

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 for the Euthanasia of Animals*. 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 for the Euthanasia of Animals*
- 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 for the Euthanasia of Animals*. 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 for the Euthanasia of Animals* 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 for the Euthanasia of Animals*. Additional background information and references are available on the Office of Laboratory Animal Welfare 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>

IV. Example (under development)