a. whistle-blowers; and
b. anyone against whom allegations are directed, while allegations are under investigation

7.2 A climate free of sanction is required to foster appropriate reports and ensure a fair review of allegations. Individuals who have in good faith made an allegation of animal misconduct (whistle-blowers) will not be the object of retaliation.

7.3 Retaliation against good faith whistle-blowers will be construed as an act of research misconduct and will not be tolerated under the NUS Code and Procedures on Research Integrity. Such cases will be reported to the Institutional Official and the Research Compliance and Integrity Office for official investigation.

8. References

1. Guide for the Care and Use of Laboratory Animals. National Research Council, 2011.

2. Guidelines on the Care and Use of Animals for Scientific Purposes. National Advisory Committee for Laboratory Animal Research. 2022
3. Office of Laboratory Animal Welfare http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html
4. AAALAC International FAQ H2. Managing and reporting adverse events

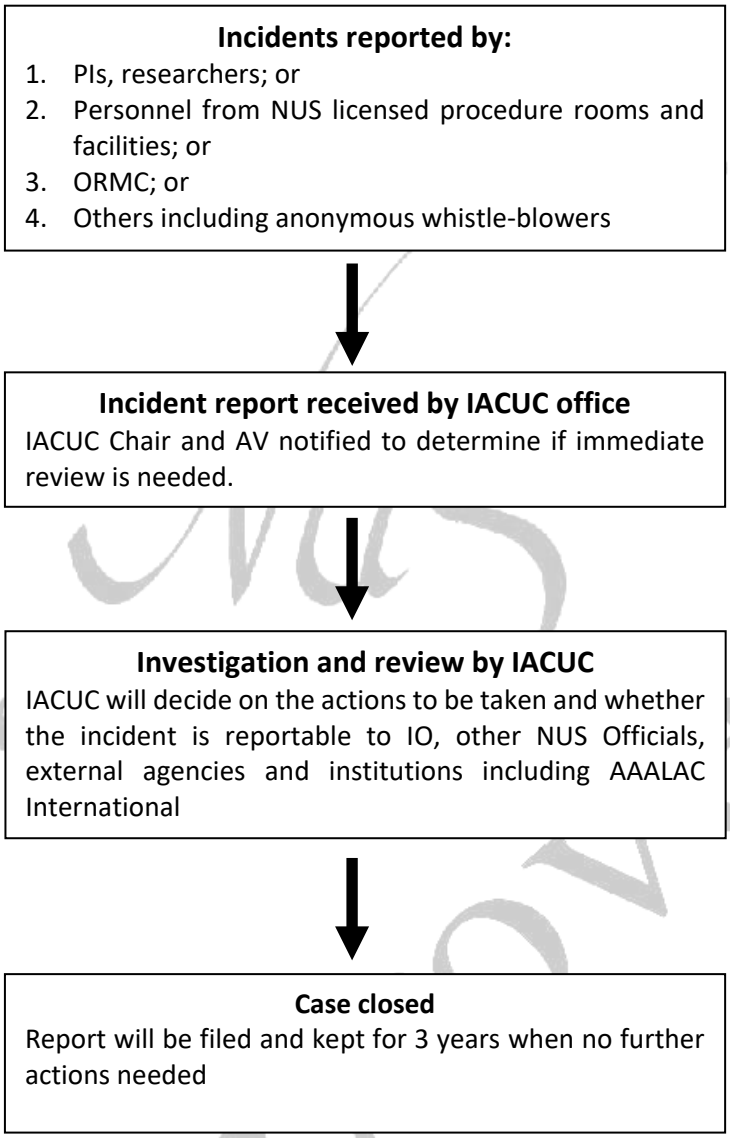
9 Related documents/SOPs

1. The NUS Code & Procedures on Research Integrity (For Academic & Research Staff)
2. P103 Notification to Investigators with Sick and Injured animals
3. IACUC SOP-007 Reporting (Whistleblowing) and Investigating Animal Concerns
4. IACUC SOP-008 IACUC Action for Non-Compliance
5. CM SOP 507 Animal Health Reporting

Revision	Author	IACUC approval date
Created	IACUC Dr Chew Li LI	20 February 2023

iacuc Approved

Annex A: Reportable incidents assessment and reporting plan



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Annex B: List of events reportable to IACUC

1. **Conditions that have a negative impact on animal wellbeing**
   a. complaints or reports regarding animal welfare concerns
   b. inadequate veterinary care, including failure of staff to carry out veterinary orders (e.g., treatments).
   c. failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anaesthesia or during recuperation from invasive or debilitating procedures);
   d. inappropriate euthanasia techniques and/or failure to confirm euthanasia, including failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO_2)
   e. unexpected research outcomes resulting in significant morbidity or mortality
   f. unexpected phenotypes resulting in significant morbidity or mortality
   g. errors or accidents resulting in actual harm or death to animals
   h. mechanical failures such as HVAC and power failures resulting in actual harm or death to the animals
   i. equipment failure resulting in actual harm or death to animals
   j. chronic failure to provide space for animals, e.g. overcrowding
   k. natural disaster that resulted in unexpected animal harm or deaths
   l. any other unexpected animal harm or deaths

2. **Conditions that have the potential to jeopardize the health or well-being of animals**
   a. significant animal rights activities, e.g. protests, break-ins, property damage
   b. internal or external reviews/inspections or other similar reports that document
      i. significant adverse events or noncompliance that resulted in animal harm or death,
      ii. investigations by national oversight bodies, and
      iii. other serious incidents or concerns that negatively impact animal well-being e.g.. failure to follow the approved protocol which resulted in compromised animal welfare, death during transport
   c. conditions that may impact colony health including
      i. Animal disease outbreaks
      ii. infestations of mold, insects, etc
   d. significant human health issue directly related to the animal care and use program, including zoonosis exposure

3. **Regulatory issues:**
   a. serious or continuing noncompliance
   b. conduct of animal-related activities or implementation of changes to IACUC-approved protocols without appropriate IACUC review and approval;
   c. failure to adhere to IACUC-approved protocols, including not adhering to humane endpoint criteria
   d. participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained
   e. conduct of animal-related activities beyond the expiration date established by the IACUC

Annex C: List of events not reportable to IACUC

a. Death or morbidity of animals related to manipulations *that are described and approved in the protocol*
b. Animal death or illness from spontaneous disease when appropriate quarantine, preventive medical, surveillance, diagnostic, and therapeutic procedures were in place and followed
c. Death of animals that have reached the end of their natural life spans
d. Death or failures of neonates to thrive when husbandry and veterinary medical oversight of dams and litters was appropriate (includes cannibalism), unless requested by vet
e. Infrequent incidents of drowning or near-drowning of rodents in cages when it is determined that the cause was water valves jammed with bedding (frequent problems of this nature, however, *must* be reported promptly along with corrective plans and schedules)

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Annex D: IACUC Self Report Form

Date of Self-report:	
Protocol Number and Project Title:	
Principal Investigator:	**Department:**
Date of incident:	**Animal species:**
Personnel involved:	
Brief description of incident:	
Brief description of the root causes:	
Clarifications from PI/researcher(s) (if any):	

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