

❖ Vertebrate Animals ❖

The following rules were developed to help pre-college student researchers adhere to the federal regulations governing professional scientists and to, therefore, protect the welfare of both animal subjects and the student researcher. When students conduct research with animal subjects, the health and well-being of the animal subjects must be considered.

All projects involving vertebrate animals must adhere to the rules below AND to either Section A or Section B rules depending on the nature of the study and the research site.

Rules for ALL Studies Involving Vertebrate Animals

- 1) The use of vertebrate animals in science projects is allowable under the conditions and rules in the following sections. Vertebrate animals, as covered by these rules, are defined as live, nonhuman vertebrate mammalian embryos or fetuses, tadpoles, bird and reptile eggs within three days (72 hours) of hatching, and all other nonhuman vertebrates (including fish) at hatching or birth.
- 2) Alternatives to the use of vertebrate animals for research must be explored and discussed in the research plan. Alternatives include the following “3 R’s”:
 - Replace vertebrate animals with invertebrates, lower life forms, tissue/cell cultures or computer simulations
 - Reduce the number of animals without compromising statistical validity
 - Refine the experimental protocol to lessen pain or distress to the animals.
- 3) **Research projects which cause more than momentary pain or suffering to vertebrate animals or which are designed to kill vertebrate animals are prohibited.** (Note: Humane euthanasia is permitted under certain conditions when the research is conducted at a regulated research institution. See Section B.)
- 4) The following types of studies on vertebrate animals are **prohibited**:
 - a. All induced toxicity studies involving a poison or toxin that could impair health or destroy life, including alcohol, acid rain, insecticide, herbicide, or heavy metals.
 - b. Behavioral experiments involving operant conditioning with aversive stimuli, mother/infant separation or induced helplessness
 - c. Studies of pain
 - d. Predator/vertebrate prey experiments
- 5) Because weight loss is one significant sign of stress, the maximum permissible weight loss or growth retardation (compared to controls) of any experimental or control animal is 15%.
- 6) If an experimental design requires food or water restriction, it must be appropriate to the species, but may not exceed 18 hours.
- 7) If there are unexpected deaths in either the experimental or control groups, the cause of the death must be investigated. If the experimental procedure is responsible for the deaths, the experiment must be immediately terminated. A death rate of 30% or greater in any group or subgroup is not permitted and the project will fail to qualify for competition.
- 8) Students performing vertebrate animal research must follow local, state, country and U.S. federal regulations.
- 9) Except for observational studies, a Qualified Scientist or Designated Supervisor must directly supervise all research involving vertebrate animals.
- 10) A Scientific Review Committee (SRC) and/or an Institutional Animal Care and Use Committee (IACUC) must approve all research before experimentation begins. (An IACUC is the review and approval body at a regulated research institution for all animal studies.) The research plan for vertebrate animal studies must include the following:
 - a. Justify why animals must be used, including the reasons for the choice of species and the number of animals to be used. Describe any alternatives to animal use that were considered, and the reasons these alternatives were unacceptable. Explain the potential impact or contribution this research may have on the broad fields of biology or medicine.
 - b. Describe in detail, how the animals will be used. Include methods and procedures, such as experimental design and data analysis. Describe the procedures that will minimize the potential for discomfort, distress, pain and injury to the animals during the course of experimentation. Identify the species, strain, sex, age, weight, source and number of animals proposed for use.
- 11) After initial SRC approval, a student with any proposed changes in the **Research Plan** of the project must repeat the approval process before laboratory experimentation/data collection resumes.
- 12) Studies involving behavioral observations of animals are exempt from prior SRC review if **ALL** of the following apply:
 - There is no interaction with the animals being observed,
 - There is no manipulation of the environment in any way and
 - All federal or state fish, game and wildlife laws and regulations are followed.
- 13) Certain types of vertebrate animal studies may be conducted at home, school or other non-regulated research sites, whereas other studies must be conducted at a regulated research institution. See A. Non-regulated Research Site and B. Regulated Research Site below for rules and site descriptions.

A. Additional Rules for Projects Conducted in a Non-regulated Site

Vertebrate animal studies may be conducted at a **non-regulated** research site (home, school, farm, ranch, in the field, etc.). This includes:

- Studies involving animals in their natural environment
 - Studies involving animals in zoological parks
 - Studies involving livestock that use standard agricultural practices.
- 1) These projects must adhere to BOTH of the following guidelines:
 - a. The research involves agricultural, behavioral, observational or supplemental nutritional studies on animals.
AND
 - b. The research involves only non-invasive and non-intrusive methods that do not negatively affect an animal's health or well-being.

(Note: All studies not meeting the above criteria must be conducted at a Regulated Research Institution. See Section B. below.)

- 2) Animals must be treated kindly and cared for properly. Animals must be housed in a clean, ventilated, comfortable environment compatible with the standards and requirements appropriate for the species used. They must be given a continuous, clean (uncontaminated) water and food supply. Cages, pens and fish tanks must be cleaned frequently. Proper care must be provided at all times including weekends, holidays, and vacation periods. Animals must be observed daily to assess their health and well-being. A Designated Supervisor is required to oversee the daily husbandry of the animals. The following documents offer space requirements and additional husbandry information:
 - *Federal Animal Welfare Regulation*
 - *Guide for the Care and Use of Laboratory Animals*
 - *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching (Ag-Guide)*
- 3) The Scientific Review Committee must determine when a veterinarian is required to certify that the research plan and animal husbandry are appropriate. This certification is required before experimentation and the prior SRC approval. A veterinarian must be consulted in experiments that involve supplemental nutrition, administration of prescription drugs and/or activities that would not be ordinarily encountered in the animal's daily life.
- 4) If an unexpected illness or emergency occurs, the affected animals must have proper medical and nursing care that is directed by a veterinarian. A student researcher is expected to stop experimentation if there is significant weight loss or death in the experimental subjects. The experiment can only be resumed if the cause of illness or death is not related to the experimental procedures and if appropriate steps are taken to eliminate the causal factors.

- 5) Animals may not be captured from or released into the wild without approval of authorized wildlife or other regulatory officials. Fish may be obtained from the wild only if the researcher releases the fish unharmed, has the proper license, and adheres to state and local fishing laws and regulations.
- 6) The final disposition of the animals must be considered and explained on **Vertebrate Animal Form (5A)**. Euthanasia for tissue removal and/or pathological analysis is not permitted for a project conducted in a non-regulated site.
- 7) **The following forms are required:**
 - a. **Checklist for Adult Sponsor (1)**
 - b. **Student Checklist (1A)**
 - c. **Research Plan**
 - d. **Approval Form (1B)**
 - e. **Vertebrate Animal Form (5A)**
 - f. **Qualified Scientist Form (2), when applicable**

B. Additional Rules for Projects Conducted in a Regulated Research Institution

All studies not meeting the criteria in Section A. must be conducted in a regulated research institution. A regulated research institution is defined as a professional research/teaching institution that is regularly inspected by the USDA and is licensed to use animals covered by the Animal Welfare Act. Also included are all federal laboratories such as National Institutes of Health, Veteran's Affairs Medical Centers and the Centers For Disease Control. In addition, pharmaceutical and biotechnology companies that utilize research animals that are not covered by the Animal Welfare Act but have an operational Institutional Animal Care and Use Committee and program structured in compliance with U.S. federal laws are included in this definition.

(NOTE: Some research that is permissible for professionals in research institutions is not appropriate for pre-college students.)

- 1) The Institutional Animal Care and Use Committee (IACUC) must approve all student research projects before experimentation begins. Such research projects must be conducted under the responsibility of a principal investigator. The local SRC must also review the project to certify that the research project complies with ISEF Rules. This SRC review should occur before experimentation begins.

- 2) Proper euthanasia at the end of experimentation for tissue removal and/or pathological analysis is permitted. Student researchers are prohibited from performing euthanasia; only the Qualified Scientist or an institutional representative may perform the euthanasia. All methods of euthanasia must adhere to current AVMA Guidelines.
- 3) Research projects that cause more than momentary pain or suffering to vertebrate animals are prohibited. The following table relates the USDA Pain Categories and the permissibility of studies for science fair projects.

USDA Pain Categories	Definition	ISEF Guidelines
Category A	Live animals will receive non-painful manipulation. Animals may be euthanized to obtain tissues, cells, etc.	Permitted
Category B	Live animals will receive momentary pain or stressful stimulus without anesthesia, which results in a short-term response. Examples include but are not limited to: injections, field trapping/tagging, blood sampling and standard agricultural husbandry practices.	Permitted
Category C	Live animals will have significant manipulations, surgery, etc., performed while anesthetized. The animals will be euthanized at the termination of the procedure without regaining consciousness.	Permitted only with proper training and certification
Category D	Live animals will have manipulations performed while anesthetized and are allowed to recover and/or animals will develop discernable clinical signs indicating pain, distress, or significant physiological changes <u>spontaneously or as a result of specific experimental procedures</u> . Examples include, but are not limited to: Survival surgical procedures of any type and some studies which would include tumor development. ALL SUCH STUDIES MUST INCLUDE TREATMENT TO ALLEVIATE PAIN OR DISTRESS.	Limited Category D procedures are permitted with proper training and certification. The project must adhere to all ISEF rules. Most Category D projects would be deemed inappropriate for high school students.
Category E	Live animals will experience significant/severe pain or distress, without benefit of anesthetics, tranquilizers or analgesics.	PROHIBITED

- 4) Research in nutritional deficiency, ingestion, inoculation or exposure to unknown or potentially hazardous materials or drugs is permitted to proceed only to the point where the first sign of the deficiency or effect appear. Appropriate measures must then be taken to correct the deficiency or drug effect, if such action is feasible. If not, the animal(s) must be euthanized.
- 5) The following forms are required:
 - a. Checklist for Adult Sponsor (1)
 - b. Student Checklist (1A)
 - c. Research Plan
 - d. Approval Form (1B)
 - e. Regulated Research Institution Form (1C)
 - f. Vertebrate Animal Form (5B)
 - g. Qualified Scientist Form (2)

Sources of Information for Animal Care and Use

1) *Guide for the Care and Use of Laboratory Animals*, Institute of Laboratory Animal Research (ILAR), Commission on Life Sciences, National Research
http://dels.nas.edu/ilar_n/ilarhome/reports.shtml

2) *Principles and Guidelines for the Use of Animals in Precollege Education* (a free pamphlet from ILAR)

Can be found online:

http://dels.nas.edu/ilar_n/ilarhome/reports.shtml

3) *Guidelines for the Care and Use of Mammals in Neuroscience and Behavioral Research* (2003), Institute for Laboratory Animal Research (ILAR).

To order these ILAR publications contact:

National Academies Press
 500 Fifth Street, NW
 Lockbox 285
 Washington, DC 20055
 phone: 888-624-8373 or 202-334-3313
 fax: 202-334-2451; <http://www.nap.edu>

4) Federal Animal Welfare Act (AWA)
 7 U.S.C. 2131-2157
 Subchapter A - Animal Welfare (Parts I, II, III)
<http://www.nal.usda.gov/awic/legislat/awicregs.htm>

Above document is available from:

USDA/APHIS/AC
 4700 River Road, Unit 84
 Riverdale, MD 20737-1234
 email: ace@aphis.usda.gov
 Tel: (301) 734-7833
 Fax: (301) 734-4978
<http://awic.nal.usda.gov>

5) *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching (Agri-Guide)*
 Federation of Animal Science Societies (FASS)
 1111 N. Dunlap Avenue
 Savoy, IL 61874
 phone: (217) 356-3182
 email: fass@assoqhq.org
<http://www.fass.org>

6) *Guidelines for the Use of Fish in Research* (2004), American Fisheries Society.
<http://www.fisheries.org/afs/publicpolicy.html>

7) Euthanasia Guidelines
AVMA Guidelines on Euthanasia (June 2007)
 American Veterinary Medical Association.
http://www.avma.org/issues/animal_welfare/euthanasia.pdf

Sources of Information for Alternative Research and Animal Welfare

- 1) The National Library of Medicine provides computer searches through MEDLINE:
Reference & Customer Services
National Library of Medicine
8600 Rockville Pike
Bethesda, MD 20894
1-888-FIND-NLM or 1-888-346-3656
(301) 594-5983; email: custserv@nlm.nih.gov
<http://www.nlm.nih.gov>
<http://www.ncbi.nlm.nih.gov/entrez/query.fcgi>
- 2) National Agriculture Library (NAL) provides reference service for materials that document a) Alternative Procedures to Animal Use and b) Animal Welfare.
Animal Welfare Information Center
National Agriculture Library
10301 Baltimore Avenue, Room 410
Beltsville, MD 20705-2351
phone: (301) 504-6212, fax: (301) 504-7125
email: awic@nal.usda.gov
<http://www.nal.usda.gov/awic>
- 3) Institute of Laboratory Animal Resources (ILAR) provides a variety of information on animal sources, housing and handling standards, and alternatives to animal use through annotated bibliographies published quarterly in ILAR Journal.
ILAR
The Keck Center of the National Academies
500 Fifth Street, NW, Keck 687
Washington, DC 20001
phone: (202) 334-2590, fax: 202-334-1687
email: ILAR@nas.edu
<http://dels.nas.edu/ilar/>
- 4) Quarterly bibliographies of Alternatives to the Use of Live Vertebrates in Biomedical Research and Testing may be obtained from:
Specialized Information Services
NLM/NIH
2 Democracy Plaza, Suite 510
6707 Democracy Blvd., MSC 5467
Bethesda, MD 20892-5467
Ph: 301-496-1131; Fax: 301-480-3537
Toll Free: 1-888-FIND NLM or 1-888-346-3656
Email: tehip@tehl.nlm.nih.gov
<http://www.sis.nlm.nih.gov>;
<http://toxnet.nlm.nih.gov/altbib.html>
- 5) John's Hopkins Center for Alternatives to Animal Testing (CAAT) has worked with scientists since 1981 to find new methods to replace the use of laboratory animals in experiments, reduce the number of animals tested, and refine necessary tests to eliminate pain and distress.
email: caat@jhsph.edu
<http://caat.jhsph.edu/>