POLICY
It is the policy of this institution to ensure congruency between the components of all grant applications or contract proposals related to the care and use of animals and the approved IACUC protocol. Obtaining IACUC approval prior to submission of the application for federal funding may prevent delays in the certification process.

NIH will not make an award for research involving live vertebrate animals to an individual unless that individual is affiliated with an organization that accepts responsibility for compliance with the Policy and has filed the necessary assurance with OLAW. The organization and all performance sites must operate in accordance with an approved Animal Welfare Assurance and provide verification that the IACUC has reviewed and approved the IACUC application in accordance with the requirements of the PHS policy.

If a project that is connected with an investigator’s institutional responsibilities will be conducted in total at an external site (not a facility of UNMC/UNO), the IACUC may accept an approval statement from another PHS approved IACUC or its equivalent in the case of institutions located abroad.

REQUIREMENTS
The Public Health Service (PHS) Policy, in accordance with, IV.D. 1-3. Applications and proposals (competing and non-competing) for awards submitted to PHS that involve the care and use of animals shall contain the following information:

• identification of the species and approximate number of animals to be used;
• rationale for involving animals, and for the appropriateness of the species and numbers used;
• a complete description of the proposed use of the animals;
• a description of procedures designed to assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesics, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals; and
• a description of any euthanasia method to be used.

PROCEDURE (UNMC)
1.0 The Principal Investigator (PI) must submit a request to Sponsored Programs Administration (SPA) to have an IACUC protocol compared to a grant/contract.

2.0 SPA will provide a copy of the grant and the IACUC protocol to the Protocol Assessment Liaison (PAL) or designee to complete the congruency check.

3.0 If there are components of the grant/contract that do not match the approved IACUC protocol PAL/designee will contact the PI to discuss inconsistencies and assist them in submitting the correct information to the IACUC or the funding agency.

3.1 The SPA representative and the Director of Research Resources should be copied on any correspondence with the PI.

4.0 Certification will be granted by PAL/designee when the components of the protocol and the grant/contract are in agreement, and SPA will link the grant/contract with the corresponding IACUC protocol for access to award funds.
4.1 The signed SPA request form, the PAL certification form, and the IACUC approval letter will be submitted to the SPA representative, and copies filed by PAL/designee in the Protocol Facilitation Office.

PROCEDURE (UNO)

1.0 The PI must submit the IACUC approval letter to be certified with the corresponding grant/contract application is congruent with the corresponding IACUC approved protocol(s).

2.0 A copy of the IACUC approval letter and the signed PI Statement of Compliance will be filed in the SPR’s grant/contract file.

SPECIAL CONSIDERATIONS

1.0 Special considerations or exceptions for certification by the institution concerning grant/contract award requirements will include but may not be limited to:

1.1 Department of Defense (DOD) grants should have a copy of the Animal Care and Use Review Office (ACURO) Animal Use Appendix for Research Involving Animals and an ACURO approval letter from DOD in order to complete a compare at UNMC or to be filed with the PI Statement of Compliance at UNO.

1.2 Unrestricted grants/contracts may not require specific animal care and use procedures to be described in the grant/contract.

1.3 Private funding agencies may have different criteria for animal care and use procedures required to certify the compare.

ATTACHMENTS

1.0 NIH Notice April 19, 2010 Instructions for Completion and Technical Evaluation of the Vertebrate Animal Section (VAS) in NIH Contract Proposals

2.0 Checklist for Review of Vertebrate Animal Section (VAS)
Worksheet for Review of the Vertebrate Animal Section (VAS) Under Contract Proposals

This worksheet is provided to assist offerors in preparing the VAS as a part of the Technical Proposal for submission to the NIH, and as guidance to reviewers in evaluating the VAS of proposals. The responsibilities of the Scientific Review Group (SRG), Project Officer and Contracting Officer (NIH Staff) are clarified on page 1. A worksheet to assist in preparing or evaluating the VAS is provided on page 2, with more detailed instructions provided on pages 3-4. An example of a complete VAS, considered ACCEPTABLE, is presented on page 5.

I. Instructions for Offerors, SRGs, and NIH Staff

Overview of requirements
If live vertebrate animals are to be used, federal policy requires that the following five points are addressed by applicants in the VAS portion of the Technical Proposal.

1. Provide a detailed description of the proposed use of the animals in accordance with the requirements of the Request for Proposal (RFP) Statement of Work. Identify the species, strains, ages, sex and number of animals to be used in the proposed work.
2. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.
3. Provide information on the veterinary care of the animals involved.
4. Describe the procedures for ensuring that discomfort, distress, pain and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.
5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the AVMA Guidelines on Euthanasia. If not, include a scientific justification for not following the recommendations.

Offeror responsibilities
Each of the five points must be addressed in the VAS portion of the Technical Proposal of NIH RFP. The discussion of all of the five points must be addressed and evaluated by reviewers as acceptable for the VAS portion to be considered ACCEPTABLE. The VAS portion must be considered as ACCEPTABLE prior to award.

Reviewer responsibilities
Members of scientific review groups (SRGs) must evaluate the VAS to determine if plans for the use of vertebrate animals are appropriate/acceptable relative to the scientific work as proposed.

NIH Staff responsibilities
- **Contracting Officer:** a) provides reviewers with instructions for reviewing the VAS (e.g., worksheet, Section M of the solicitation), noting that all points must be evaluated as appropriate for the VAS to be “acceptable”; b) subsequent to SRG review, determines the competitive range, as applicable, and if discussions are held, provides the offeror with the opportunity to address the concerns raised by the reviewers; c) with the advice of the Project Officer and OLAW, as necessary, determines if the concerns have been resolved and the VAS section of the Technical Proposal can be considered “acceptable”; d) confirms whether the offeror has an OLAW-approved Assurance and IACUC approval; e) makes contract awards.
- **Project Officer:** assists the Contracting Officer in determining the acceptability of the revised VAS of the Technical Proposal.
II. Worksheet to Assist in Addressing the Required Five Points of the VAS

**Performance site(s):** The five points must be addressed for all performance sites.

- If the offeror’s institution is not where animal work will be performed, are all collaborative performance site(s) identified?
- If more than one performance site is proposed, are descriptions of animal care and use addressing the five points provided for each site?

**Point 1** Describe the animals and their proposed use; address the following for all species to be used:

- Species
- Strains
- Ages
- Sex
- Number of animals to be used
- A concise, complete description of proposed procedures (i.e., sufficient information for evaluation)

**Point 2** Provide justifications for:

- The use of animals
- Choice of species
- Number of animals to be used (cite power calculations, if appropriate) with specific justification for large numbers of animals
- Use of animals that are in short supply or are costly

**Point 3** Provide a general description of veterinary care, including veterinary support that is relevant to the proposed procedures. Examples of the kinds of items that may be appropriate to include are:

- A brief account of veterinary staff and their availability
- The regular schedule of monitoring of animals by veterinary staff
- Any additional monitoring and veterinary support that may be required to ensure humane care, if relevant to the procedures proposed (e.g., post-surgical)
- Indicators for veterinary intervention to alleviate discomfort, distress or pain, if relevant

**Point 4** Describe procedures to minimize discomfort, distress, pain and injury to that which is scientifically unavoidable in the conduct of research. Examples of the kinds of items that may be appropriate to include are:

- Circumstances relevant to the proposed work, when animals may experience discomfort, distress, pain or injury
- Procedures to alleviate discomfort, distress, pain or injury
- Identify (by name or class) any tranquilizers, analgesics, anesthetics and other treatments (e.g., antibiotics) and describe their use
- Provisions for special care or housing that may be necessary after experimental procedures
- Plans for post-surgical care, if survival surgeries are proposed
- Indicators for humane experimental endpoints, if relevant
- Describe the use of restraint devices, if relevant

**Point 5** Describe methods of euthanasia:

- Describe the method(s) of euthanasia and rationale for selection of method(s)
- Indicate if the method is consistent with AVMA Guidelines on Euthanasia
- Provide a scientific justification for the choice of method if not AVMA recommended
III. Detailed Instructions for Preparation and Review of the VAS

The SRG will evaluate information provided in the VAS in accordance with the technical evaluation criteria specified in Section M of the RFP. During discussions, the Contracting Officer will provide any concerns expressed during the review by the SRG and provide the offeror an opportunity to respond to the concerns. After award, the contract will be coded in the Departmental Contracts Information System (DCIS) as a contract where animals will be used. Offerors should be aware that NIH may release information contained in contract awards pursuant to a Freedom of Information Act request or pursuant to a protest, either before or after award.

Performance site(s): This is defined as the institutions where procedures with animals will be performed. If the offeror's institution is not the site where animal work will be performed, the performance site must be identified. If there is more than one performance site, the description of animal care and use at each site must be included in addressing the five points.

Preparation of the VAS:
Typically, all of the required elements for the VAS can be addressed within 1-2 pages. Following the detailed guidelines below, an example of a concise, but complete VAS section is included on the last page of this document.

Point 1 Description of animals and how they will be used
A concise, complete description of the proposed procedures must be included in the VAS. While additional details may be included, a coherent, albeit brief, description of the proposed use of the animals must be provided within the VAS. The description must include sufficient detail to allow evaluation of the procedures. Examples of the types of procedures that may be described include blood collection, surgical procedures, administration of substances, tumor induction and post-irradiation procedures. In describing the animals, the offeror must provide the following information for each species or strain:
- Species
- Strain
- Ages
- Sex
- Number of animals to be used

Point 2 Justifications for use of animals
Investigators must justify the use of animals in the proposed research. U.S. Government Principles require contractors to consider mathematical models, computer simulation, and in vitro biological systems. The justification should indicate why alternatives to animals (e.g., computer models, cell culture) cannot be used and the potential benefits and knowledge to be gained. In addressing this point, researchers are encouraged to consider means to replace, reduce and refine the use of animals. Rationale for the choice of species must be provided (e.g. advantages of the species chosen and why alternative species are not appropriate). If less highly evolved or simpler animal models are available, justification should be provided for using more advanced species. For example, the use of non-human primates (NHP), dogs or cats should be thoroughly justified. If NHP species are to be used, a comparison to other NHP species may be appropriate. If animals are in short supply, costly, or to be used in large numbers, an additional rationale for their selection and the number of animals to be used is required.

Estimates for the number of animals to be used should be as accurate as possible. Justification for the number of animals to be used may include considerations of animal availability, experimental success rate, inclusion of control groups and requirements for statistical significance; cite power calculations where appropriate.
Point 3  Veterinary care
Descriptions of veterinary care should indicate the availability of veterinarians or veterinary technicians. For example, the VAS might indicate the number of veterinarians and veterinary technicians associated with the offeror, and their proximity to the performance site(s). The frequency with which veterinary staff observe or monitor animals may also be stated.

If survival surgeries are proposed, descriptions of veterinary involvement or post-surgical monitoring may be described. For example, if animal use involves invasive approaches that might result in discomfort, distress or pain, the investigator may describe the indicators for veterinary intervention and the ways in which veterinary staff may intervene.

Point 4  Provisions to minimize discomfort, distress, pain and injury
Procedures or circumstances that may result in more than momentary discomfort, distress, pain or injury should be identified. Methods to alleviate discomfort, distress or pain should be described. If pharmacological agents are used, the agent(s) may be specified by name or class. Any additional (e.g., non-pharmaceutical) means to avoid discomfort, distress, pain or injury may be briefly described. The manner, circumstances and duration of all post-surgical provisions and care may be described. If special housing is necessary following surgery or manipulations, the VAS may describe these. If procedures (e.g., pharmacological or surgical) might lead to severe discomfort, distress, pain or injury, indicators for humane endpoints and euthanasia (e.g., severe infection, respiratory distress, failure to eat, tumor size) may be described. All of these issues are particularly important for survival surgeries. If multiple surgeries are proposed, these should be well justified and provisions to avoid any potential complications may be described. Describe how restraining devices will be used, if applicable.

Point 5  Euthanasia
The method(s) of euthanasia must be described and must comply with the AVMA Guidelines on Euthanasia. If the method(s) do not comply with AVMA recommendations, the rationale and scientific justification for use of the method(s) must be provided. The indicators for euthanasia (i.e., termination of experiment or humane endpoints) may be stated. It is not sufficient to state simply that humane methods will be used, that are consistent with the recommendations of the AVMA Guidelines on Euthanasia or the Institutional Animal Care and Use Committee (IACUC).

References
Guidance in this document is based on PHS Policy and federal requirements. The PHS Policy incorporates the standards in the Guide for the Care and Use of Laboratory Animals and the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training, and requires that euthanasia be conducted according to the AVMA Guidelines on Euthanasia. Additional background information and references are available on the Office of Laboratory Animal Welfare website (http://olaw.nih.gov).

IV. Example (under development)
Instructions for Completion and Technical Evaluation of the Vertebrate Animal Section (VAS) in NIH Contract Proposals

Notice Number: NOT-OD-10-049

Key Dates
Release Date: April 19, 2010

Issued by
National Institutes of Health (NIH), (http://www.nih.gov)

Other Relevant Notice
March 17, 2010: see NOT-OD-10-027, Instructions for Completion and Peer Review of the Vertebrate Animal Section (VAS) in NIH Grant Applications and Cooperative Agreements.

Purpose
This Notice is to clarify the information that must be included in a separate section of the Technical Proposal titled the Vertebrate Animal Section (VAS) of contract proposals for biomedical and behavioral Research and Development (R&D), research training, and biological testing activities that use live vertebrate animals. It also explains how the VAS is evaluated as part of the NIH technical evaluation process for award of a contract. 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) specifies the information required in all contract proposals 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/oijaw/references/phspol.htm#USGovPrinciples

This PHS Policy is implemented by the HHSAR at 370.4.

This Notice summarizes and clarifies current requirements.

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Section I. Required Elements of the VAS – Five Points
Section II. Review of the VAS – Responsibilities of Offerors, SRGs, and NIH Staff

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

I. Required Elements of the VAS

Any proposed use of vertebrate animals for experimental research including use as a source of tissues constitutes research involving use of live vertebrate animals and requires completion of the VAS. Federal policy requires that the following five points are addressed in all contract proposals involving live vertebrate animals. Potential offering organizations are strongly encouraged to familiarize themselves with the required elements for completion of the VAS in the Contract Proposal VAS Worksheet (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 contract proposals. While additional details may be included in other sections of the contract proposal, the description of the proposed procedures within the VAS must be cohesive and include sufficient detail to allow evaluation by reviewers and NIH staff.

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

Overview: As part of the technical evaluation of contract proposals for scientific and technical merit, SRGs verify that any proposed research involving vertebrate animals is scientifically appropriate. Proposals lacking the completed five points of the VAS will be considered unacceptable with regard to the Care of Live Vertebrate Animals provision of the solicitation’s Technical Proposal Instructions. If the offeror is included in the competitive range, the unacceptable VAS may be discussed and the offeror may be permitted to revise its proposal. If the offer is still considered unacceptable in terms of the VAS response, the offeror may not be considered for award of a contract.

If there are concerns related to the VAS, these must be resolved during the discussions with the offeror regarding animal care and use. The Project Officer and the Office of Laboratory Welfare (OLAW) may advise the Contracting Officer, who will obtain additional information or a revised proposal from the offeror to resolve all concerns and assure that the research involving animals will be conducted in compliance with PHS Policy. Prior to contract award, the Contracting Officer will confirm whether the offeror 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. After award, the contract will be coded in the Departmental Contracts Information System (DCIS) as a contract where animals will be used.

Although contractors are primarily responsible for the proper care and use of animals used in activities performed under the contract, the responsibilities of individuals associated with the NIH contract acquisition and technical evaluation processes are described briefly.

Offeror responsibilities: As indicated in the Care of Live Vertebrate Animals provision of the solicitation’s Technical Proposal, each of the five points must be addressed in the VAS of the contract proposal. The discussion of all of the five points must be addressed and evaluated by reviewers as acceptable for the VAS portion to be considered “acceptable”. The VAS portion must be considered as “acceptable” prior to award.

SRG responsibilities: The SRG will evaluate the involvement of live vertebrate animals as part of the technical evaluation of proposals submitted to NIH according to the following five points: 1) proposed use of animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and
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 result in a rating of "unacceptable" requiring revision of the VAS prior to award, or as "acceptable", which would require no further discussion on this topic.

NIH Staff responsibilities:

- **Contracting Officer** a) provides reviewers with instructions for reviewing the VAS (e.g., Worksheet – PDF, Section M of the solicitation), noting that all points must be evaluated as appropriate for the VAS to be "acceptable"; b) subsequent to SRG review, determines the competitive range, as applicable, and if discussions are held, provides the offeror with the opportunity to address the concerns raised by the reviewers; c) with the advice of the Project Officer and OLAW, as necessary, determines if the concerns have been resolved and the VAS section of the Technical Proposal can be considered "acceptable"; d) confirms whether the offeror has an OLAW-approved Assurance and IACUC approval; e) makes contract awards.
- **Project Officer** assists the Contracting Officer in determining the acceptability of the revised VAS of the Technical Proposal.

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

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

### Inquiries

For questions or further information, contact:

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[Weekly TOC for this Announcement](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-049.html)  
[NIH Funding Opportunities and Notices](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-049.html)
Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files.