Worksheet for the Vertebrate Animals Section (VAS) under Contract Proposals

This is a worksheet to assist offerors in preparing the VAS as a part of the Technical Proposal for submission to NIH, and to assist reviewers in evaluating the VAS of contract proposals. It provides an overview of the requirements, offeror and reviewer responsibilities, a checklist, and detailed instructions.

Applicability

A VAS is required if the work proposed in a contract proposal involves live vertebrate animals, including animals obtained or euthanized for tissue harvest and generation of custom antibodies.

The criteria in the VAS must be addressed for work proposed at every performance site – this is the site (institution) where procedures with animals will be performed. If the offeror's institution is not the site where animal work will be performed or if the work will be performed at several sites, these performance sites must be identified.

Requirements

If live vertebrate animals are to be used, federal policy requires applicants to address the following criteria:

1. **Description of Procedures.** Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the Request for Proposal (RFP) Statement of Work. Identify the species, strains, ages, sex and total number of animals by species to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.
2. **Justifications.** Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).
3. **Minimization of Pain and Distress.** Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.
4. **Euthanasia.** State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

Offeror Responsibilities

Each of the first three criteria must be addressed, and the fourth if applicable, in the VAS portion of the Technical Proposal of NIH RFP. All of the items must be addressed and evaluated by reviewers as appropriate for an application to be rated as 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 and acceptable relative to the scientific work proposed. Reviewers will assess the VAS for proposals proposing the use of chimpanzees as they would any other proposal.

NIH Staff Responsibilities

*   **Project Officer**
    a) Assists the contracting officer in determining the acceptability of the revised VAS.

- **Contracting Officer**
    a) Provides reviewers with instructions for reviewing the VAS (e.g., worksheet), noting that all criteria 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 can be considered ACCEPTABLE.
    d) Confirms whether the offeror has an OLAW-approved Assurance and IACUC approval.
    e) Makes contract awards.

Checklist

Performance sites:
- __ If the applicant's institution is not where animal work will be performed, are all collaborative performance sites identified?
- __ If more than one performance site is planned, are descriptions of animal use addressing the required criteria provided for each site?

1. **Describe the animals and their proposed use. Address the following for all species to be used:**
    - __ Species
    - __ Strains
    - __ Ages
    - __ Sex
    - __ Total number of animals by species to be used
    - __ Concise, complete description of proposed procedures (i.e., sufficient information for evaluation)
    - __ Source, only if dogs or cats are proposed

2. **Provide justifications for:**
    - __ Choice of species
    - __ Why research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro)

3. **Describe interventions to minimize discomfort, distress, pain and injury. 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 palliative 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

4. **State if method of euthanasia is consistent with AVMA Guidelines. If method does not follow the guidelines:**
    - __ Describe the method of euthanasia
    - __ Provide a scientific justification

Instructions

Typically, all of the required elements for the VAS can be addressed within 1-2 pages. The SRG will evaluate information provided in the VAS according to 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.

1. Description of Procedures

Offerors must include a concise, complete description of the proposed procedures. 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
- post-irradiation procedures

In describing the animals, offerors must provide the following information:
- Species
- Strain
- Ages
- Sex
- Total number of animals to be used by species
- Source of the animals, if dogs or cats are proposed

2. Justifications

Offerors 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 the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro). Rationale for the choice of species must be provided (e.g., advantages of the species chosen and why alternative species are not appropriate). Discuss why less highly evolved or simpler animal models are not appropriate. For example, the use of non-human primates, dogs or cats should be thoroughly justified.

3. Minimization of Pain and Distress

Offerors should identify procedures or circumstances that may result in more than momentary discomfort, distress, pain or injury. Interventions to alleviate discomfort, distress or pain should be described. If pharmacological agents are used, the agents 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, including palliative care. 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, 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.

4. Euthanasia

Investigators should state whether euthanasia will be performed and indicate if the method of euthanasia is

consistent with AVMA guidelines. If consistent, no further information is needed. If it isn't consistent, they must describe the method of euthanasia and provide scientific justification.

Resources

- [Grant Application VAS Worksheet](#) (PDF) – an optional tool for grant application review
- [Contract Proposal VAS Worksheet](#) (PDF) – an optional tool for contract proposal review
- [VAS Factsheet](#) (PDF)
- [What Investigators Need to Know About the Use of Animals](#) (PDF)
- [NOT-OD-16-006](#): Simplification of the Vertebrate Animals Section of NIH Grant Applications and Contract Proposals

References

The guidance in this worksheet is based on Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (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 for the Euthanasia of Animals*. Additional background information and references are available on the OLAW website (http://olaw.nih.gov).

- PHS Policy
  http://grants.nih.gov/grants/olaw/references/phspol.htm
- U.S. Government Principles
  http://grants.nih.gov/grants/olaw/references/phspol.htm#USGovPrinciples
- Guide for the Care and Use of Laboratory Animals
  http://www.nap.edu/catalog.php?record_id=12910
- AVMA Guidelines for the Euthanasia of Animals
  https://www.avma.org/KB/Policies/Documents/euthanasia.pdf