

## UCAR Policy Regarding Continuing Reviews of Animal Protocols

### **36-Month Review**

All protocols are approved for period of 36 months from the date of initial approval. According to the Public Health Service (PHS) policy, approved protocols must have a *de novo* review every 36 months, and cannot be administratively extended past the 36-month termination date. Failure to obtain reapproval by 36 months from the approval date will result in termination of the protocol. At the point of protocol termination, all animal work (including breeding) on the protocol must cease. Likewise, **protocols for active grants may not be allowed to lapse**. The **PHS Policy** states “When IACUC approval expires, it is no longer valid. Continuation of animal activities beyond the expiration is a **serious and reportable violation** of the PHS Policy”. If the grant associated with a lapsed protocol is still active, and animal work is currently being performed or planned for the future, **UCAR must notify the Office of Laboratory Animal Welfare (OLAW)** that the animal work on the grant no longer has approval. UCAR will notify ORPA (Office of Research and Project Administration). It is ORPA’s responsibility to notify NIH of the lapse in animal use approval. The UCAR will also notify the Institutional Official, the appropriate dean, and the PI’s Department Chair.

- A letter (via e-mail) requesting submission of forms for 36-month review will be sent to the PI four months prior to the expiration date of protocol. **If PI does not plan to renew the protocol, he/she must notify UCAR.**
- UCAR will e-mail PI one month after the original request (i.e., approximately 90 days), a reminder notice to submit the appropriate animal care and use forms.
- ORPA will be contacted to confirm this is a funded and active grant, requesting an accurate grant number.
- UCAR must receive the completed protocol for 36-month review, at least **60 days** before the expiration date. This review must take place even if there have been no changes in the protocol or the research described per PHS policy.
- If no protocol has been received by **30 days** from protocol termination, a final notice is sent to the PI, copying the Chair and Administrator of the Department.
- The Research and Training Coordinator (RTC) is notified at this time of the PI Name and protocol number. The RTC will check with the vivarium to see if there are animals in house.
- At 5 PM on the day of expiration (or 5 PM of the last business day before expiration, if expiration falls on a weekend or holiday), the protocol will be terminated. UCAR will check to see if the PI still has animals in house under that protocol. The PI will no longer be allowed access to these animals, and all animal work on that protocol (including breeding) must stop immediately. Animal care will then be governed by the Animal Holding SOP until an appropriate plan can be made for their use or euthanasia.
- PHS policy does not allow for charges associated with animal per diems, or research to occur if there is no active protocol. All per diem charges for animals transferred to the Animal Holding SOP will need to be moved to a department or other nonfederal discretionary account that will allow charges related to animal housing.
- If the protocol is for an active grant, UCAR will notify ORPA that approval for animal use has been allowed to lapse for an active grant. ORPA is responsible for notifying NIH. In addition the appropriate dean and PI’s chair are notified.
- If animal use continues on an expired protocol, UCAR will report this serious PHS Policy violation to OLAW, Institution Office, appropriate Dean and Department Chair.
- If the grant is no longer active, the protocol will be allowed to terminate. Animals on that protocol must be transferred to another approved protocol or euthanized within five working days before the protocol is allowed to terminate.

### **Annual Protocol Reviews (APR)**

The University Committee on Animal Resources is also required by PHS policy to conduct “continuing reviews of each previously approved, ongoing activity.” The mechanism we use for this continuing review is the Annual Protocol Review (APR). This procedure has also been modified to comply with OLAW’s clarification of the PHS *Guide (REF)*.

Principal Investigators are sent the APR (via e-mail) one month prior to the anniversary date of the approval of an animal protocol. If the PI has not returned the APR by 8 AM on day of expiration, UCAR will check to see if the PI has animals in house under that protocol and the protocol will be terminated if

the census is zero. If animals are housed in the vivarium or associated facilities, the PI and research associates will no longer have access to these animals, and all experiments on them must stop immediately. Animal care will then be governed by the Animal Holding SOP until an appropriate plan can be made for their use or euthanasia.

The PHS *Policy* states “IACUC review following the provisions at IV.C.2. of the PHS *Policy* must be accomplished at least once every three years <sup>1</sup>. The IACUC may not extend the three-year approval by any means other than IACUC review and approval using the procedures of IV.C.2. When IACUC approval expires, it is no longer valid. Continuation of animal activities beyond the expiration is a serious and reportable violation of PHS *Policy*.”

If the protocol is for an active grant, UCAR will notify OLAW and ORPA that animal use approval has been allowed to lapse for an active grant. ORPA is responsible for notifying NIH.

Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, revised May, 2015)

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