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

Title: Required Record Keeping

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Approval/Date:

Jamie Peno — 12/22/2020

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REVISION HISTORY

Date	Section	Author

PURPOSE

This procedure is to ensure animal research activities at the University of North Texas are adequately documented in accordance with all regulations and policies. Regulations for animal use require written documentation of all procedures performed on live animals in a manner that provides the ability to track the use of animal(s) over time, as well as provide mandatory reports to regulatory oversight or accrediting agencies. Researchers should maintain and report accurate, consistent and organized records and should be able to provide them upon request to members of the IACUC and inspecting agencies during announced and unannounced inspections.

SCOPE

It is the responsibility of the Principal Investigator to maintain accurate, consistent, and organized records of all animal research.
It is the responsibility of the Principal Investigator to follow appropriate storage and retention guidelines for all research records and be able to provide applicable records upon request.
It is the responsibility of the Principal Investigator to ensure all research personnel are trained on best practices and requirements for required record keeping.

DEFINITIONS AND ABBREVIATIONS

UNT- University of North Texas, Denton
IACUC- Institutional Animal Care and Use Committee
SOP/SOP's- Standard Operating Procedure(s)
AUP- Animal Use Protocol
PI- Principal Investigator

AV- Attending Veterinarian

PROCEDURES

I. Required Records

A. Records must be sufficiently detailed to convey comprehensive and concise information that demonstrates adequate care and use standards. Records that should be maintained include:

1. Animal procurement, acquisition and health history
   a) I.e., animal origination or breeding colony, vaccinations, veterinary evaluations, transfers of custody, any previous Animal Use Protocols the subjects was used or housed under.
2. Specific animal location(s) throughout the study
3. Animal Identification
   a) For animals with multiple methods of identification, a key should be kept with the animal record that lists each method. (ie. name, tattoo number, microchip number, USDA number, Lab ID number, ear tag number, ear notching, etc.)
4. Feed and Watering schedules and details of any approved withholding and/or fasting
5. AUP # assignment and Principal Investigator, including any and all records of transfer between protocols
6. Animal Health Records
   a) Group records may be maintained for animals used and/or treated as a colony or group. (eg. fish colonies, grouped rodent breeding colonies, etc.)
   b) Individual subject records must be maintained for all USDA regulated animals and animals used and/or treated in an individual manner.
   c) Individual animal health records should include:
      i. Identity of the animal (any and all methods of animal identification should be easily found in the record)
      ii. Food and water restriction records
      iii. Descriptions of any illness, injury, distress and/or behavioral abnormalities and the resolution of any noted problem.
      iv. Dates, details and results (if appropriate) of all medically-related observations, tests, and other such procedures.
      v. Dates, details of all treatments plans, including the name, dose, route, frequency, and duration of treatment with drugs or other medications.
         (i) Treatment plans should also include a diagnosis and prognosis, and detail the criteria and/or schedule for re-evaluation(s) by the attending veterinarian.
      vi. Dates, details of periods of restraint
      vii. Dates, details of animal acclimation training, hands-on enrichment (ie. behavioral training, handling, playing) and non-invasive procedures
      viii. Dates, details of all invasive procedures including blood and tissue sampling and/ or surgical procedures. Surgical records should include detailed pre-operative and post-operative, as well as intra-operative, notes. Information should include, but may not be limited to:
         (i) all procedure reports and outcomes of procedures performed on live animals to include procedural description and methods used.
         (ii) monitored vital parameters and objective data on health status of the animal
         (iii)times, types and amounts of drugs administered (ie. anesthetic agents, analgesics, emergency drugs, euthanasia drugs, etc.) (See UNT IACUC Procedure 02-17 Standards for Anesthesia)

(iv) complications arising during or from any procedures
(v) copies of controlled substance scripts (See UNT IACUC Procedure 02-18 Use of Controlled Substances)

ix. Documentation of unanticipated adverse event reporting (See UNT IACUC Procedure 02-13 Reporting of Adverse and Unanticipated Events)

x. Records of Final Disposition (ie. euthanasia, transfer, adoption, etc.)

II. Record Storage

A. Animal Research Records should be maintained in an organized manner in a location that ensures safe-keeping throughout retention periods (see below) from environmental damage.

B. Related controlled substance records should be maintained according to federal regulations. Copies of animal subject specific controlled substance records should also be maintained as part of the animal subject record.

C. Records should be maintained near the animal subject until the animal has reached the study endpoint.

1. Following endpoints, records should be reconciled and maintained by the Principal Investigator.
2. If euthanasia is not the final disposition of the animal at the endpoint of a study, all original health related documentation should be retained and transferred with the animal. Exact copies should be made of health documents and retained with the rest of the study records.

D. Records should always be kept in a secure area that is only accessible to approved lab personnel and IACUC staff.

E. Records stored and/or backed-up electronically should be kept in the same manner as described above.

III. Record Retention

A. All animal research records should be retained for a minimum period of 3 years following closure of a study.

1. Records involving the final disposition of genetically modified species must be retained permanently through the Biosafety Office.

B. Related controlled substance records should be maintained and retained in accordance with Federal, State, and Local regulations.

C. Destruction of research animal records should be documented and carried out in a secure and final manner (ie. shredded, incinerated, removable electronic media erased and/or physically destroyed, etc.)

REFERENCES

1. The Guide for the Care and Use of Laboratory Animals.
2. Animal Welfare Act
3. DEA Code of Federal Regulations on Food and Drugs, Title 21
4. UNT IACUC Procedure 02-17 Standards for Anesthesia
5. UNT IACUC Procedure 02-18 Use of Controlled Substances
6. UNT IACUC Procedure 02-13 Reporting of Adverse and Unanticipated Events

APPENDICES

IACUC Standard Operating Procedures