STANDARD OPERATING PROCEDURES

DIVISION OF COMPARATIVE MEDICINE
UNIVERSITY OF SOUTH FLORIDA

TITLE:	**USDA-Regulated Rodent Species Medical Records**
SCOPE:	All Animal Program Personnel
RESPONSIBILITY:	Clinical Veterinarians, Facility Manager, All Research and Animal Personnel
PURPOSE:	To Outline the Procedures for the Development and Maintenance of USDA Rodent Medical Records

I. PURPOSE

1. Adequate animal care includes adequate medical record keeping.

2. The following outlines the proper procedures for the development and maintenance of medical records for USDA-regulated rodent species as defined by the Animal Welfare Act Title 9 CFR which includes species other than mice and rats of the genera *Mus* and *Rattus*, respectively, and establishes the appropriate forms used to record information, the minimal entries required, and the minimal schedule of entries to be made.

II. RESPONSIBILITY

1. It is the responsibility of the Facility Manager in conjunction with the veterinary staff to ensure that adequate animal medical records are established and kept for all USDA-regulated rodent species received and housed at their facility.

2. The PI and associated research staff named on an IACUC-approved protocol serve as the primary attending clinicians of all animals housed on behalf of that protocol. As such, research staff are responsible for providing adequate clinical oversight, and post-operative or post-procedural care of the animals, for anticipating and alleviating animal pain or discomfort whenever possible, and for maintaining complete medical records, with entries made in sufficient detail and at intervals specified by this SOP, the IACUC protocol, and the IACUC Principles and Procedures.

3. It is the responsibility of the Animal Care Technician to monitor the medical records of their assigned animals to ensure that all the required entries by research and animal care staff are recorded, and to report noncompliance with this SOP, the IACUC protocol, or current IACUC Principles and Procedures as an animal health concern as described in ***SOP #006*** entitled "***Animal Health and Environmental Surveillance"***.

4. All program staff contribute to successful compliance with this policy.

III. ANIMAL MEDICAL RECORDS

1. Regulated rodent species are assigned a unique intramural USF identification number by the Program Assistant, indicating federal fiscal year received, species, and cumulative number used. A batch of unique identification numbers can be assigned to a group of animals arriving as a group, or during inventory adjustment for animals being weaned as a group.

2. **Medical records for USDA-regulated rodent species** (e.g., guinea pigs, hamsters, naked mole rats, and gerbils) may be maintained as **colony records** for procedures performed on all animals in a group (e.g., arrival, routine husbandry, vaccinations, preventative medical procedures, surgery, research procedures, or treatments). However, **individual treatment(s) of an animal must be an entry specific to that animal.**

3. An ***Arrival Status*** form**, *CMDC# 008*** is completed for USDA regulated species that describes the condition and characteristics of the animal(s) upon arrival. A single ***Arrival Status*** form may be used to represent a group of animals that arrive as a group and assigned to the same IACUC protocol. USF identification numbers assigned to the arriving animal(s) will be recorded on the ***Arrival Status*** form.

4. **Individual entries** made to an animal medical record in response to individual procedures/treatments require that an animal be individually identified with a unique USF identification number. If an animal has not previously been assigned a specific USF ID number, a number will be selected from the set of numbers assigned to the animal's group and this ID number will be recorded on the animal's cage card and referenced when entries are made to the animal's medical record(s).

5. Although a USDA-regulated rodent medical record may be initially established by Comparative Medicine it is **maintained by the PI** and associated research staff.

6. Procedures for health surveillance and clinical record development in non-USDA-regulated rodent species are described in ***SOP# 006*** entitled ***"Animal Health and Environmental Surveillance".***

7. Research staff are **responsible for maintaining all USDA-regulated rodent medical records** as stated below unless a written justification is made by the PI requesting to defer this responsibility to the veterinary and/or animal care staff, and this request is approved by the Director or Associate Director of Comparative Medicine, or their designee.

8. Procedures or assessments that are approved by the IACUC must be performed and recorded by the research staff at the intervals indicated in the approved IACUC protocol.

9. **Log entries** must be made by the PI and research staff on the ***Progress Notes*** sheets, ***CMDC #013*** describing all procedures, substance administrations, tissue collections, observations, treatments, and use involving USDA-regulated species, and records must be kept in the animal facility.

10. **Log entries describing surgical procedures, or procedures involving a surgical plane of general anesthesia,** of USDA-regulated rodent species must be kept by the PI and research staff in the animal facility on a ***Rodent Surgical/Procedural Record*** form, ***CMDC #139*** developed and provided by Comparative Medicine. Log entries must include the surgeon, procedure, anesthetic plan, analgesic plan, patient's group/ID, body weight, time of induction, time of recovery, time of analgesia administration, and amount of analgesia administered, then initialed. For protracted surgical procedures, including terminal procedures (e.g., lasting >30 minutes), depth of anesthesia monitoring and adjustments should be made every fifteen minutes***.***

11. **Post-operative/post-procedural assessments** for USDA-regulated rodent species include, but are not limited to, analgesic administrations, condition of incision site, abnormalities, treatments, observations, and, if applicable, suture/staple removal and are recorded on the ***Rodent Surgery/Procedural Record*** form, ***CMDC #139***. A **daily entry** by the research staff must be made in the medical records of USDA-regulated species **until the third post-operative or post-procedural day following a surgical plane of general anesthesia**, which indicates that the attending research clinicians have assessed each animal and have provided any necessary or required treatments. In addition, the **dose and route of all post-operative analgesics, antibiotics or treatments, and the date of skin suture removal must be noted**.

12. The PI and associated research staff **must maintain written records** of activities **whenever painful or stressful outcomes are manifested in any animal(s)**. Records should be kept within the animal facility on forms provided by Comparative Medicine, with entries that describe when the painful or stressful outcome is first recognized, what treatments or care are instituted, and when the concerning condition is resolved, or when the animal reaches a humane or experimental endpoint resulting in euthanasia.

13. USDA-regulated rodent colony medical records **must include**, at a minimum, **weekly entries** made by the research staff on ***Progress Notes*** forms, which at least summarize the following for the colony:
    a. An impression of overall condition
    b. Food and water intake and voidings
    c. Any clinical abnormalities or complications
    d. Any treatments administered in response to observed abnormalities
    e. Any experimental procedures

    Whenever health status/observations for an individual animal differ from colony animal's health status/observations, an entry specific to that animal must be made in the colony records.

14. If a **health concern** is observed which has not been previously noted or anticipated, especially those not attributable to the research activity or for which treatment has not been initiated, Animal Care Staff must record and report the concern as described in ***SOP #006*** entitled ***"Animal Health and Environmental Surveillance".***

15. When **clinical abnormalities** are communicated to the veterinary staff that cannot be resolved immediately and requires the initiation of treatment or scheduled follow-up examinations, entries are made on the ***Progress Notes Form.***

16. When **clinical abnormalities** are recognized in USDA-regulated rodents, the PI and research staff and/or Clinical Veterinarian(s) must make entries into the colony medical record on ***Progress Notes***, which at least document the following:
    a. The abnormal physical/physiological parameters observed.
    b. Description of specimens taken for diagnosis.
    c. The treatments initiated.
    d. The identifier unique to the animal being described (e.g., cage number, tattoo number, or ear tag).

17. **All treatments**, post-treatment follow ups, and scheduled observations prescribed by the Clinical Veterinarian **must be recorded** on the ***Progress Notes Form***, and the entry initialed.

18. Animal care staff are responsible for ensuring that all treatments, post-treatment follow-ups, and scheduled observations prescribed by the Clinical Veterinarian(s) are carried out and recorded on the ***Progress Notes Form*** until the concern is resolved.

19. Clinical Veterinarians or their designee must routinely review **colony records** to ensure that the prescribed treatments and observations are being performed and recorded as ordered.

20. The Facility Manager, or their designee, must **routinely review** the ***Room Log Book*** to ensure all colony medical record-keeping requirements are being fulfilled by both the research and animal care staff and, if record keeping is found to be inadequate, contact the responsible individual for resolution. Inadequate colony medical record keeping that cannot be satisfactorily resolved is reportable to the IACUC and can result in the suspension of animal use privileges in accordance with IACUC Principle X.

21. Research staff **must make entries** to USDA-regulated rodent colony records which summarize the clinical diagnostic and necropsy findings of any **unanticipated animal morbidity or mortality,** which is thought to have occurred unrelated to the specific research protocol, so that research methods can be refined.

22. The **final disposition** of USDA-regulated species must be clearly described in the colony medical record on ***Progress Notes***.

23. The original colony medical record, when complete, must be delivered to the Facility Manager and subsequently submitted to the Assistant Director for **archival**.

24. USDA animal medical records are archived by federal year on the private shared drive in a Portable Document Format (PDF) See ***SOP #010 Handling, Storage, and Retrieval of Records and Data***.

Approved: **Date:**