UNT DIVISION OF RESEARCH & INNOVATION Research Integrity & Compliance	**Institutional Animal Care and Use Committee** **Standard Operating Procedures**

Title: Reporting of Unanticipated Adverse Events

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Approval/Date:

Jamie Peno — 12/22/2020

Jamie Peno — **Date**

Director, Research Integrity and Compliance

REVISION HISTORY

Date	Section	Author

PURPOSE

Regulations require that the IACUC and Attending Veterinarian be apprised of any Adverse or Unanticipated Events that occur on an approved Animal Use Protocol. This procedure is in place to standardize the process for reporting adverse events or unanticipated outcomes to the IACUC and Attending Veterinarian.

SCOPE

It is the responsibility of the Principal Investigators, and Lab Animal Staff to ensure the IACUC and Attending Veterinarian are informed in a timely matter of all Adverse and/or Unanticipated Events that occur under an approved Animal Use Protocol.

DEFINITIONS AND ABBREVIATIONS

UNT- University of North Texas, Denton
IACUC- Institutional Animal Care and Use Committee
SOP/SOP's- Standard Operating Procedure(s)
PI- Principal Investigator
AV- Attending Veterinarian
Unanticipated Adverse Event- Any happening that is not consistent with routinely expected outcomes that result in any unexpected animal welfare issues (death, disease, or distress) or human health risks (zoonotic disease or injuries).

PROCEDURES

I. The IACUC, as a part of post-approval monitoring, requires investigators and animal care staff to notify the IACUC and AV of any adverse events or unanticipated outcomes to

animals during the course of the project.

A. The IACUC expects that everyone involved in the care and use of animals is aware of the need to report and procedure to report adverse events and/or unanticipated outcomes.

B. Reporting must be in a timely manner to identify ongoing trends, to ensure adequate veterinary care, and to minimize the effect on animal welfare.

C. Examples of adverse events and/or unanticipated outcomes include:

1. Unexpected clinical signs, either related or unrelated to a protocol procedure
2. Unexpected euthanasia that is not part of the approved animal activities
3. Increased or unexpected morbidity or mortality
4. Surgical complications such as anesthetic deaths, infection or wound dehiscence
5. Phenotypes associated with transgenic animals (e.g., tumor development, early death) that negatively impact the welfare of an animal
6. Facility or weather-associated events (e.g., HVAC or power failure, flooding, fire) that negatively impact the welfare of an animal.

D. Unanticipated outcomes do not include those described in a protocol or amendment, as they are potentially expected from the animal activities.

E. Animals removed from study or euthanized under early removal criteria are not considered adverse events and/or unanticipated outcomes, as they are potentially expected from the animal activities.

F. If there is a question as to the need for reporting, IACUC staff or the UNT AV will be able to provide guidance.

II. Reporting an adverse event or unanticipated outcome

A. If immediate veterinary assistance is required, contact the AV directly.

B. Report adverse events or unanticipated outcomes directly to IACUC by completing an IACUC Form 14- Unanticipated Adverse Event Form and emailing it to untiacuc@unt.edu.

1. The form is available at the Research Integrity and Compliance IACUC website.
2. The IACUC staff or the UNT AV will help finalize the report including establishing corrective action plans when appropriate.
3. When an Adverse Event/Unanticipated Outcome form is received, the following steps occur:
   a) The AV is notified of the event and may request discussion by the full committee, in which case the report will be discussed at a fully convened IACUC meeting.
   b) Based on AV and/or IACUC review, modifications to the protocol activities or other corrective actions such as additional training or post-approval monitoring may be required.
   c) Reporting to external agencies may be necessary depending on the type of event and method of funding for the study.

REFERENCES

1. PHS Policy
2. USDA Animal Welfare Regulations
3. UNT IACUC Form 14- Reporting of Unanticipated Adverse Events

APPENDICES

IACUC Standard Operating Procedures