MONTCLAIR STATE UNIVERSITY

Policy on Adverse Events or Incidents

Institutional Animal Care and Use Committee		**Original Date: 5/6/2016**
Research Integrity and Compliance		**Minor Revisions:** **April 2020**
Reviewed by: **IACUC committee**	**Date:** **5/23/16** **4/29/2020**	
Reviewed by: **IACUC Office**	**Date:** **4/8/20**	

I. Policy Statement and Scope

This policy defines the concept of “adverse event(s)” or “incident” in animals used in approved animal research manipulation at Montclair State University and lists the institutional requirements and methods to document such problems. The reporting of adverse events, review of circumstances surrounding them, and subsequent determination as to whether procedural changes are necessary to prevent additional problems (via completion of the Incident Reporting Form) has been designed to be an interactive process between the investigators, veterinary staff and the IACUC. It is not intended as a punitive action against investigators, but as an effort to facilitate research effectiveness and improve animal welfare.

II. Applicability

The requirements specified in this policy for reporting Adverse Events apply to all vertebrate animal species used in all animal housing facilities. In some protocols, proactive project status reporting, including mortality accountability, has been required by the IACUC as a condition for project approval. Any such conditions mandated as part of the approval process in such protocols will supersede requirements specified in this policy.

III. Definitions of Adverse Event or Incident

Adverse events or Incidents in the context of this policy refer to unexpected or excessive unfavorable outcomes to research or wildlife subjects resulting in either:

a) levels of mortality 10% or greater than those anticipated in the approved protocol* (This includes both spontaneous animal deaths and animals euthanized at study-specified or other humane endpoints.)[1]

b) mortality due to complications unanticipated in the approved protocol

c) high levels of “cluster” mortality**

Adverse events in the context of this policy are generally associated with animal deaths. However, investigators should also report animal morbidity occurring either in frequency or severity beyond that anticipated in the approved protocol. In particular, morbid complications leading to unanticipated animal discomfort – especially those creating difficult to manage levels of pain and distress or situations of uncontrollable pain or distress (i.e. - Category E conditions) – should be reported.

** In many studies initial mortality may be higher than that experienced later in the project – a “learning/experience curve” effect. Although adverse event reporting is not definitively required until animal losses in absolute terms exceed those predicted in the protocol, it is considered advantageous to report unexpectedly high levels of early, relative mortality (i.e. mortality to date divided by animals used to date).*

*** Cluster mortality is defined as a grouping of animal deaths occurring closely together which are significantly above anticipated study loss levels.*

IV. Procedure

The PI (or his/her designee) should report Adverse Event or Incident as defined under definitions by electronically filing a completed Incident Reporting Form online at the IACUC website. If direct prior communications concerning such problems have already occurred with a specific LAR staff member, the completed form must still be completed. Questions as to whether events qualify as reportable should be directed to the Attending Veterinarian (A/V) or IACUC. If levels of morbidity or mortality (hereinafter M&M) cannot be maintained at protocol-specified levels with the implementation of the corrective action plan, a protocol modification reflecting this and justifying new M&M standards/levels along with other appropriate procedural adjustments should be submitted to the IACUC office.

V. Roles and Responsibilities

A. Investigator

Filing Incident Reports is the responsibility of the Principal Investigator (PI) (or his/her designee) on whose IACUC protocol those animals were listed. Investigative consultation with the A/V or Vivarium Director (if applicable) is encouraged prior to the

completion and submission of this form, especially with respect to the development of an appropriate corrective action plan (CAP).

B. IACUC Compliance Staff will:

§ acknowledge the receipt of the Incident Report in a timely fashion;
§ notify the A/V and Vivarium Director (if applicable)

C. A/V and Vivarium Director (if applicable) will:

· work with the investigative group and Vivarium staff (if applicable) in helping identify the pathogenesis of the reported event(s) and formulating or refining the formulation of an acceptable corrective action plan; and

· provide to the investigative group any feedback as to further action(s) necessary. Incident report summaries will be reported to the IACUC at meetings along with the corrective action plans established.

Normal clinical surveillance, monitoring, and problem reporting as conducted by the veterinary services and animal care staff will serve as an adjunct means to notify both the PIs and A/V of high or excessive levels of animal morbidity or mortality.

D. IACUC

The IACUC will review summaries of all Incident Reports filed. The Committee retains the final right of approval of proposed corrective action plans, and/or may require any further action(s) it deems necessary, such as additional formal follow-up reporting, specific mandated protocol refinement through modification to address concerns, or even ordering a temporary cessation of animal use pending further review and information. Any actions taken or requirements made on the part of the Committee as a result of Adverse Event Review will be reported to the Principal Investigator by representatives of the IACUC.

VI. Acknowledgment

This guidance is adapted from the content of Princeton University's policy. We appreciate Princeton in granting us permission to adapt its content for Montclair State University's benefit.

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[1] Reference to related policy: LAR Policy on Humane Endpoints for Rodents