# Vertebrate Animals Rules involving Vertebrate Animals

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

SSP strongly endorses the use of non-animal research methods and encourages students to use alternatives to animal research. If the use of vertebrate animals is necessary, students must consider additional alternatives to reduce and refine the use of animals.

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.

A project is considered a tissue study and not a vertebrate animal study if tissue is obtained from an animal that was euthanized for a purpose other than the student's project. (Documentation is required of the IACUC approval for the original animal study from which tissues are obtained.) In tissue studies, a student may observe the vertebrate study, but may not manipulate or have any direct involvement in the vertebrate animal experimental procedures.

# **Rules for ALL Vertebrate Animal Studies**

- 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:
  - a. Live, nonhuman vertebrate mammalian embryos or fetuses
  - b. Tadpoles
  - c. Bird and reptile eggs within three days (72 hours) of hatching
  - d. All other nonhuman vertebrates (including fish) at hatching or birth.

Exception: Because of their delayed cognitive neural development, zebrafish embryos are not considered vertebrate animals until 7 days (168 hours) post-fertilization.

- 2. Alternatives to the use of vertebrate animals for research must be explored and discussed in the research plan. The guiding principles for the use of animals in research include the following "Four R's":
  - a. **Replace** vertebrate animals with invertebrates, lower life forms, tissue/cell cultures and/or computer simulations where possible.
  - b. **Reduce** the number of animals without compromising statistical validity.
  - c. **Refine** the experimental protocol to minimize pain or distress to the animals.
  - d. **Respect** animals and their contribution to research.

- 3. All vertebrate animal studies must be reviewed and approved before experimentation begins. An Institutional Animal Care and Use Committee, known as an IACUC, is the institutional animal oversight review and approval body for all animal studies at a Regulated Research Institution. The affiliated fair SRC serves in this capacity for vertebrate animals studies performed in a school, home or field. Any affiliated fair SRC serving in this capacity must include a veterinarian or an animal care provider with training and/or experience in the species being studied.
- 4. All vertebrate animal studies must have a research plan that includes:
  - a. Justification why animals must be used, including the reasons for the choice of species, the source of animals and the number of animals to be used; description, explanation, or identification of alternatives to animal use that were considered, and the reasons these alternatives were unacceptable; explanation of the potential impact or contribution this research may have on the broad fields of biology or medicine.
  - b. Description of how the animals will be used. Include methods and procedures, such as experimental design and data analysis; description of the procedures that will minimize the potential for discomfort, distress, pain and injury to the animals during the course of experimentation; identification of the species, strain, sex, age, weight, source and number of animals proposed for use.
- 5. Studies involving behavioral observations of animals are exempt from prior SRC review if ALL of the following apply:
  - a. There is no interaction with the animals being observed,
  - b. There is no manipulation of the animal environment in any way, and
  - The study meets all federal and state agriculture, fish, game and wildlife laws and regulations.
- 6. Students performing vertebrate animal research must satisfy US federal law as well as local, state, and country laws and regulations of the jurisdiction in which research is performed.
- 7. Research projects which cause more than momentary or slight pain or distress are prohibited. Any illness or unexpected weight loss must be investigated and a veterinarian consulted to receive required medical care. This investigation must be documented by the Qualified Scientist, Designated Supervisor who is qualified to determine the illness or a veterinarian. If the illness or distress is caused by the study, the experiment must be terminated immediately.
- 8. No vertebrate animal deaths due to the experimental procedures are permitted in any group or subgroup.
  - a. Studies that are designed or anticipated to cause vertebrate animal death are prohibited.

- b. Any death that occurs must be investigated by a veterinarian, the Qualified Scientist or the Designated Supervisor who is qualified to determine if the cause of death was incidental or due to the experimental procedures. The project must be suspended until the cause is determined and then the results must be documented in writing.
- c. If death was the result of the experimental procedure, the study must be terminated, and the study will not qualify for competition.
- 9. All animals must be monitored for signs of distress. Because significant weight loss is one sign of stress, the maximum permissible weight loss or growth retardation (compared to controls) of any experimental or control animal is 15%.
- 10. Students are prohibited from designing or participating in an experiment associated with the following types of studies on vertebrate animals:
  - a. Induced toxicity studies with known toxic substances that could cause pain, distress, or death, including but not limited to, alcohol, acid rain, pesticides, or heavy metals.
  - b. Behavioral experiments using conditioning with aversive stimuli, mother/infant separation or induced helplessness.
  - c. Studies of pain.
  - d. Predator/vertebrate prey experiments.
- 11. Justification is required for an experimental design that involves food or fluid restriction and must be appropriate to the species. If the restriction exceeds 18 hours, the project must be reviewed and approved by an IACUC and conducted at a Regulated Research Institution.
- 12. Animals may not be captured from or released into the wild without approval of authorized wildlife or other regulatory officials. All appropriate methods and precauthions must be used to decrease stress. Fish may be obtained from the wild only if the researcher releases the fish unharmed, has the proper license, and adheres to state, local and national fishing laws and regulations. The use of electrofishing is permissible only if conducted by a trained supervisor; students are prohibited from performing electrofishing.
- 13. A Qualified Scientist or Designated Supervisor must directly supervise all research involving vertebrate animals, except for observational studies.
- 14. 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.

# Additional Rules for Projects Conducted at School/Home/Field

Vertebrate animal studies may be conducted at a home, school, farm, ranch, in the field, etc. This includes:

- a. Studies of animals in their natural environment.
- b. Studies of animals in zoological parks.
- c. Studies of livestock that use standard agricultural practices.
- d. Studies of fish that use standard aquaculture practices.

These projects must be reviewed and approved by an SRC in which one member is either a veterinarian and/or an animal care provider/expert with training and/or experience in the species being studied.

- 1. These projects must adhere to BOTH of the following guidelines:
  - a. The research involves only 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.

All vertebrate animal studies that do not meet the above guidelines must be conducted in a Regulated Research Institutions. See Section B.

2. Animals must be treated kindly and cared for properly. Animals must be housed in a clean, ventilated, comfortable environment appropriate for the species. 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. Any of the following U.S. documents provide further guidance for animal husbandry:

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 Teaching (Ag-Guide) Quality Assurance Manuals (for the appropriate species)

3. The affiliated fair Scientific Review Committee must determine if a veterinarian's certification of the research plan and animal husbandry plans is required. This certification is required before experimentation and SRC approval and is documented on Vertebrate Animal Form 5A. A veterinarian must certify 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 illness or emergency occurs, the affected animal(s) must receive proper medical or nursing care that is directed by a veterinarian. A student researcher must stop experimentation if there is unexpected 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. If death is the result of the experimental procedure, the study must be terminated, and the study will not qualify for competition.
- 5. The final disposition of the animals must be described on Vertebrate Animal Form 5A.
- 6. Euthanasia for tissue removal and/or pathological analysis is not permitted for a project conducted in a school/home/field site. Livestock or fish raised for food using standard agricultural/aquacultural production practices may be euthanized by a qualified adult for carcass evaluation.
- 7. The following forms are required:
  - a. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan, and Approval Form (1B)
  - b. Vertebrate Animal Form (5A)
  - c. Qualified Scientist Form (2), when applicable

# Additional Rules for Projects Conducted in a Regulated Research Institution

All studies not meeting the criteria in Section A. but are otherwise permissible under Intel ISEF rules must be conducted in a Regulated Research Institution (RRI). A Regulated Research Institution within the U.S. 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 and may also be subject to U.S. Public Health Service Policy. 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 and research institutions that utilize research animals that are not covered by the Animal Welfare Act but have an operational Institutional Animal Care and Use Committee and are in compliance with U.S. federal laws are included in this definition. For project conducted outside of the United States, a Regulated Research Institution would be a comparable research institution that adheres to country laws governing the care and use of vertebrate animals.

Some protocols permitted in a Registered Research Institution are not permitted for participation in the Intel ISEF; adherence to RRI rules is necessary but may not be sufficient.

- 1. The Institutional Animal Care and Use Committee (IACUC) or the comparable animal oversight committee must approve all student research projects before experimentation begins. Such research projects must be conducted under the responsibility of a principal investigator. The local and regional SRC must also review the project to certify that the research project complies with Intel ISEF Rules. This local and regional SRC review should occur before experimentation begins, if possible.
- 2. Student researchers are prohibited from performing euthanasia. Euthanasia at the end of experimentation for tissue removal and/or pathological analysis is permitted. All methods of euthanasia must adhere to current American Veterinarian Medical Association (AVMA) Guidelines.
- 3. Research projects that cause more than momentary or slight pain or distress to vertebrate animals are prohibited unless approved anesthetics, analgesics and/or tranquilizers are used.
- 4. Research in nutritional deficiency or research involving substances or drugs of unknown effect is permitted to the point that any clinical sign of distress is noted. In the case that distress is observed, the project must be suspended and measures must be taken to correct the deficiency or drug effect. A project can only be resumed if appropriate steps are taken to correct the causal factors.
- 5. The following forms are required:
  - a. <u>Checklist for Adult Sponsor (1)</u>, <u>Student Checklist (1A)</u>, <u>Research Plan</u>, and <u>Approval Form (1B)</u>
  - b. Regulated Research Institution Form (1C)
  - c. Qualified Scientist Form (2)
  - d. Vertebrate Animal Form (5B)
  - e. PHBA Risk Assessment Form (6A) –for all studies involving tissues and body fluids.
  - f. Human and Vertebrate Animal Tissue Form (6B) for all studies involving tissues and body fluids.

#### Sources of information: Vertebrate Animals

#### **Animal Care and Use**

1. Laboratory Animals, Institute of Laboratory Animal Research (ILAR), Commission on Life Sciences, National Research

### http://dels.nas.edu/ilar

- 2. Guide for the Care and Use of Laboratory Animals, 8th Edition (2011)

  <a href="http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laborato...">http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laborato...</a>
  <a href="http://www.nap.edu/catalog.php?record\_id=12910">www.nap.edu/catalog.php?record\_id=12910</a>
- 3. Guidelines for the Care and Use of Mammals in Neuroscience and Behavioral Research (2003), Institute for Laboratory Animal Research (ILAR).

dels.nas.edu/report/guidelines-carey/10732

To order these ILAR publications contact:

National Academies Press

500 Fifth Street, NW

Washington, DC 20055

phone: 888-624-8373 or 202-334-3313 fax: 202-334-2451; www.nap.edu

4. Federal Animal Welfare Act (AWA)

7 U.S.C. 2131-2157

Subchapter A - Animal Welfare (Parts I, II, III)

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)

1800 S. Oak Street, Suite 100

Champaign, IL 61820-6974

phone: 217-356-3182

email: fass@assochq.org; www.fass.org

- 6. Guidelines for the Use of Fish in Research (2004), American Fisheries Society.

  www.fisheries.org

  www.fisheries.org/afs/docs/policy\_16.pdf
- 7. Euthanasia Guidelines AVMA Guidelines on Euthanasia (June 2007) American Veterinary Medical Association.

# www.avma.org/KB/Policies/Documents/euthanasia.pdf

#### **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

888-FIND-NLM or 888-346-3656 301-594-5983; email: info@ncbi.nlm.nig.gov

www.nlm.nih.gov

www.ncbi.nlm.nih.gov/sites/entrez

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: <a href="mailto:awic@ars.usda.gov">awic@ars.usda.gov</a> 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

phone: 301-496-1131; Fax: 301-480-3537 Toll Free: 888-FIND NLM or 888-346-3656

email: tehip@teh.nlm.nih.gov

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: <a href="mailto:caat@jhsph.edu">caat@jhsph.edu</a> http://caat.jhsph.edu/