

Instructions for Completion and Peer Review of the Vertebrate Animal Section (VAS) in NIH Grant Applications and Cooperative Agreements

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Key Dates

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Purpose

This Notice is to clarify the information that must be included in the Vertebrate Animal Section (VAS) of grant applications and cooperative agreements (subsequently referred to as applications) that use live vertebrate animals in research. It also explains how the VAS is evaluated as part of the NIH peer review process and is considered as part of the overall scoring. Distinction is made between the oversight role of the Institutional Animal Care and Use Committee (IACUC) and review responsibility of the NIH Scientific Review Group (SRG).

Background

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals ([PHS Policy](#)), NIH Grants Policy Statement, and instructions for the PHS398 and SF424 grant application forms specify the information required in all research applications submitted to the NIH that involve live vertebrate animals. The PHS Policy derives its authority from the [Health Research Extension Act of 1985](#). The PHS Policy incorporates the principles and procedures described in the following documents:

The Guide for the Care and Use of Laboratory Animals (National Academy of Sciences)

http://www.nap.edu/openbook.php?record_id=5140

American Veterinary Medical Association (AVMA) Guidelines on Euthanasia

http://www.avma.org/issues/animal_welfare/euthanasia.pdf (PDF)

U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training

<http://grants.nih.gov/grants/olaw/references/phspol.htm#USGovPrinciples>

Reiteration of the required elements for the VAS at this time is appropriate as investigators plan submissions using the restructured application forms and shorter page limits implemented in January 2010 (<http://enhancing-peer-review.nih.gov/> or <http://grants1.nih.gov/grants/guide/notice-files/not-od-10-002.html>). This Notice reviews current requirements; there are no new requirements related to the VAS in the restructured application packages.

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I. Required Elements of the VAS

Any proposed use of live vertebrate animals for experimental research, including use as a source of tissues, constitutes research involving use of vertebrate animals and requires completion of the VAS. As indicated in the instructions for completing the VAS in the PHS398 and SF424, if live vertebrate animals are to be used, federal policy requires that the following five points are addressed in all applications. Principal Investigators/Program Directors are strongly encouraged to familiarize themselves with the required elements for completion of the VAS in the [Worksheet for the Review of the Vertebrate Animal Section](#) (PDF).

1. Detailed description of the proposed use of the animals, including species, strains, ages, sex and number to be used
2. Justification for the use of animals, choice of species, and numbers to be used
3. Information on the veterinary care of the animals
4. Description of procedures for minimizing discomfort, distress, pain, and injury
5. Method of euthanasia and the reasons for its selection

A concise (e.g., 1-2 pages), complete description of the animals and proposed procedures must be provided within the VAS of the Research Plan. While additional details may be included in the Research Strategy, the responses to the five required points within the VAS must be cohesive and include sufficient detail to allow evaluation by peer reviewers and NIH staff.

II. Review of the VAS: Responsibilities of Applicants, SRGs, and NIH Staff

Overview: As part of the initial peer review of applications for scientific and technical merit, SRGs verify that any proposed research involving vertebrate animals is scientifically appropriate. Applications lacking a required

VAS or that do not address all five points may be deferred, or, alternatively, the application's impact/priority score may be negatively affected. An application is coded as "Vertebrate animals involved-no SRG concerns noted" (30), "Vertebrate animals involved-SRG concerns" (44), or "no live vertebrate animals involved for competing application" (10). An SRG concern is an issue involving animal welfare requiring resolution prior to award, such as inappropriate animal model or number; 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 AVMA Guidelines on Euthanasia without adequate justification. If the SRG has insufficient information from the application to make a determination, then it is a concern.

If there are SRG concerns related to the VAS, these must be resolved prior to award. The Program Officer works with the applicant and the Office of Laboratory Welfare (OLAW) to obtain additional information or a revised VAS that resolves all concerns and assures that the research involving animals will be conducted in compliance with PHS Policy. Subsequent to resolution of all concerns and approval of the revised VAS by OLAW, a National Advisory Council may recommend funding of the application. If NIH decides to fund the application, NIH Grants Management staff verifies that the applicant organization has an Animal Welfare Assurance (Assurance) on file with OLAW, and that verification of approval by the Institutional Animal Care and Use Committee (IACUC) has been provided. IACUC approval is not required of foreign grantees ([Foreign Grants Information](#)).

Although applicant organizations and investigators are primarily responsible for the proper care and use of animals, the responsibilities of individuals associated with the application and peer review processes are described briefly.

Applicant responsibilities: As indicated in the PHS398 and SF424 instructions, each of the five points must be addressed in the VAS of NIH grant applications. Failure to address the five points may result in the application being designated as incomplete and will be grounds for the PHS to defer the application from the peer review round. Alternatively, the application's impact/priority score may be negatively affected.

SRG responsibilities: SRGs evaluate the involvement of live vertebrate animals as part of the scientific assessment of the applications submitted to the NIH according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. The results of the VAS review may negatively affect the overall impact/priority score assigned to the application and/or, after the initial peer review, require revision of the VAS and its approval by OLAW.

NIH Staff responsibilities:

- Review staff a) performs an administrative review of each application, checking that it includes a VAS if the use of vertebrate animals is indicated; b) provides reviewers with instructions for reviewing the VAS ([VAS Worksheet](#), PDF) instructing them that the responses to all five points must be appropriate for the VAS to be acceptable; c) codes the application according to the SRG's recommendation and includes reviewers' comments in the Resume of the summary statement.
- Program staff a) obtains additional information or clarification to resolve concerns related to any application for which the VAS is found to be unacceptable, if the application is to be recommended for funding; b) works with the applicant to provide revisions to OLAW, facilitating approval of the VAS.
- Grants Management staff a) verifies that the organization's Assurance number is provided; b) obtains verification of IACUC approval.

III. Role of the IACUC in the Oversight of Animal Care and Use Protocols

Organizations receiving NIH funding for research involving vertebrate animals must negotiate an Assurance with OLAW prior to the use of animals. Approval by OLAW of an organization's animal care and use program requires that their facilities and procedures conform to PHS Policy, and that research involving animals within their facilities is monitored by a requisite IACUC.

A fundamental component of the Assurance is the IACUC, which is responsible for the review of proposed research and oversight of individual animal care and use protocols at each organization. IACUC approval indicates that the proposed protocol has been determined by the investigator's IACUC to conform to PHS Policy. While the IACUC considers the appropriateness of the proposed protocol to the investigator's scientific goals, the primary goal of the IACUC's detailed evaluation and oversight of the protocol is to assure that the procedures involving animals conform to all federal animal welfare requirements and PHS Policy. The applicant organization also has a responsibility to ensure that the protocol approved by the IACUC is congruent with the proposed use of animals described in the Research Plan.

Inquiries

For questions or further information, contact:

Office of Laboratory Animal Welfare
 National Institutes of Health
 Rockledge 1, Suite 360, MSC 7982
 6705 Rockledge Drive
 Bethesda, MD 20892-7982
 phone: 301-496-7163
 fax: 301-915-9481

e-mail: olaw@mail.nih.gov

web: <http://olaw.nih.gov/>

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