

this case, the PI would need to describe the appropriate experimental procedures in the continuation application and account for the number of animals that will be transferred.

1. Public Health Service. *US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training*. Policy No. 102.02. (US Department of Health and Human Services, Washington, DC, 2002).
2. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* (National Academies Press, Washington, DC, 1996).

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RESPONSE

Plan ahead

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A submitted protocol must include all animal work to be done under that protocol; this includes work in a renewal protocol being conducted using animals remaining from an expiring protocol. It is the responsibility of the IACUC to develop mechanisms by which a PI can transfer animals from an expiring protocol to a renewal protocol that covers the activities involving those animals. The simplest way to do that is to provide a place in the protocol application for the PI to list animals that need to be transferred from an expiring protocol and to explain what, if any, procedures were done with those animals under the previous protocol and what procedures or studies will be done under the renewal protocol. The transferred animals should be counted and added to the number of new animals requested by the PI in the renewal protocol to calculate the total number of animals approved. Timing can complicate the transfer process. For example, on the day the renewal protocol is submitted to the IACUC office, the PI may have 30 rats remaining on the expiring protocol. But at the time of final approval of the renewal protocol, 10 rats may have reached the study endpoint, leaving only 20 rats; yet the new protocol was approved for 30 transferred rats. This difference does not constitute a problem, however, as regulatory language (Public Health Service *Policy on Humane Care and Use of Laboratory Animals* (PHS Policy)¹ and the Animal Welfare Act

and Regulations²) on IACUC approval of animal numbers always uses the term 'approximate', giving both the IACUC and the PI the necessary leeway to plan animal studies in a dynamic environment.

While it is the IACUC's responsibility to ensure that animal activities are not done in the absence of an approved protocol³, it is the PI's responsibility to determine the disposition of animals remaining on an expiring protocol. If the animals will not be used under the renewal protocol, the PI may choose to terminate them and collect research data or may consider offering them for sale or transfer to other PIs who may be able to use them. The latter activity would require oversight from the animal resource department or the IACUC to ensure appropriate accounting of animal use.

1. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
2. Animal Welfare Act and Regulations.
3. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals – Frequently Asked Questions* (US Department of Health and Human Services, Washington, DC, 2006; revised 2009). <<http://grants1.nih.gov/grants/olaw/faqs.htm>>.

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RESPONSE

No 'ongoing' work

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Animal use protocols must be reviewed by the IACUC at appropriate intervals in accord with the Animal Welfare Act and Regulations¹, the PHS Policy² (not less than once every three years), USDA¹ (not less than annually), the US Government Principles for Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training³ and the *Guide for the Care and Use of Laboratory Animals*⁴.

Our animal use protocols include an identification of the species and approximate number of animals to be used; the rationale for involving animals and for the appropriateness of the species and numbers used; and a complete description of the proposed use of the animals.

Annual renewals and modifications can be monitored by the use of a standard form containing basic protocol information: status of the project, assurance that activities are being done in accordance with the approved protocol and proposed departures from the protocol in the upcoming year. The USDA regulations¹ (9 CFR Part 2, Subpart C, 2.31(c)(7); 2.31(d)) and the PHS Policy² (IV.C.1) require that proposed significant changes to the currently approved protocol be reviewed and approved by the IACUC prior to implementation.

Once IACUC approval of a protocol has expired, the PI may not carry on any ongoing experimental work. Any work that is to be continued must be included in the newly submitted protocol and approved by the IACUC before the work can resume. The new protocol can be reviewed either at a regularly scheduled IACUC meeting or, if available, by designated member review. Carrying out any animal activities in the absence of valid approval is a serious and reportable violation⁵.

Any animals remaining on a protocol at the expiration of the approval period must be disposed of unless they can be transferred to an IACUC-approved protocol or renewal. These animals must be of the appropriate species, strain, age, genotype or sex listed in the new protocol, and the number of animals transferred contributes to the total animal numbers approved by the IACUC. If the institution has an IACUC-approved 'holding' protocol in place, animals may be temporarily transferred pending committee review and approval of a new animal use protocol.

1. Animal Welfare Act and Regulations.
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
3. Public Health Service. *US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training*. Policy No. 102.02. (US Department of Health and Human Services, Washington, DC, 2002).
4. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* (National Academies Press, Washington, DC, 1996).
5. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals – Frequently Asked Questions* (US Department of Health and Human Services, Washington, DC, 2006; revised 2009). <<http://grants1.nih.gov/grants/olaw/faqs.htm>>.

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