



Division of Research

SUBJECT: Expired & Suspended Protocols	Effective Date: 12/13/2019	Policy Number: 10.4.19	
	Supersedes: 12/15/2016 8/28/2009 12/13/2013	Page 1	of 4
	Responsible Authorities: Vice President, Research Institutional Animal Care and Use Committee Director, Research Integrity Director, Comparative Medicine		

I. Background

All Florida Atlantic University Animal Care and Use Protocols must be renewed every three years by the Principal Investigator to ensure that the study remains in compliance, that the activities have been conducted in accordance with the approved protocol, that significant modifications receive prior IACUC approval, and to ensure that any new requirements of PHS, USDA, and/or FAU are conveyed to the Principal Investigator.

II. Purpose

The purpose of this document is to describe the process for animal care and maintenance in the event a Principal Investigator's animal care and use protocol has expired or has been suspended by the IACUC.

III. Policy

An animal care and use protocol expires at 12:01 a.m. three years after the approval date (for instance, a protocol approved on December 15, 2010 expires December 15, 2013 at 12:01 a.m.). If a previously IACUC approved animal activity, as described in an Animal Care and Use protocol is allowed to expire, regardless of the circumstances, all experimental animal activity conducted under that expired protocol must cease. Continuation of experimental animal activities in the absence of a valid approved protocol is a violation of PHS Policy, terms and conditions of PHS-funded grants, FAU Policy and FAU Assurance of Compliance with PHS Policy. This activity becomes an issue of noncompliance.

Every three years the Principal Investigator must submit a new Protocol for Animal Care and Use if the project is to be continued. If the study involves USDA covered animals, annual IACUC review and approval is required of the protocol and the investigator is responsible for submitting continuing review documentation to the IACUC.

If the IACUC Protocol approval expires, animals are transferred to the holding protocol to be maintained by the Director of Comparative Medicine (CM) until such time that an active, approved IACUC protocol is in place again to transfer the animals back to. In this way, animals will always be cared for, but no experimental procedures are permitted. During times of transfer to holding protocol, the per diem charges will continue to be the responsibility of the Principal Investigator.

IV. Accountability

The Principal Investigator (PI) will be responsible for:

- Assuring that all active Animal Care and Use protocols are reviewed by the IACUC and renewed at appropriate intervals to avoid expiration of a protocol.
- Ensuring compliance to all applicable Federal and University regulations pertaining to the care and use of animals in research, teaching or testing.
- In the event of an expired or suspended protocol, will work as quickly as possible with the IACUC to re-activate a suspended protocol or renew an expired protocol.

The IACUC will be responsible for:

- Reviewing and approving, requiring modifications to secure approval or withholding approval of IACUC protocols.
- Providing oversight for all animal procedures conducted.

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
- Notification of OLAW and all applicable regulatory agencies following identification of non-compliance resulting in suspension of an approved animal care and use protocol or by PIs engaging in animal use activities following the expiration of an approved animal care and use protocol.

The Office of Comparative Medicine (CM) will be responsible for:

- Veterinary review of IACUC protocol.
- Maintenance of all animals transferred to a holding protocol from an expired or suspended protocol as necessary while the PI works with the IACUC to re-activate a suspended protocol or submit a new application to the IACUC for renewal following protocol expiration.
- Keep all applicable records during the maintenance of the animals and provide them as necessary to the PI upon transfer back to an active protocol.

V. Procedures

Expired Protocols

The day a protocol expires, the IACUC office will send a letter to the Principal Investigator informing him/her that the protocol has expired. If there are still animals on that protocol:

1. The Principal Investigator will be notified of the protocol expiration, consequences, including the transfer of animals to the Comparative Medicine Holding Protocol and cessation of research with the animals on the protocol as well as the process for correction including the submission of a new animal care and use application for review by the IACUC.
2. The location, species, and number of animals will be determined by Comparative Medicine.

3. The animals will be transferred to the holding protocol using the “Animal Transfer Form.”
4. The Facilities Manager or Technicians will post the animal room door and/or cages with a notice that indicates that no research associated with the expired protocol is to be conducted.
5. Upon IACUC approval of the new protocol, the animals will be transferred back to the Principal Investigator’s protocol and the research may resume.
6. If the three-year approval period has expired and the teaching or research associated with the expired protocol has continued, it is considered non-compliance with IACUC and federal policy, and a “prompt report” to the Office of Laboratory Animal Welfare (OLAW) is required.
7. The IACUC Office, in conjunction with the Chair and Institutional Official (IO), will report promptly to OLAW. After completion of internal procedures, the IACUC Chair and IO will submit a written summary report to OLAW outlining the facts surrounding the violation and all corrective actions taken.

Suspended Protocols

The procedure for protocols suspended by the IACUC is the same as for expired protocols with the addition of required “prompt reports” to OLAW, the funding agency (if applicable), and any relevant regulatory or accrediting agencies. The IACUC Office will ensure that all appropriate notifications are performed in a timely manner. The Principal Investigator will receive a letter from Research Integrity to which s/he has to respond with an action plan. Additionally, if the Principal Investigator does not respond to the IACUC with a corrective plan of action as requested in a timely manner, the IACUC can proceed with closure of the protocol among other possible actions following a majority vote of the full committee.

Maintenance of Animals Associated with Expired or Suspended Protocols

The CM Director will maintain an Animal Holding Protocol (AHP) for animals on an expired protocol that are housed at FAU.

If an expired/suspended protocol covers animals purchased and maintained by CM:

1. CM identifies active cage cards under the expired protocol, transfers those cages and animals to the AHP, and contacts the principal investigators.
2. The cages are tagged with an identifying mark so that all staff will recognize that these animals may not be used in any way, only maintained.
3. Maintenance may include the provision of special diets, medicines, and procedures necessary to maintain the animals in a condition suitable for further studies. However, no data collection in conjunction with the research described in the protocol may be done.

If an expired/suspended protocol covers animals not purchased or maintained by CM (e.g., turtles, stingrays, fish, wildlife, etc.)

1. The IACUC Office notifies the responsible group and requires response as to ongoing presence of animals on that expired protocol.
2. Maintenance may include the provision of special diets, medicines, and procedures necessary to maintain the animals in a condition suitable for further

studies. However, no data collection in conjunction with the research described in the protocol may be done.

3. Charges might be incurred and invoiced to the research lab associated with husbandry and care.

Breeding colonies may be maintained and litters weaned. CM will determine and oversee the individuals (whether CM or research staff) performing maintenance procedures.

CM shall establish a service fee associated with keeping animals on the AHP. Service fees and per diem fees will continue to be the responsibility of the PI (see CM service fee chart <http://www.fau.edu/research/comparative-medicine/service-fees.php>).

Holding Protocol Timelines

- If a renewal protocol has been submitted, the animals may remain on the AHP for up to three months from the expiration date of the prior protocol while awaiting IACUC review and approval.
- If a renewal protocol *has not yet been* submitted, the animals may remain on the AHP for no more than one month from the expiration date of the prior protocol unless a renewal protocol is submitted during that month, at which time the animals may remain on the AHP for a total of two months from the submission date of the renewal protocol while awaiting IACUC review and approval.
- After holding protocol timelines have elapsed, animals on the AHP may be transferred to another protocol, if appropriate, or humanely euthanized by CM or the husbandry/veterinary staff responsible for non-CM administered facilities. *In the case of wildlife studies, it may not be appropriate to euthanize the animals. In such cases, the investigator may release the animals in accordance with any applicable guidelines and regulations.*

VI. Policy Renewal Date
12/13/2022

VII. References

1. PHS Policy on Humane Care and Use of Laboratory Animals
2. Guide for the Care and Use of Laboratory Animals, 8th edition, 2011

POLICY APPROVAL

Initiating Authority

Signature: _____

Date: _____

Name: Daniel C. Flynn, Ph.D., Vice President for Research

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