

## LABORATORY ANIMAL WELFARE: CHANGE IN PHS POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS

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National Institutes of Health (NIH)

In the March 28, 2002, Federal Register (and the April 5, 2002, NIH Guide for Grants and Contracts), the NIH announced that it was considering a change in the PHS Policy on Humane Care and Use of Laboratory Animals to allow institutions to provide IACUC approval in a "just-in-time" fashion prior to award, as is now permitted for IRB approval. The comment period ended on May 28, 2002, and responses from the research community and institutional officials were overwhelmingly in favor of this change. Consequently, the NIH now announces that beginning with applications submitted for the October 1, 2002, receipt date (and any other receipt dates that result in applications being reviewed for May/June 2003 Councils), IACUC "just-in-time" will be in effect. That is, institutions will be permitted flexibility in the timing of IACUC review relative to submission of an application.

The NIH wants to emphasize certain principles and expectations of the "just-in-time" process for IACUC review and approval.

- o The fundamental PHS Policy requirement that no award may be made without an approved Assurance and without verification of IACUC approval remains in effect. This change only affects the timing of the submission of the verification of that review.
- o This change is intended to permit flexibility and discretion on the part of the institution. It is not a requirement that IACUC approval be deferred. Institutional officials retain the discretion to require IACUC approval prior to peer review in certain circumstances of their choosing if they so desire.
- o Under no circumstances may an IACUC be pressured to approve a protocol, or be overruled on its decision to withhold approval. NIH peer review groups will continue to address the adequacy of animal usage and protections in their review of an application, and will continue to raise concerns about animal welfare issues. However, in no way is peer review intended to

supersede or serve as a replacement for IACUC approval. An institution that elects to use IACUC "just-in-time" bears the responsibility for supporting the role of the IACUC.

o It remains incumbent upon investigators to be totally forthcoming and timely in conveying to their IACUCs any modifications related to project scope and animal usage that may result from the NIH review and award process. Should an institution find that one of its investigators disregards his/her responsibilities, the institution may, for example, determine that all animal protocols from that investigator be subject to IACUC approval before it will permit submission of an application from that investigator.

o The existing PHS Policy requirement that modifications required by the IACUC be submitted to the NIH with the verification of IACUC approval remains in effect, and it remains the responsibility of institutions to communicate any IACUC-imposed changes to NIH staff.

o The NIH understands its responsibility to ensure that institutions are given adequate notice to allow for timely IACUC review prior to award, and will take appropriate internal measures to fulfill its responsibility to establish timely feedback.

An announcement is published in the Federal Register (67 FR 51289), giving the precise language change and citation in the PHS Policy.

To see the Federal Register Notice in HTML format, go to:

[http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002\\_register&docid=fr07au02-108](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=fr07au02-108).

To see the Federal Register Notice in PDF format, go to:

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