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UNIVERSITY COMMITTEE ON USE
AND CARE OF ANIMALS (UCUCA)

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UCUCA Policy and Procedures for Continuing Review of Animal Research Protocols

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I. Federal Regulatory Requirements for Continuing Review of Animal Research Protocols

Public Health Service Policy

The Public Health Service Policy on the Humane Care and Use of Laboratory Animals (PHS Policy) states that animal protocol approvals may not be granted for more than 3 years, and extensions may not be approved administratively. That is, every three years a protocol must undergo *de novo* review.

Conducting animal activities – including housing, breeding, interventions/ experimental manipulations, and euthanasia – after a protocol has expired is a violation of NIH grants Policy, as well as the PHS Policy. The Office of Laboratory Animal Welfare (OLAW) views such activity as a serious violation of the PHS Policy and these instances must be promptly reported to OLAW by the University's Institutional Official. Institutions are also required to report to the appropriate NIH Institute/center any charges to grant awards for the conduct of animal activities during lapses or after expiration of UCUCA approval.

USDA Animal Welfare Act

The USDA also requires continuing review of animal use protocols by the institution's committee for the care and use of animals. The USDA stipulates that these renewals must be done no less than annually.

II. Institutional Definitions, Policy, and Procedures for Prior Notification of Three-Year Expiration of Protocol and for Prevention of Non-Compliance Associated with Expiration

A. Definitions:

- i) **Expiration Date** – the 3 year anniversary date of approval (i.e. expiration under PHS Policy). The UCUCA reserves the right to define expiration date prior to the 3 year anniversary, if necessary.
- ii) **Institutional Official** – the individual ultimately held accountable for institutional compliance with PHS and USDA animal policies, currently the Vice President for Research.

- iii) **Submission Deadline** – eight weeks (~60 days) prior to the expiration date (see above). It is this date by which the protocol ***must*** be submitted to the UCUCA if it is to continue without a lapse in approval status (i.e. if animals will be housed and/or experiments will continue after the expiration date).

B. Policy on Expired Protocols

The University of Michigan does not permit any experimental manipulations with vertebrate animals that have not been reviewed and approved by the UCUCA. No NIH grant award may be charged for non-experimental animal maintenance activities absent explicit prior approval of the NIH Institute/Center funding the award.

C. Procedure for Prior Notification of Three-Year Expiration of Protocol and for Prevention of Non-Compliance Associated with Expiration

1. *One hundred twenty (120) days (approx 16 weeks)* before the protocol expiration date (8 weeks prior to the submission deadline) an email entitled “Expiration Notice” will be sent to the Principal Investigator (PI) and laboratory contact stating that the protocol is due for renewal and the date that it will expire. The email will provide the following information, and request a response from the PI:
 - i. The submission deadline for the renewal application
 - ii. The procedures for submitting a renewal protocol in eSirius
 - iii. An explanation of PHS and NIH Policies that pertain to protocol expiration and the effect of expiration on continued animal work and funding
 - iv. A request that the PI notify the UCUCA office regarding the plan of action regardless of whether the protocol will be continued
 - v. Instructions regarding submission of any required transfer approval forms
2. *Ninety (90) days* before protocol expiration (approximately 4 weeks prior to the submission deadline), if the renewal protocol (or an action decision to expire) has not been received, the UCUCA office will send another notification entitled “Second Expiration Notice” to the Principal Investigator (PI) restating the information in the first notice. This notice will also be sent to the PI’s department administrator and laboratory contact, and will include a notice reminding the PI of the consequences of a lapsed protocol, as outlined in C.5 below.
3. *Sixty (60) days* before protocol expiration, which is the submission deadline, if the renewal protocol (or an action decision to expire) has not been received, the UCUCA office will send another notification entitled “Third Expiration Notice” to the Principal Investigator (PI) that reiterates the information provided in the first expiration notice and in C.5 below, but also states that the UCUCA is unlikely to be able to renew the protocol prior to the expiration date. This notification will also be sent to the PI’s department chair and administrator and laboratory contact.
4. *Thirty (30) days* before protocol expiration, if the PI is currently housing animals on the expiring protocol, correspondence will be sent to the PI with instructions for how to transfer the animals off of the soon-to-expire protocol number along with an

explanation for why this is necessary in order to avoid non-compliance. The PI also must identify a non-federal account that will pay for charges associated with their care.

5. On the *protocol's expiration date*,
 - a. If the UCUCA Office has been notified that the protocol will be allowed to expire and there are no animals in house, the PI and a contact with the Unit for Laboratory Animal Medicine (ULAM) will receive an email that states the following information:
 - i. No further experimental manipulation under this protocol will be permitted unless the renewal protocol has been approved by the UCUCA
 - ii. Animal ordering privileges for this expired protocol have been suspended
 - b. If the renewal protocol has been approved, the PI and a contact with the Unit for Laboratory Animal Medicine (ULAM) will receive an email that states the following information:
 - i. No further experimental manipulation under the expired protocol will be permitted
 - ii. Animal ordering privileges for this expired protocol have been suspended
 - c. If a renewal protocol has been submitted and there are animals currently in house which have been moved to another approved protocol, the PI and a contact with the Unit for Laboratory Animal Medicine (ULAM) will receive an email that states the following information:
 - i. No further experimental manipulation under this protocol will be permitted unless the renewal protocol has been approved by the UCUCA
 - ii. Animal ordering privileges for this expired protocol have been suspended
 - d. If a renewal protocol has not been received by UCUCA and animals are being housed and have not been transferred off of the expiring protocol, the PI, the PI's Department Chair and Administrator, a contact within the Unit for Laboratory Animal Medicine (ULAM), and UCUCA Manager will receive an email that states the following information:
 - i. No further experimental manipulation under this protocol will be permitted
 - ii. Effective on the day following the expiration date, all animal charges associated with the expired protocol will be moved to University accounts not associated with the corresponding NIH grant or any other government funds
 - iii. Animal ordering privileges for this protocol have been suspended
 - iv. The ULAM husbandry staff will be alerted that the protocol has been terminated and will be asked to provide verification that no animals are being housed under this protocol number.
 - v. If animals remain in the facility, the UCUCA Office will transfer the animals to the holding protocol, the investigator and staff may be denied access to the housing room, and care will be taken over by ULAM. The PI also must identify a non-federal account that will pay for charges

associated with their care. These animals should not be sacrificed because of protocol expiration.

6. All correspondences related to the procedures above are appropriately filed in the UCUCA offices.