# Checklist for Review of Vertebrate Animal Section (VAS)

**1. Performance site(s):**

— If applicant's institution is not where animal work will be performed, collaborative performance site should be identified
— If more than one performance site is planned, include description of animal care and use for each site

**2. Description of animal use:**

— Concise, but complete description, including sufficient information for evaluation of procedures

**3. Animals to be used:**

— Species
— Strain
— Ages
— Sex
— Number of animals to be used

**4. Justification:**

— The use of animals (e.g., instead of cell culture, computer models)
— Choice of species (e.g., why not a simpler or less evolved vertebrate)
    — For non-human primates (NHP) or companion animals (e.g., dogs, cats), thorough justification is required
— Number of animals to be used (cite power calculations if appropriate)

**5. Veterinary care (indicate for each performance site):**

— Availability of veterinary care
— Frequency of animal monitoring and observation by veterinary or animal care staff
— Where does monitoring occur? (e.g., home cages in animal facility, laboratory) Under what conditions? (e.g., during behavioral or surgical procedures)
— Description of circumstances when veterinary staff will intervene and what steps will be taken

**6. Provisions to minimize distress, discomfort, pain and injury:**

— Describe specific measures and circumstances when such provisions will be used
— Identify specifically (iby name) tranquilizers, analgesics, anesthetics and antibiotics to be used; state concisely when they will be used
— Care, monitoring or special housing following surgery or treatments
— Indicators of humane endpoints to minimize pain and distress
— Brief description of restraint devices, if relevant

**7. Euthanasia:**

— Method(s) for euthanasia
— Justification for choice of method
— Consistent with recommendations of the AVMA Guidelines on Euthanasia

**8. Other VAS-related items:**

— Institutional Assurance number (face page of PHS398, or "other project information" page of SF424)
— Status of IACUC approval (e.g., requested, pending, approved)

**Review of Vertebrate Animal Section (VAS) in NIH Applications and Proposals**
**Guidelines for Reviewers and NIH Staff**

**Review responsibilities:**
Although applicant institutions and investigators are primarily responsible for the proper care and use of animals, responsibility for oversight is shared by scientific review groups, Advisory Councils and Boards. All procedures (e.g., housing, veterinary care, anesthesia, analgesia, surgical, euthanasia) must comply with federal animal welfare law and Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

**References:**
The PHS Policy incorporates the principles stated in The Guide for the Care and Use of Laboratory Animals and mandates that euthanasia be conducted according to the American Veterinary Medical Association guidelines. The following documents are available on the Office of Laboratory Animal Welfare (OLAW) website in searchable format and may be accessed to answer any questions you may have while conducting a review:

- PHS Policy
  http://grants.nih.gov/grants/olaw/references/phspol.htm
- The Guide for the Care and Use of Laboratory Animals
  http://www.nap.edu/openbook.php?record_id=5140
- The AVMA Guidelines on Euthanasia
  http://www.avma.org/issues/animal_welfare/euthanasia.pdf

**No vertebrate animals:**
If animal tissue used in the study is obtained from other sources (e.g., tissue repository or from animals euthanized for an unrelated purpose), the application may be classified as "no vertebrate animals used." A statement indicating the source of the tissues is required in the VAS to validate the coding as "no vertebrate animals."

If animals are manipulated prior to euthanasia or obtained specifically for tissue harvest as part of the proposed research, this constitutes using animals and must be classified as "use of live vertebrate animals." Activities, such as the generation of custom antibodies, constitutes using live vertebrate animals and must be classified as "use of live vertebrate animals."

**Points to consider while reviewing the VAS (replace, reduce, refine):**

- Can the proposed research be conducted without animal experimentation?
- Does the proposed approach minimize the number of animals to be used, and do the methods minimize animal distress, discomfort and pain?
- Does the proposed research involve animal pain or distress? If so, are procedures to alleviate pain and distress described adequately, and are they justified by the anticipated advances in knowledge or health care?
- Is particular care taken to describe and justify research involving non-human primates (NHP) or companion animals (e.g., cats, dogs)?

**Requirements of review:**
Federal guidelines require that the following items are addressed in NIH applications. It is the responsibility of reviewers to confirm that the information is provided and that plans for the use of vertebrate animals are appropriate. If live vertebrate animals are to be used, the following must be addressed by the applicant within the VAS. Typically,

these items can be addressed within 1-2 pages. Reviewers must consider the investigator's response to all five points required by the PHS398 application:

- A detailed description of the use of animals
- Justification of the use of animals
- Veterinary care information
- Procedures for ensuring humane treatment
- Method of euthanasia.

Any reviewer concerns will be cited in the Vertebrate Animal section of the summary statement. Applicants are given the opportunity to resolve such concerns prior to award.

**1. Performance site(s):**

If applicant institution is not the site where animal work will be performed, is the performance site identified? If there is more than one performance site, a full description of animal care and use for each site must include the required five points listed above.

**2. Description of how the animals will be used:**

A concise, complete description of the proposed procedures must be included in the VAS. While additional details may be included in the Methods section of the Research Plan, a coherent, albeit brief description of the protocols must be provided in the VAS. The description must include sufficient detail to allow evaluation of the procedures.

**3. Animals to be used:**

Investigators must indicate each of the following:

- Species
- Strain
- Ages
- Sex
- Number of animals to be used

**4. Justification:**

Investigators must justify the use of animals in their research. The justification must indicate why alternatives to animals (e.g., computer models, cell culture) cannot be used, and should indicate the potential benefits and knowledge to be gained.

Rationale for the choice of species must be provided. The rationale should indicate the advantages of the species chosen and why alternative species are not appropriate. In the case of non-human primates (NHP), thorough justification for the choice of species is required; comparison of the species chosen to other NHP species may be appropriate. The use of NHP should be noted during review.

Estimates for the number of animals to be used should be as accurate as possible. Justification for the number of animals to be used should include considerations of animal availability, experimental success rate, inclusion of control groups and requirements to reach statistical significance

**5. Veterinary care:**

Descriptions of veterinary care should indicate the availability of veterinarians or veterinary technicians; if multiple performance sites are included, veterinary care at each site must be described. The frequency, circumstances and conditions under which the veterinary or animal care staff monitors animals, either in their home cages or during procedures should be indicated. The mechanism and regularity of

communication with veterinary staff should be cited. The circumstances and manner in which veterinary staff will intervene must be described briefly. Adequate training of personnel handling animals should be indicated; particular attention to this issue is required for research involving NHP.

**6. Provisions to minimize discomfort, distress, pain and injury:**
The type of discomfort, pain or distress and the circumstances leading to them should be identified; efforts to avoid pain, discomfort or distress should be described. The description should identify (name) the specific pharmacological agents whose use is anticipated; any additional means used to avoid discomfort or distress should be described briefly. The manner, circumstances and duration of all post-surgical provisions and care should be described. Humane endpoints should be described.

**7. Euthanasia:**
The method(s) of euthanasia must be described, and should state briefly the rationale or justification for the method chosen. The indicators for euthanasia (i.e., time point, termination of experiment, humane indicators) should be stated. It is not sufficient to state simply that humane methods or procedures will be used that are consistent with the recommendations of the AVMA Guidelines on Euthanasia.

**8. In addition to reviewing the required items, it may be useful to note the following information:**
Institutional Assurance number, IACUC approval and institutional accreditation -

- The Institutional Animal Welfare Assurance (Assurance) number should be provided on the face page (PHS398) or "other project information" page (SF424) at the time of submission, if available. The Assurance number indicates that the applicant organization has an animal care program approved by the Public Health Service, and that all procedures will be administered under the guidelines of that animal care program.
- If the applicant organization lacks an Assurance, one will be negotiated with the Office of Laboratory Animal Welfare (OLAW). The process of negotiating an Assurance is initiated by the NIH grants management staff. If the applicant institution does not have an Animal Welfare Assurance and the animal work will be conducted at an institution with an Assurance, the grantee must obtain an Inter-institutional Assurance from OLAW prior to award. When the grantee is a domestic institution and there is a foreign performance site using animals, the grantee must ensure that the performance site has an appropriate Foreign Assurance and must provide verification of approval of the animal care and use protocol by the domestic grantee's Institutional Animal Care and Use Committee, certifying to NIH that the activity as conducted at the foreign performance site is acceptable to the grantee.
- Although not required in the VAS, the date of approval of the animal care and use protocol must be provided by the Investigator prior to award (i.e., "Just In Time"). Therefore, if this information is provided in the application, it may be useful when reviewing to cite the status of the protocol approval (e.g., protocol has/has not been submitted for approval, is pending, or is approved).
- Although not required, some applicants may indicate that their institution is accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC). Each institution's animal care program/facilities must be assured as a category I or II program; AAALAC accreditation is classified as category I. If AAALAC accreditation is cited, it may be useful to indicate this.