Institutional Animal Care & Use Committee

Policy for Expiring Protocols (P6.02)

The Tulane University Institutional Animal Care and Use Committee (IACUC) approve protocols for a period of three (3) years. Federal Regulations mandate that research procedures cannot continue once a protocol has expired.

The following procedure is used for all protocols that approach end of the approval period.

- Approximately 120 days before the expiration date a notice is sent to the Principal Investigator (PI), or his/her representative. This notice will state (a) the date on which the protocol will expire, (b) the need to have a renewal protocol approved before the expiration date if the study is to continue. Additional notices are sent at 90 and 60 days prior to expiration. If the PI responds to the notice indicating that the animal research is to continue, it is his/her responsibility to ensure that a renewal protocol is submitted to the IACUC office in time to obtain approval before the expiration date.

The following procedures will be used for all protocols that expire and have animals assigned.

1. If a renewal protocol is not approved prior to the expiration date, the PI will be notified that animals assigned to the study will be placed under the care of the Department of Comparative Medicine (DCM) or the Division of Veterinary Medicine (DVM). The PI and the PI’s staff will be denied access to the animals until the renewal protocol is approved. The Director of the DCM/Chairman of the DVM and/or designated personnel will be notified that the animals assigned to the expired protocol must be placed under the care of the DCM / DVM. No research procedures will be allowed to be conducted and the DCM / DVM will provide clinical care as needed. Animals can be maintained under the care of the DCM / DVM for up to 2 months. At the end of 2 months, the IACUC in consultation with the Institutional Official (IO) will determine the disposition of the animals.

The Office of Management and Budget Cost Principles and the National Institutes of Health (NIH) Grants Policy Statement (NIHGPS) do not permit charges to grant awards for the conduct of animal activities during periods of time that the terms and conditions of the NIHGPS are not upheld. Specific situations under which charges are not allowable are:

- The conduct of animal activities in the absence of a valid Assurance on file with the Office of Laboratory Animal Welfare (OLAW).
- The conduct of animal activities in the absence of valid IACUC approval of the activity. Absence of IACUC approval includes failure to obtain IACUC approval, expiration, or suspension of IACUC approval. ([http://grants.nih.gov/grants/olaw/references/phspol.htm](http://grants.nih.gov/grants/olaw/references/phspol.htm))

2. Institutions are required to report any such incidence to the Institute/Center (IC) supporting the award. NIH expects grantees to continue to maintain and care for animals during the periods described above. Funding components may allow expenditure of NIH grant funds for maintenance and care of animals on a case-by-case basis.
3. Additionally, continued conduct of animal-related activities beyond the expiration date constitutes serious noncompliance with Section IV.F.3. of the Public Health Service (PHS) Policy and as such must be promptly reported to OLAW in accord with the PHS Policy (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html)

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