**Clarification on the Roles of NIH Scientific Review Groups (SRG) and Institutional Animal Care and Use Committees (IACUC) in Review of Vertebrate Animal Research**

**Notice Number:** NOT-OD-10-128  
**Key Dates  
Release Date:**   September 1, 2010  
**Related Notices:** [March 17, 2010](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-027.html): see NOT-OD-10-027, Instructions for Completion and Peer Review of the Vertebrate Animal Section (VAS) in NIH Grant Applications and Cooperative Agreements.   
 **Issued by;** National Institutes of Health ([NIH](http://www.nih.gov))  
   
**Purpose**This Notice is to clarify how the Vertebrate Animal Section (VAS) of applications for grants, fellowships, and cooperative agreements is evaluated as part of the NIH peer review process and is considered as part of the overall scoring. Further clarification is provided on the oversight role of the Institutional Animal Care and Use Committee (IACUC) and review responsibility of NIH Scientific Review Groups (SRG).  
  
**Background**In 2002, NIH changed the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals ([PHS Policy](http://grants.nih.gov/grants/olaw/references/phspol.htm)) to allow institutions to provide IACUC approval for competing applications subsequent to peer review but prior to award unless specifically required earlier by the funding component. This process is often referred to as “just-in-time.” The purpose of the change was to enhance the flexibility of institutions and reduce the burden on applicants and IACUCs, allowing resources to be focused on substantive review of applications likely to be funded. In a notice in the Federal Register (FR Doc. 02–19867) announcing the amended policy statement, NIH clarified expectations for the IACUC and the SRG. This guidance is provided again and expanded to reinforce the distinction between the two entities and to clarify when the impact/priority score is likely to be affected during review of the VAS by the SRG. Responsibilities of the institution in supporting the IACUC and of the investigator in communicating to the IACUC are reiterated.   
  
**Review of the VAS by NIH Scientific Review Groups**As part of the initial peer review of applications, NIH SRGs verify that any proposed research involving vertebrate animals is scientifically appropriate, including the suitability of animal usage and protections for research animals. If the VAS is missing, the application may be deferred. If one or more of the five required elements are not addressed, the application’s impact/priority score may be negatively affected. Because reviewers are asked to consider the VAS as an additional review criterion in the determination of scientific and technical merit for each application that proposes the use of vertebrate animals, the impact/priority score may be affected when scientific questions related to the proposed animal model(s) arise. Although the VAS is not given a separate score, it is part of the reviewers’ deliberations of scientific and technical merit that occur before final scoring for the application and, as such, is reflected as deemed appropriate by the reviewers in the final score for the application. (More detailed information on the required elements for completion of the VAS is available in the [Worksheet for the Review of the Vertebrate Animal Section](http://grants.nih.gov/grants/olaw/VASchecklist.pdf).)  
Reviewers rate the application as Acceptable or Unacceptable with respect to the proposed use of vertebrate animals and include specific comments assessing the information provided in the application. A vertebrate animal concern is defined as an issue involving animal care and use requiring resolution prior to award. Examples of vertebrate animal concerns include but are not limited to inappropriate animal model or unjustified number of animals; unnecessary pain or distress; lack of veterinary care; inappropriate anesthetic or inappropriate use of tranquilizing drugs or restraining devices; or method of euthanasia that is inconsistent with the recommendations of the American Veterinary Medical Association Guidelines on Euthanasia without adequate justification. If the SRG has insufficient information from the application to make a determination regarding acceptability as defined in the five points, the application is noted as havinga vertebrate animal concern. Vertebrate animal concerns must be satisfactorily resolved before an award may be made. Appropriately addressing a concern helps to ensure that required information on vertebrate care and use is in place prior to award. Protection of research animal welfare is a responsibility that is carried out in every phase of the grant process. Investigators may consider consulting the veterinarian for assistance in the development of a grant application involving new procedures with animals prior to submitting the application. Note that the SRG review is not intended to supersede or serve as a replacement for IACUC review or IACUC approval of an animal study protocol.  
  
**Role of the IACUC in the Oversight of Animal Protocols**Institutional Responsibilities

* An institution that elects to proceed according to “just-in-time” procedures for IACUC approval bears the responsibility for supporting the decisions of the IACUC.
* Under no circumstances may an IACUC be pressured to approve a protocol or be overruled on its decision to withhold approval.
* The PHS Policy requires that modifications required by the IACUC be submitted to the NIH with the verification of IACUC approval, and it is the responsibility of institutions to communicate any IACUC-imposed changes to NIH staff.

Investigator Responsibilities

* It is incumbent upon investigators to be totally forthcoming and timely in conveying to the IACUC any modifications related to project scope and animal usage that may result from the NIH review and award processes.
* 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 prior to allowing that investigator to submit an application.

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