

Document:	Policy for Assessment and Reporting of Adverse Events		
Author:			
Approved By:	IACUC		
Page:		Copy Number:	
Version:	1	Date:	23 July 2024

Background: SEMC/NLARF Animals involved in research may be subjected to events that can adversely impact their health and welfare. Adverse events must be reported internally to the Attending Veterinarian and the SingHealth Institutional Animal Care and Use Committee (IACUC). Reports externally to NParks/AVS, MOH, AAALAC International or OLAW may be considered.

Adverse Events:

- A. Any unexpected incidents that negatively affect the health and welfare of the animals
- B. Unexpected animal mortalities
- C. Anonymous reports of animal welfare concerns.
- D. Serious, unapproved deviations from NACLAR Guidelines or the PHS Guide
- E. Inadequate Veterinary Care
- F. Accidents, equipment failure, natural disasters
- G. Inappropriate euthanasia techniques/ failure to confirm euthanasia
- H. Animal escape outside the facility
- I. Disease outbreaks
- J. Suspension of IACUC protocol approval

3) INTERNAL REPORTING

- Adverse events must be reported to the Attending Veterinarian and the IACUC.
- Adverse events that require immediate action must be addressed by the veterinary team to protect animal health, safety and welfare in addition to IACUC reporting.

4) EXTERNAL REPORTING CONSIDERATIONS

- Reporting to AVS on significant adverse events will be done promptly. Less significant events may be included in the annual report to AVS, depending on the judgement of the IACUC.
- Reporting to MOH on adverse events occurring in HBRA Restricted Research Projects will be done promptly or in the annual report, depending on the judgement of the IACUC.
- Reporting to AAALAC International will be done promptly for significant adverse events. Less significant events may be included in the annual report to AAALAC, depending on the judgement of the IACUC. Examples of adverse events to be promptly

reported to AAALAC include: Unexpected animal deaths, inadequate veterinary care, significant animal rights activities, and public allegations regarding compromised animal welfare must be reported promptly to AAALAC.

- Reporting to OLAW may be done for PHS-funded projects, depending on the judgement of the IACUC.

PROCESS OF ASSESSMENT AND REPORTING:

- Once an adverse event has occurred it will be investigated by the veterinary team and reported to the Attending Veterinarian and the IACUC. A subcommittee may be assigned to investigate and report to the IACUC.

- The adverse event will be reviewed by the IACUC, either in a convened meeting with a quorum present or via email communications. A corrective and preventative action plan will be considered. A decision will be made on whether the adverse event is significant enough to recommend external reporting. The Institutional Official will be informed of external reports.