FLORIDA ATLANTIC UNIVERSITY

Division of Research

SUBJECT:	**Effective Date:**	**Policy Number:**
Number Tracking and Disposition of Animals including Transfer, Reuse, Death and Reporting of Adverse Events	6/30/2023	10.4.15
	Supersedes: 6/26/2020 6/30/2017	**Page** **1** **of** **6**
	Responsible Authorities: Principal Investigator Vice President, Research Institutional Animal Care and Use Committee Assistant Vice President for Research, Research Integrity Assistant Vice President for Research, Comparative Medicine	

I. Background

Both the Animal Welfare Act Regulations (AWAR §2.31, e, 1 + 2) and the Public Health Service Policy (PHS section IV, D, 1, b; Guide p.25) require that IACUC protocols specify and include a rationale for the number of animals proposed to be used while limiting to the appropriate quantity necessary to obtain valid results. This implicates that institutions are required to establish mechanisms to monitor and document the number of animals collected, acquired or produced and used in approved activities. The Office of Laboratory Animal Welfare (OLAW) provides further guidance on what constitutes an animal at which developmental stage. The Animal Welfare Act Regulations (AWAR §2.31, d, 1, x) and the Guide for the Care and Use of Laboratory Animals (8th edition, pg. 5) discuss and discourage animal reuse as a reduction strategy as well as specify requirements for approval on a case by case basis.

II. Purpose

All research, testing, and teaching activities performed with vertebrate animals must be approved by the IACUC and the numbers of animals used in these activities will be accounted. This policy describes which animals require counting, the process of tracking animal numbers, transfer of animals between protocols, reporting of adverse events, and unanticipated deaths.

III. General Statement

Institutions are required to approve the use of vertebrate animals. Tracking the numbers of animals is essential to assure only approved numbers have been used. The reasons for identifying and tracking animal numbers are to a) fulfill federal obligations for reporting animal use and assuring compliance with IACUC-approved activities and b) to validate

statistical significance and justify the experimental groups of animals in a study, i.e. the IACUC protocol. Realizing that precise accounting of non-USDA animals is not always required nor practical, it is reasonable to expect a valid estimation of animal numbers taking into account unforeseen technical challenges or animal related complications such as unexpected disease, death, or adverse events leading to early termination of experiments. Animal numbers for USDA regulated species is required to stringently account for each individual animal.

IV. Definitions

1. **Embryos/Fetuses** are defined as the period from implantation to birth in mammals or egg to hatching in egg laying species such as in most reptiles, amphibians, fish, and all birds.
2. **Neonates/pre-weanlings/fledglings** are young animals that require parental protection and nursing.
3. **Adult animals** are defined as
   a. Animals that are mature or
   b. Have aged beyond the common weaning date specific for the species or
   c. Are old enough to be able to reproduce or
   d. Offspring of egg-laying vertebrates after hatching, including larval forms of amphibians and fish.
4. **Transfer** of animals can occur between protocols of the same PI, between protocols of different PIs or between housing locations while staying on the same protocol.
5. **Adverse events** for the purpose of this policy are defined as unexpected side effect(s) to a study compound, experimental procedure, or new animal model (e.g. new genetically modified strain) that leads to injury or illness, unrelieved pain or distress, or death of an animal enrolled in a research study.

V. Policy

A. The PI must provide an adequate justification for the requested number of animals before approval is granted by the IACUC for the use of animals in a proposed research, testing, or teaching project.
B. It may be difficult to forecast animal requirements accurately for the 3 year lifetime of an IACUC protocol since results and their impact on subsequent research direction cannot typically be predicted. Therefore, requested numbers of animals in an IACUC protocol should account for unforeseen technical challenges, experimental error, expected disease/death typical for the species and/or study incompatibility of individual animals. Requests for an additional 10% of animals over the statistically justified experimental total is commonly accepted by the IACUC, especially when invasive procedures or trapping/catching of wildlife species are involved.
C. High risk procedures/models may have higher associated death rates than uncomplicated procedures, which should be taken into account. The rationale for extra animals will be considered on a case by case basis in the context of protocol review.
D. If it becomes apparent at any time during a study that additional animals will be needed, the IACUC protocol must be amended before more than the approved number of animals can be utilized. The IACUC expects a logical explanation of why previous estimations were incorrect and why more animals are needed.
E. The IACUC must ensure that animal numbers are tracked and accounted against the approved number in the IACUC protocol. Research personnel is responsible for tracking and reporting the numbers of animals used to the staff in Comparative Medicine or Research Integrity.

F. PIs responsible for satellite facilities and PIs performing field studies will be prompted regularly to report animal numbers used during the course of their research. If a PI does not respond to the initial and follow up emails, the IACUC will be notified. The IACUC will initiate appropriate actions including protocol suspension if necessary.
G. For purposes of annual reporting of species to the USDA or other regulatory and accreditation agencies, animals are to be counted only once and in the most painful or distressful category (i.e. USDA pain categories B, C, D, E).
H. All live born vertebrate animals are to be counted as animals at any age independent of origin such as either being procured through a commercial vendor, produced within FAU animal facilities' breeding colonies, caught in the wild and then housed in captivity or involved in field studies.
I. Embryos and fetuses are not counted but the breeder animals needed to produce those need to be tallied against approved animal numbers. PIs need to describe the number of embryos/fetuses and breeder animals needed in a study based on commonly expected reproductive data of the species in the relevant IACUC protocol.
J. Larval forms of amphibians and fish are covered by the PHS Policy and need to be counted as soon as they hatch. OLAW states as an example that zebrafish larvae typically hatch 3 days post-fertilization.
K. Although avian and other egg-laying vertebrate species develop backbones prior to hatching, the interpretation of the regulation by OLAW is such that the PHS Policy does not apply to those before hatching. PIs, however, are expected to inform the IACUC about the use of eggs (e.g. of chicken, turtle) in their research and a plan for their disposition including care or euthanasia if they hatch unexpectedly. PIs must complete the egg use form if not already included in another IACUC protocol.
L. Wildlife species involved in field research that go beyond detached observation with the potential or real possibility to alter or influence the study animals and their environment must be counted. Federal regulation dictates that approximate numbers are addressed in the IACUC protocol.
M. Reuse of animals as a strategy for reduction of animal numbers is strongly discouraged by the IACUC, especially if invasive or other potentially painful/distressful procedures are involved. Any request for reuse of animals will be carefully reviewed by the IACUC on a case by case basis to determine the impact on the animal and to preserve the animal's well-being.
N. Transfers of animals must be approved by the IACUC to assure that the total number of animals used and the species of animal are appropriate in terms of the approved protocol and that multiple, unrelated major survival surgical procedures are prevented.
O. The PI must state in the transfer request whether the animal is still experimentally naïve. Rodent breeder animals and their offspring that have undergone tissue collection for genotyping only as per IACUC Policy 10.4.8 are still considered experimentally naïve for the purpose of this policy.
P. The Attending Veterinarian or their designee are authorized by the IACUC to review and approve requests for transfer of animals.
Q. Any adverse events including unexpected deaths must be reported to the IACUC in enough detail for the IACUC members to understand the circumstances. The IACUC will determine whether further investigation will be necessary and what kind of action must be implemented going forward to avoid the same or similar adverse events. This will be communicated to the PI in writing.

VI. Accountability

The Principal Investigator (PI) will be responsible for:

- Assuring requested animal numbers and associated justifications are described in detail in the IACUC protocol.
- Amending the protocol if additional animal numbers will be required.
- Keeping track of animal numbers by IACUC protocol and pain category.
- Reporting unexpected adverse events including deaths of animals to the IACUC.
- Completing transfer requests via VSATS if animals need to be moved between protocols and/or PIs.

The IACUC will be responsible for:

- Reviewing and approving, requiring modifications to secure approval of original IACUC protocols as well as amendments including proper animal number justification.
- Overseeing animal number tracking and accounting toward proposed/approved animal numbers per IACUC protocol.
- Set forth policy on reuse of animals and transfer procedures.
- Reviewing and approving actions related to reported adverse events including unexpected death(s) of animals.

The Research Integrity office will be responsible for:

- Administrative support of the IACUC members to facilitate their regulatory function.
- Maintaining policy and assure regular review and update as necessary by the IACUC.

The Attending Veterinarian/Comparative Medicine (CM) will be responsible for:

- Tracking animal numbers of animals housed within CM managed centralized facilities and providing PIs with regular updates as to the numbers used.
- Performing transfers of animals physically between different vivaria or rooms within the same vivarium as well as within the animal tracking database, crediting and debiting animal numbers as appropriate.
- Reviewing appropriateness of transfer of an animal that is not experimentally naïve.
- Supporting research personnel in investigating adverse events and unexpected mortality.

VII. Procedures

A. Numbers of any vertebrate animal procured through a commercial vendor will be entered into the CM database (VSATS) as soon as the animals are received at a CM managed vivarium.
B. If additional animals are shipped by the vendor the PI will be informed to decide whether to keep the animal(s) exceeding the ordered number. If kept by the PI the additional animal(s) will be counted against the approved number of the protocol. If the PI decides not to keep the additional animal(s), CM will make every effort to find another appropriate use such as the training protocol.
C. Animals imported from another institution, deemed a non-approved vendor, will be received into quarantine at which time they will be counted against the importing PI's protocol via VSATS.
D. Animals produced at CM managed vivaria will be entered into VSATS at the time of weaning and debited against a numeric ceiling approved by the IACUC including both those designated for use in research and those that will not be used due to inappropriate genotype, sex or other specified parameters.

E. Pre-weanling animals used in a research study must be reported to CM to enter it in the database (VSATS) and counted against the protocol.
F. Twice a year all PIs responsible for species solely housed in satellite facilities and PIs performing field studies will receive an email from the IACUC office asking PIs to report animal numbers. PIs are expected to report the following separated by species and IACUC Protocol for the time period indicated:
    1. Number of animals used including larval and pre-weanling animals
    2. Number of animals injured and subsequently euthanized
    3. Number of animals that died
G. In large-scale tank production systems, where fish are propagated, used for research in larval form, held for subsequent research projects with adults or used in production aquaculture research the large number of animals might make it impractical to be counted precisely. In those cases an estimation of the number of fish is sufficient to be reported.
H. If animals are carryovers from an old protocol they will be counted again in the new/renewal protocol. PIs need to account for this while justifying the animal numbers in the new protocol.
I. Movement of animals within animal housing rooms is discouraged. **Transfer** of animals must be requested and approved by the IACUC.
    1. Transfer of animals housed in CM managed centralized vivaria must be requested via VSATS using the *Animal Transfer Form. Any* previous experiments performed on animals must be described.
    2. If animals are experimentally naïve, the originating protocol will be credited while the new protocol will be debited the number of animals transferred. Note: The remaining number of animals on an IACUC protocol will be reported to the PI on the invoice at each billing cycle.
    3. If animals already have undergone experimental procedures the Attending Veterinarian or designee will decide whether a transfer between protocols is appropriate depending on approved procedures and numbers in the relevant protocol and the impact on the animal(s)' well-being. The veterinarian might bring the request to the attention of the IACUC for final decision at any time, especially if multiple survival surgeries are involved or the level of pain/distress would be elevated.
    4. If the request is a transfer between rooms/facilities of CM managed vivaria, the health status of animals at both locations in addition to the impact of the transfer on animal well-being will be reviewed by the AV or their designee before a final decision.
    5. Transfer of animals housed in satellite facilities must be requested via VSATS using the Animal Transfer Form – Satellite Facilities. The process of approval is the same as described above for CM managed centralized facilities except for crediting or debiting animal numbers on associated protocol(s) since animal numbers will be accounted for during the regular request to report animal numbers.
J. All animals housed in captivity must be observed at least once a day and veterinary staff must be consulted if any health concerns arise.
    1. Any animals found dead have to be noted on the daily room check sheet for both CM managed centralized vivaria and PI managed satellite facilities.
    2. The AV or their designee will check daily room check sheets regularly to spot any abnormal mortality rates for the particular species housed or animal model used.

3. PIs are expected to report health problems, unusual mortality and/or adverse events to the AV and the IACUC.

K. For wildlife research protocols, mortality resulting from anything other than a planned euthanasia as described in the original approved protocol should be reported as soon as practical, but not more than 7 days from the date of the incident.

VIII. Policy Renewal Date
6/30/2026

IX. References

1. PHS Policy on Humane Care and Use of Laboratory Animals, NIH, 2015
2. Animal Welfare Regulations, 9 CFR Ch. 1, 2 and 3
3. Guide for the Care and Use of Laboratory Animals, 8th ed
4. OLAW website: https://grants.nih.gov/grants/olaw/olaw.htm
5. Silverman, J. Collaborative Studies and Animal Reuse. Lab Animal (2008). 37(2):61-63.

POLICY APPROVAL

Initiating Authority

Signature:_____ Date:_____

Name: Gregg B. Fields, Ph.D., Interim Vice President for Research

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Executed signature pages are available in the Initiating Authority Office(s)