POLICY

TITLE:	**Adverse Event Reporting**
Policy Number:	**2014-010**
Responsible Department:	**Institutional Animal Care and Use Committee**
Policy Contact:	**IACUCOffice@westernu.edu**
Approval Date:	**7/9/14**
Reviewed:	**5/10/17; 2/12/2020**
Revised:	**5/10/17 (clarified reports reviewed by IACUC, reporting to NIH, OLAW & USDA & who files report); 2/12/2020 (added Example a) below)**

Purpose of Policy: States the minimum responsibilities of an investigator for reporting any teaching- or research-related adverse event involving the use of animals.

Policy Information: To improve animal welfare, investigators must report in a timely fashion, taking into consideration the severity of the event, any teaching- or research-related adverse event involving the use of animals owned by or under the jurisdiction of Western University of Health Sciences (WesternU).

I. Definition: For the purposes of this policy, WesternU has adopted the following definition of an adverse event: Any event that results in harm or potential harm to a vertebrate animal that is either

a) teaching- or research-related but not identified in the approved protocol or is occurring at a rate or severity higher than indicated in the approved protocol; or

b) not teaching- or research-related, but is unanticipated or due to a facility, physical plant, equipment, or personnel failure, malfunction, or error.

II. Examples: Events that would be considered adverse events under this policy include, but are not limited to,

a) Negative impacts on animals from procedures or administered items that exceed what was anticipated.
b) Failures in HVAC systems, automated feeders, or watering systems.
c) Untoward experimental surgical or anesthesia outcomes that were not anticipated in the protocol.
d) Higher than anticipated morbidity or mortality.
e) A grouping of unanticipated animal illnesses or deaths occurring closely together.

The principal investigator (PI) is responsible for filing a written report with the IACUC or the Attending Veterinarian for any research-related adverse event as defined in I. a) above.

Any person involved in the care or use of research animals is responsible for informing the PI, Animal Facilities Manager, IACUC or Attending Veterinarian of any non-research-related adverse event as defined in I. b) above.

Depending on the severity, the IACUC shall review reports and decide on the appropriate course of action. Such actions may include, but are not limited to, requests for follow-up reporting, requiring protocol amendments, temporary suspension of animal use pending additional personnel training or exclusion of specific personnel from the protocol, full suspension of an approved protocol, suspension of access to animal facilities, and suspension of animal use privileges. Regulations require that suspension of any protocol involving funding from the National Institutes of Health (NIH) be reported to the NIH funding agency and to the Office of Laboratory Animal Welfare (OLAW). A similar requirement might be made by private sector funding agencies. For USDA-covered species, protocol suspension must also be reported to the United States Department of Agriculture (USDA). Reports to OLAW and the USDA must be made by the Institutional Official (IO).

The IACUC must inform the IO of all reported adverse events in a timely manner and the course(s) of action decided upon by the committee. The IO may, at his or her discretion, impose a more stringent course of action than that recommended by the IACUC. However, the IO may not under any circumstances impose a less stringent action than that imposed by the IACUC.

The PI will be informed, in writing, by the IACUC or IO of any actions taken or requirements made regarding a teaching- or research-related adverse event.