



TITLE: Adverse Event Reporting

Purpose: This procedure provides a definition of “Adverse Events” and identifies the minimum reporting and reviewing responsibilities for both protocol-related and non-protocol-related adverse events. The purpose of the reporting system is to improve monitoring for problematic trends, focus scarce time and resources on problem areas, help ensure appropriate follow-up when problem areas are identified, and clarify and harmonize expectations between the IACUC, PIs, and animal care staff, with the ultimate goal of improving animal welfare.

Definition: An adverse event is defined for the purposes of these procedures as any event that harmed or posed a threat of harm to a vertebrate animal and that meets either of the following conditions:

- The event is research-related but is not identified in the approved protocol or occurring at a rate or severity higher than is indicated in the approved protocol; or
- The event is not research-related but is unanticipated or due to a facility, physical plant, equipment, or personnel failure, malfunction, or mistake.

Examples of events that count as adverse events under this procedure include:

- Failures in HVAC systems, automatic feeders, or water systems.
- Adverse experimental treatment outcomes that were not anticipated in the protocol.
- Adverse outcome related to animal housing procedures.
- High levels of “cluster” morbidity or mortality, a grouping of animal illnesses or deaths occurring closely together, significantly above anticipated incidence.

Examples of events that do not count as adverse events under this procedure include:

- Breeding animals without an approved protocol. (The breeding would still need to be reported to the IACUC as noncompliance).
- Mortality resulting from treatment complications anticipated in the approved protocol at or below the rate anticipated in the approved protocol.

PROCEDURE: Email reporting and reviewing responsibilities for adverse events are as follows:

The PI is responsible for filing with the Animal Welfare Program Manager or IACUC via email, within 3 business days, an “Adverse Event Report” for any research-related adverse events [(1) in the definition].

The Animal Facility Lab Manager is responsible for filing with the Animal Compliance Welfare Program Manager or IACUC via email, within 3 business days, an “Adverse Event Report” for any nonresearch-related adverse events [(2) in the definition].

The IACUC is responsible for reviewing Adverse Event Reports routinely to identify potential problem areas or trends that merit attention. The IACUC maintains the right of approval of proposed corrective plans and may require further actions it deems necessary such as additional formal follow-up reporting, mandating protocol amendments, or even ordering a temporary cessation of animal use pending further review and information. Any actions taken or requirements made regarding a research-related adverse event will be reported to the PI by representatives of the IACUC.

Approved by the IACUC 14 July 2015 Author(s): S. Emer, C. Bashur

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