

SCIENTIFIC REVIEW COMMITTEE (SRC) PACKET

To be read by all students considering science fair projects involving humans, invertebrate and non-human vertebrate animals, bacteria, recombinant DNA, tissue, pathogenic agents, or controlled substances. Teachers, parents or guardians, and qualified scientists should read this material as well.

TEACHERS: MAKE AS MANY COPIES OF THE ENCLOSED GUIDELINES AND FORMS AS NEEDED. ONLY ONE STUDENT PER FORM, PLEASE.

TO THE STUDENT, SPONSORING ADULT, AND/OR QUALIFIED SCIENTIST

1. The form you need to initially complete, the PROJECT PROPOSAL FORM, is enclosed. Additional paperwork may be required of you depending on the nature of your project. You will be contacted by phone if this is the case.

2. The Project Proposal form must be completed and submitted to the SRC BEFORE starting the project and no later than February 1.

3. If you do not hear by telephone from the SRC within ten (10) days of mailing in your form, you should assume that your project proposal has been approved and that you have no additional paperwork to complete. If you have any questions or concerns, please do not hesitate to contact Erica Hughes, the SRC chairperson, at (510) 525-2744.

4. Though the SRC approves project proposals from October through January, it does not actually see any finished projects until they are brought to the Fair in March. If it is determined by the SRC, upon inspection at the Fair, that your actual project doesn't reflect the approved project proposal, or if other concerns arise regarding the finished project, you will be contacted by phone prior to the judging.

5. Any project not conducted in conformity with these guidelines and the humane laws of California will be eliminated from competition and display.

6. If you are conducting a survey project, an informed consent/waiver form must be signed for each human subject involved in the project; a sample form is available from your teacher or from the SFBSASF Website. These signed forms must be submitted to and kept by your sponsoring teacher.

GUIDELINES FOR THE USE OF ANIMALS IN SCIENCE PROJECTS

INTRODUCTION

A strong allegiance to the principles of bioethics is vital to any discussion of responsible research practices. In accordance with the actions of several governing bodies (the State Humane Association of California, the Belmont Report, 1979; the Animal Welfare Act; the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, 1985; the Council for International Organizations of Medical Sciences, 1985; the Public Health Service Act; the NASA Guide for the Care and Use of Laboratory Animals, 1996; the National Institute of Health), the following principles are offered to guide careful consideration of the ethical challenges that arise in the course of animal research, a process that must balance risks, burdens, and benefits. It is recognized that awareness of these principles will not prevent conflicts. Rather, these principles are meant to provide a framework within which challenges and conflicts can be rationally addressed.

BASIC PRINCIPLES

The use of animals in research involves responsibility - not only for the stewardship of the animals, but to the scientific community and society as well. Stewardship is a universal responsibility that goes beyond the immediate research needs to include acquisition, care, and disposition of the animals, while responsibility to the scientific community and society requires an appropriate understanding of and sensitivity to scientific needs and community attitudes towards the use of animals.

Among the basic principles generally accepted in our culture, three are particularly relevant to the ethics of research using animals: respect for life, societal benefit, and nonmaleficence.

1. **RESPECT FOR LIFE** Living creatures deserve respect. This principle requires that animals used in research should be of an appropriate species and health status and should involve the minimum number required to obtain valid scientific results. It also recognizes that the use of different species may raise different ethical concerns. Selection of appropriate species should consider cognitive capacity and other morally relevant factors. Additionally, methods such as mathematical models, computer simulation, and in vitro systems should be considered and used whenever possible.
2. **SOCIETAL BENEFIT** The advancement of biological knowledge and improvements in the protections of the health and well being of both humans and other animals provide strong justification for biomedical and behavioral research. This principle entails that where animals are used, the assessment of the overall ethical value of such use should include consideration of the full range of potential societal goods, the population affected, and the burdens that are expected to be borne by the subjects of the research.
3. **NONMALEFICENCE** Vertebrate animals are sentient (conscious and sensitive organisms, aware of their environment). This principle entails that the minimization of distress, pain, and suffering is a moral imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in humans may cause pain or distress in other sentient animals.

REQUIREMENTS AND RULES REGARDING VERTEBRATE ANIMALS

All projects involving vertebrate animals must conform to the following:

REQUIREMENTS

1. The basic aim of any project involving living animals should be to increase the knowledge or understanding of life processes. It should not include the demonstration or development of surgical techniques. All projects involving animals must therefore have a clearly defined objective which requires the use of animals to demonstrate a biological principle or to answer a specific question.
2. A lower form of life should be selected for the project, rather than a higher form, whenever possible. Students are strongly urged to select invertebrate animals, plants, or tissue cultures.

3. California humane laws (enclosed) specifically forbid the mistreatment or neglect of animals, including animals used in schools and school-sponsored activities. Students, teachers, and supervisors must know and obey these laws.
4. All projects involving living animals must be preplanned and conducted with respect for life and for the humane needs and rights of the animals involved. This consideration must extend to the disposition of the animals after the conclusion of the project.

RULES

1. The comfort of all animals used in any project shall be a prime concern. Animals must be obtained from a reliable source and the following basic needs **MUST** be assured: appropriate, comfortable quarters, adequate food and water, cleanliness and humane treatment, exercise when required for the species of animal used. Students **MUST** make arrangements to provide these basic needs at all times, including weekends, vacations, and holiday periods.
2. No vertebrate animal will be subjected to any procedure or condition, including nutritional deficiency experiments, which results, **EITHER BY INTENTION OR NEGLIGENCE**, in pain, distinct discomfort, abnormal behavior, injury, or death. The term "vertebrate animal" includes vertebrate embryos and fetuses, and fowl embryos within three days of hatching.
3. No surgery, including biopsy, will be performed on any living animal.
4. To assure the humane treatment of animals, a qualified supervisor other than the student's sponsoring teacher or parent **MUST** assume responsibility for the condition of all living animals used. For all projects, this supervisor must be trained on the college or professional level in the proper care and handling of animals.
5. When planning the project, the student **MUST** arrange for the humane disposition of all animals involved after the project is completed. This may be done by placing them in an environment where they are assured of continued humane care, by releasing undomesticated species into a suitable wildlife environment, or by arranging for their humane euthanasia by a qualified adult. Students must **NOT** perform euthanasia of vertebrate animals under any circumstances. A complete account of the final disposition of all animals used **MUST** be included in the final report of all projects involving living animals.

SPECIFIC SFBASF SRC RULES (for 10th, 11th, and 12th grades)

(In accordance with the rules of the International Science and Engineering Fair)

FOR HUMAN SUBJECTS:

1. All human research projects, including surveys and questionnaires, are subject to SRC review before experimentation begins.
2. Student researchers must assess the risks to their human subjects when developing research plans. The following are examples of activities that may contain risks a student researcher might overlook: exercise, emotional stress resulting from invasion of privacy, ingestion of any substances or physical contact with any potentially hazardous materials. The following are examples of groups of humans that may contain risks a student researcher might overlook: any member of a group that is naturally at-risk: pregnant women, individuals with diseases such as cancer, asthma, diabetes, AIDS, etc.; special vulnerable groups covered by federal regulations: prisoners, handicapped or mentally disabled persons, economically or educationally disadvantaged persons.
3. Subjects 18 years and under require consent from a parent or guardian except in observational research where subjects cannot be identified and in situations in which no interaction takes place between the subject(s) and the researcher. A sample Informed Consent Form is enclosed in this packet.
4. A student may observe and collect data for analysis of new procedures and medications only under direct supervision of a licensed professional. Students are prohibited from administering medications to human subjects.
5. It is illegal to publish information in a report that identifies the human subjects directly or through identifiers linked to the subjects, including photographs. Names or photographs of human subjects may not be displayed with a project without informed consent of the subjects.

FOR NON-HUMAN VERTEBRATE ANIMALS:

1. Alternatives to vertebrate animals for research must be explored.
2. Students performing animal research must follow local, state, and federal regulations.
3. All common laboratory animals must be legally obtained from licensed animal breeders.
4. Animals must be treated kindly and cared for properly.

Website: www.sfbasf.org

Phone: (510) 215-1152

email: sfbasf AT gmail.com

5. Experimental procedures that cause pain/discomfort may not be attempted on any vertebrate animals.
6. Experiments designed to kill vertebrate animals or where there is a chance of death are not permitted.
7. Acid rain, insecticide, and herbicide toxicity studies on live vertebrates are prohibited.
8. Only the qualified scientist* or licensed animal care supervisor may perform euthanasia.
9. For grades 10-12, the SRC will consider projects provided that the project complies with all SFBASF rules and requirements as well as all local, state, and federal laws regarding the use of non-human vertebrate animals.

FOR HUMAN AND ANIMAL TISSUE:

1. Human blood and blood products must be documented free of Human Immunodeficiency Virus (HIV) and hepatitis B and C virus before the student receives them.
2. Students using their own blood do not need the HIV or hepatitis certifications described in #1 above.
3. Types of tissue that are exempted, and hence do not require the Tissue Provider signature or prior SRC approval include: plant tissue and meat or meat-by-products obtained from food stores or restaurants.

SPECIFIC SFBASF SRC RULES, continued

FOR RECOMBINANT DNA (rDNA):

1. The SFBASF adheres to NIH Guidelines and accepts the following definitions as rDNA molecules:
 - a. Molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell.
 - b. Molecules that result from the replication of those described above.
2. Student researchers working with any microorganism, whether or not they involve DNA, must always follow standard microbiological practices.
3. Students may conduct studies on both exempt and non-exempt rDNA and host organisms.
 - a. Non-exempt rDNA studies must be conducted in a federally registered research institution under direct supervision of a qualified scientist*.
 - b. Exempt rDNA studies may be conducted in non-federally registered laboratories, but must follow federal regulations. Exempt host organisms include the following: bacterium Escherichia, bacterium Bacillus subtilus, yeast Saccharomyces cerevesiae.
 - c. Exempt DNA insert molecules include the following: DNA molecules that are not in the DNA of organisms or viruses; DNA from single non-chromosomal or viral sources; DNA that is entirely from a prokaryotic host, including its indigenous plasmids or viruses when propagated only in the host.

FOR PATHOGENIC AGENTS:

1. Pathogenic agents are disease-causing or potentially disease-causing agents such as bacteria, viruses, rickettsia, fungi, and parasites.
2. Student research with pathogenic agents may be performed only under the direct supervision of an experienced and qualified scientist* in an institutional laboratory.

FOR CONTROLLED SUBSTANCES:

1. Student researchers must adhere to all federal regulations governing controlled substances. For further information:
 - on prescription drugs, contact the U.S. GPO; (202) 783-3238
 - on alcohol and tobacco, contact the Bureau of Alcohol, Tobacco, and Firearms (BATF) at (202) 927-8210.
 - on narcotics and addictive drugs, contact the Drug Enforcement Administration; (202) 307-7255 and contact appropriate state agencies concerning additional laws.
2. Production of alcohol is federally regulated; contact the BATF;
3. Only under the direct supervision of a qualified scientist* may a student use any federally controlled or experimental substance for therapy or experimentation, including over-the-counter drugs and potential new therapeutic substances.

*****QUALIFIED SCIENTIST:**

A qualified scientist should possess an earned doctoral degree in science or medicine. However, a master's degree with equivalent experience and/or expertise is acceptable when approved by the SRC. The qualified scientist must be thoroughly familiar with the local, state, and federal regulations that govern the student's area of research.