Section I Roles and Responsibilities of Students, Sponsors and Supervisors (Applicable to All Teachers and Students)

All student research projects involving tissue samples, human subjects, vertebrate animals or microbes must comply with the following guidelines from the International Science and Engineering Fair (ISEF) as modified by the Los Angeles County Science Fair Executive Committee:

- 1. <u>The Student Researcher(s)</u> are responsible for all aspects of the research project including enlisting any needed supervisory adults (i.e., Animal Care Supervisor, Biomedical Scientist or Designated Adult Supervisor) obtaining necessary approvals from the student's Teacher/ Advisor, following the LACSEF Regulations for Projects and completing the experimentation, engineering, data analysis, etc. involved in the project. *Any team members must all come from the same school.*
- 2. The Teacher/Advisor (Adult Sponsor) is the person in whose school or lab the student is working. This individual must have a solid background in science and should have close contact with the student during the course of the project. The Teacher/Advisor is ultimately responsible, not only for the health and safety of the student conducting the research, and for the tissue, human subjects, animals, hazardous materials and/or microbes used in the experiment. The Teacher/Advisor must review the student's Research Plan making certain of the following:
 - (a) Experimentation is done within local, state and federal laws and the Los Angeles County Science & Engineering Fair Project Screening Guidelines.
 - (b) Required Certification Form 601-068 (for Junior Division) and ISEF Certification Forms (for Senior Division) is completed by the student involved in the project and other adults involved in approving or supervising any part of the experiment prior to the start of research; and
 - (c) The qualifications of the Biomedical Scientist adhere to the criteria as indicated in Item #3.

The **Teacher/Advisor** must be familiar with the regulations that govern potentially dangerous research as it applies to a specific student project. This may include chemical and equipment usage, experimental techniques and research involving human or vertebrate animals, cell cultures, microorganisms, animal or human tissues. The regulations must be discussed with the student when completing the Research Plan.

Some experiments involve procedures or materials that are regulated by State and Federal laws. If not thoroughly familiar with these regulations, the Teacher/Advisor should help the student enlist the aid of a qualified Biomedical Scientist. *The <u>Teacher/Advisor</u> is responsible for ensuring that the student's research is eligible for entry in the Los Angeles County Science and Engineering Fair.*

3. A qualified <u>Biomedical Scientist</u> should possess an earned doctoral/professional degree in the biological or medical sciences as it relates to the student's area of research. However, a master's degree with equivalent experience and/or expertise in the student's area of research is acceptable when approved by the Teacher/Advisor. The Biomedical Scientist must be thoroughly familiar with local, state and federal regulations that govern the student's area of research.

The **Biomedical Scientist** and the Teacher/Advisor may be the same person, if that person is qualified as outlined above. A student may work with a Biomedical Scientist in another city or state. In this case, the student must also work locally with a Designated Adult Supervisor who has been trained in the techniques the student will use.

4. The <u>Designated Adult Supervisor</u> is an adult who is directly responsible for overseeing student experimentation. The Designated Adult Supervisor need not have an advanced degree, but should be thoroughly familiar with the student's project and *must be trained in the student's necessary research techniques*. The Teacher/Advisor *or the parent* may act as the Designated Adult Supervisor.

If a student is experimenting with live vertebrates and the animals are in a situation where humans influence their behavior or habitat, the Designated Adult Supervisor must be knowledgeable about the humane care and handling of the animals. If the Designated Adult Supervisor is *not knowledgeable*, the Teacher/Advisor must ensure that the student enlists the help of an Animal Care Supervisor.

5. An <u>Animal Care Supervisor</u> is required for all nonhuman vertebrate animal projects. This person must be familiar with the proper care and handling of research animals used in the project. The Biomedical Scientist, Designated Adult Supervisor or animal care professional can usually serve as the Animal Care Supervisor. Animal Care Supervisor may also be the Site Science Fair Coordinator.

Section I Roles and Responsibilities of Students, Sponsors and Supervisors (Applicable to All Teachers and Students)

<u>Los Angeles County</u> Science Review Committee (SRC)

The Los Angeles County Science Review Committee (SRC) is responsible for approval of any student project involving tissue/cell lines, human subjects, vertebrate animals, hazardous materials and/or microbes that may be entered in the Los Angeles County Science Fair.

A minimum of three persons will pre-screen project Research Plans involving the above categories. (Additional members may be appointed to the SRC to avoid conflict of interest.) The Los Angeles County Science Review Committee includes:

- (a) A Biomedical Scientist (Ph.D., M.D., D.V.M., D.D, S., etc.)
- (b) A Science Teacher/Advisor that is not sponsoring a project at the Los Angeles County Science & Engineering Fair.
- (c) A Science Fair Committee member that is not involved as a Teacher/Advisor or Animal Care Supervisor

The Los Angeles County Science Review Committee will examine the completed Research Plan (Certification Form No. 601-068, Junior Division or ISEF Certification Forms for Senior Division) for the following:

- (a) Evidence of literature search.
- (b) Evidence of required and proper supervision.
- (c) Use of accepted research techniques.
- (d) Complete signatures on Certification Forms.
- (e) Evidence of search for alternatives to animal use.
- (f) Humane treatment of animals.
- (g) Compliance with Los Angeles County Science
 & Engineering Fair guidelines, state and federal laws governing human, tissue and vertebrate animal research and adherence to the California Education Code.

- (h) Compliance with Los Angeles County Science
 & Engineering Fair guidelines and state and federal laws governing the use of recombinant
 DNA, pathogenic organisms, controlled substances, tissues and hazardous substances and devices.
- (i) Appropriate documents and substantial expansion for continuation projects.

NOTE: If a project is a continuation of a project that was previously entered into the Los Angeles County Science and Engineering Fair, the student must document, in the Research Plan, how the current year's project is new and must contain at least 2/3 new information. Repetitions of previous experimentation or increasing sample size are examples of unacceptable continuations. Display boards must reflect the current year's work. Supporting documentation, log books from previous related research, may be exhibited, if they are properly identified.

Scientific fraud and misconduct are not condoned at any level of research or competition. <u>Plagiarism</u>, use or presentation of other researcher's work as one's own, forgery of approval signatures and fabrication or falsification of data or approval dates will not be tolerated. *Fraudulent projects will fail to qualify for competition in affiliated Science Fairs*.

All students please note the following:

- 1. If the student project involves <u>tissue/cell lines</u>, you must be familiar with the regulations in Section II.
- 2. If the student project involves <u>human subjects</u>, you must be familiar with the regulations in Section III.
- 3. If the student project involves <u>live vertebrate animals</u>, you must be familiar with the regulations in Section IV.
- 4. If the student project involves <u>hazardous materials</u>, you must be familiar with the regulations in Section V.
- 5. If the student project involves <u>microbes</u>, you must be familiar with the regulations in Section VI.

Section II Regulations for Experiments with Tissue/Cell Lines

<u>ALL</u> projects involving research with tissue/cell lines must be pre-approved by the LA County Science Review Committee (SRC) before experimentation is begun.

Definition: Human or non-human tissue samples are defined as fresh tissue, organs, human or animal parts, blood, blood products (including *Blood Agar*), teeth, cell(s) and established cell lines and tissue cultures, DNA source material and body fluids (i.e., saliva, tears, urine.)

Research that DOES NOT need pre-approval

Plant tissue, cut hair samples, tissue samples, etc. obtained from commercial businesses, food stores, restaurants, or packinghouses **DO NOT need pre-approval.**

Prohibited Research

Students may not collect blood or tissue from living human or vertebrate animals. *California law only allows medical doctors, registered nurses or licensed phlebotomists (lab technicians) to collect blood from a vein or artery.* Animals may not be sacrificed **solely** to obtain tissue samples.

Safety Precautions

- 1. <u>All projects</u> must conform to the <u>CA Education Code</u> <u>Title 2, Division 2, Part 28, Chapter 4, Article 5, 51540.</u>
- Students may conduct research on human blood, blood products or other body fluids only if tissues are handled in accordance with standards and guidelines set forth in <u>OSHA 29CFR, Subpart z, 1810.1930</u> – Blood Borne Pathogens under the supervision of a qualified scientist.
- 3. <u>All bodily fluids</u> shall be treated in the same manner as pathogenic or potentially pathogenic agents as defined in Biosafety in Microbiological and Biomedical Laboratories (BMBL), http:// www.lascifair.org/wp-content/uploads/2014/05/BMBL.pdf
- 4. Any project involving human or non-human tissue samples shall have a **Research Plan** that includes the objectives and goals for the project and a list of the tissues, organs or parts involved in the experiment. The Research Plan shall describe fully the methods and techniques involved in the project including the procurement and disposition of all proposed tissue samples. The Research Plan shall also include the source for the tissue samples, genus, species and common name. The Research Plan shall indicate the date of sample acquisition and be certified by the person providing the tissue sample that *the student was not involved in the direct acquisition of the samples from living human or vertebrate animals*.
- 5. Human blood and blood products *(including Student Researcher's own blood)* <u>must be documented</u> by a research institution or certified blood test as free of *Acquired Immune Deficiency Syndrome (AIDS)* and *Hepatitis antibodies and antigens* prior to the student

receiving the tissue. **Teeth** shall be sterilized and <u>certified</u> <u>free of blood and blood products</u>.

6. When live or preserved tissue samples or parts of human or vertebrate animals are obtained by the student from an institution or Biomedical Scientist, *a statement signed by the adult providing the tissues is required.* Student researchers who collect specimens of body fluids from human subjects are also required to fill out a <u>Written</u> <u>Consent Form (see JR and SR forms below.)</u>

Supervision Regulations

- The student and Designated Adult Supervisor may consult with the Biomedical Scientist (if required) for detailed guidance in the techniques to be used by the student under the direct continuous supervision of the Designated Adult Supervisor.
- The Biomedical Scientist or Designated Adult Supervisor must be in the same locality as the student for the length of the experimental work. A project started in one city may not be continued in another unless an alternate Designated Adult Supervisor, approved by the Biomedical Scientist prior to the continuation of the experimental work, agrees to supervise the project.

Any proposed changes in the Research Plan and Attachments by the student after initial Los Angeles County Science Review Committee approval must have subsequent SRC approval before such changes are made and before experimentation resumes.

Human or Non-Human Tissue/Cell Lines Summary

Students conducting experiments with Human or Non-Human Tissue or Cells must submit the following **ONLINE at our Pre-approval Site.**

- 1. Information entered from the downloadable <u>Tissues-Cells</u> <u>Pre-approval template</u>
- 2. Download the **appropriate sample Written Consent Form** if tissues will be used from human subjects.
 - Jr-Div-Human-Consent-Form
 - Sr Human Informed Consent Form
 - Human-Subject-Consent-Form-EXAMPLE

SR projects need to also complete the downloadable 2015 SrDiv Tissue-Cells CertForms and keep them, with original signatures, for the judges.

For further information concerning these rules, regulations, and Certification Forms, contact:

Jennifer Moses, President

Los Angeles County Science & Engineering Fair 8504 Firestone Boulevard #247 Downey, CA 90241 Email: jmoses@lascifair.org Email: certforms@lascifair.org

Section III Regulations for Experiments with Human Subjects

ALL projects involving research with human subjects must be pre-approved by the LA County Science Review Committee (SRC) before experimentation is begun.

DEFINITION: Human subjects research includes projects involving: human subjects participating in physical activities (physical exertion, eating/drinking any substance, any medical procedure), psychological and opinion studies (survey, questionnaire, test of any kind), behavioral observations, studies in which the researcher is the subject of the research.

Prohibited Research and Disclosure

- 1. Student researchers may **NOT** publish or display information in a report that identifies the human subject directly or through identifiers linked to the subjects (including photographs), without written consent.
- 2. Students are **prohibited** from administering medications and performing medical procedures on human subjects.
- 3. Students under the age of 21 are prohibited by federal and state law from using <u>controlled substances</u> in their research projects. These substances include *all forms of alcohol, explosive materials, tobacco and firearms.*

Regulations and Supervision

There are **federal regulations** that must protect the rights and welfare of human subjects. Therefore, students must plan carefully before starting research that involves the use of human subjects in either behavioral or biomedical studies. This will protect subjects from unnecessary contact to physical or psychological complications.

- All Research Plans/Questionnaires involving human subjects must be received ONLINE at our new <u>Pre-approval Site</u> and certified by the Los Angeles County Science Fair Science Review Committee (SRC) *before research begins*.
- 2. A <u>Written Consent Form</u> (see downloadable forms below) is required for all projects. Children/Minors (under 18 years old) participating in research will require consent of the parent/guardian.
- The <u>Research Plan</u> must list objectives of the project and describe fully the methods and techniques involved (including planned use of anesthetics, drugs, thermal procedures, physical stress, and organisms causing diseases to humans or other vertebrates, radiation, carcinogens or surgical procedures).
- 4. When the use of <u>electrical current</u>, <u>laser beams</u>, <u>strong</u> <u>sounds or other artificial stimuli</u> are a basic part of the project, it must not exceed what humans or their tissues can tolerate.One place to look is the CA Ed Code or our **Hazardous Materials pre-approval page** if you are unsure.

- 5. The **use of the Internet** to obtain data for human subjects research is permitted. The Student Researcher and the Adult Sponsor must take additional care to ensure that survey responses remain confidential and informed consent *(the subject's written permission)* is documented.
- 6. When research activities involve **collection of personal information**, fingerprints) or health related data (genetic material, blood, tissue), the student must consider risks related to the violation of privacy.
- A student may observe and collect data for analysis of medical procedures and medication administration only under the direct supervision of a qualified professional. The qualified professional <u>must be named</u> in the Research Plan.

Any proposed changes in the Research Plan and Written Consent by the student <u>after</u> the initial SRC approval must have a <u>second</u> SRC approval before such changes are made and before experimentation resumes.

Risk Assessment

Risk Groups: Naturally at-risk groups include *pregnant* women, with diseases such as cancer, asthma, diabetes, AIDS, cardiac disorders, psychiatric disorders, etc. Special vulnerable at-risk groups include: children/minors, prisoners or mentally disabled persons.

Once a study population is chosen, the student researcher must consider any potential physical and/or psychological risks when developing the **Research Plan**. The federal definition of minimal risk is as follows: *No more than minimal risk exists when the probability and magnitude of harm or discomfort anticipated in the research are not greater (in and of themselves) than those ordinarily encountered in DAILY LIFE or during performance of routine physical or psychological examinations or tests.* Student researchers must be aware of the following:

Risk Activities – PHYSICAL:

- 1. **Exercise** other than ordinarily encountered in daily life by that subject.
- 2. Eating or drinking of any substance or exposure to any potentially hazardous materials, including environmental, drug and/or food allergies. Allergy symptoms including hives, rashes, swelling and or constricted breathing usually develop within a few minutes to two hours after eating the offending food and <u>must be considered in the Human Consent Form</u>.

Risk Activities – PSYCHOLOGICAL:

Any activity (survey, questionnaire, viewing of stimuli) or experimental condition that could potentially result in **emotional stress**

Page 4 Revised- June, 2015

Human Subjects Summary

Students conducting experiments with Human Subjects must submit the following ONLINE at our new **Pre-approval Site**.

- 1. Information entered from the downloadable <u>Human Subjects Pre-approval template</u>
- 2. Download the **appropriate sample Written Consent Form** to be given to human participants in your project, to understand the project procedures, risks and confidentiality.
 - Jr-Div-Human-Consent-Form
 - <u>Sr Human Informed Consent Form</u>
 - Human-Subject-Consent-Form-EXAMPLE

SR projects need to also complete the downloadable <u>2015 SrDiv ISEF Humans CertForms</u> and keep them, with original signatures, for the judges.

For further information concerning these rules, regulations and Certification Forms, contact:

Jennifer Moses, President

Los Angeles County Science & Engineering Fair 8504 Firestone Boulevard #247 Downey, CA 90241 Email: <u>jmoses@lascifair.org</u> Email: <u>certforms@lascifair.org</u>

Section IV Regulations for Experiments with Live Vertebrate Animals

<u>ALL</u> projects involving research with <u>vertebrate animals</u> must be pre-approved by the Los Angeles County Science Review Committee (SRC) before experimentation is begun. Any student research involving animals must comply with the requirements of the <u>State of California Education Code Title</u> 2, Division 2, Part 28, Chapter 4, Article 5, 51540.

DEFINITION: Vertebrate animals, as covered by these rules, includes all live, <u>non-human</u> vertebrate, <u>non-human</u> mammalian embryos or fetuses, bird and reptile eggs within three days (72 hours) of hatching and all other non-human vertebrates at hatching or birth. Any project involving vertebrate animals must have clearly defined objectives requiring the use of animals to demonstrate a biological principle or answer a specific scientific proposition.

Research that NEEDS NO PRE-APPROVAL

The use of Protista and other invertebrates is encouraged for most research involving animal and NEEDS NO PRE-APPROVAL.

Alternatives to the use of vertebrate animals for research <u>must</u> be explored and discussed in the Research Plan.

Prohibited Research:

In the public elementary and high schools or in public elementary and high school sponsored activities and classes held elsewhere than on school premises, <u>live vertebrate</u> <u>animals</u> **shall not, as part of a scientific experiment or any purpose whatever:**

- Be experimentally medicated or drugged in a manner to cause painful reaction or induce painful or lethal pathological conditions.
- Be injured through any other treatments, including, but not limited to, anesthetization or electric shock.
- Be involved in induced toxicity studies such as those using alcohol, acid rain, insecticide, herbicide, heavy metals, cosmetics, cleaning products, etc.
- Be exposed to behavioral experiments involving operant conditioning with aversive stimuli mother/infant separation or induced helplessness.
- Predator/prey experiments where one animal is deliberately being encouraged to hunt and eat another animal, with the exception of behavioral observations in the wild.

Students will **NOT** be involved in the <u>sacrifice or euthanasia</u> of a living vertebrate <u>or cause pain</u>, *for whatever reason*, to a vertebrate animal.

HUMANE TREATMENT OF ANIMALS

Live animals on the premises of a public elementary or high school shall be housed and cared for in a humane and safe manner.

All projects involving vertebrate animals shall be conducted in Page 7

compliance with the CA Education Code (above) AND Senior Projects must also follow the International Science and Engineering Fair (ISEF) Rules and Regulations regarding procurement, housing, husbandry, and experimental conditions available at following website: https://student.societyforscience.org/vertebrate-animals

- 1. **COMFORT:** <u>ALL</u> Animals (vertebrate or invertebrate) 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. Animals must be given a continuous, clean (uncontaminated) water and food supply. Cages, pens and fish tanks must be cleaned regularly and appropriately. 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 Animal Care Supervisor is required to oversee the daily husbandry of the animals.
- 2. **STRESS:** Experiments involving stress will follow the guidelines for CA Ed Code "Humane Treatment of Animals" above, stay within normal stress limits for the species and NOT produce pathological lesions (diseased patches or cancers). 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%.
- 3. **DIETARY RESTRICTIONS:** If an experimental design requires food or water restriction, it must be appropriate to the species, but may not exceed 18 hours.
- 4. UNEXPECTED DEATHS: 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.
- 5. **RESEARCH PLANS** for vertebrate animal studies must include the following:
 - **Justify** why animals must be used, including the reasons for choice of species and the number of animals. Describe any alternatives to animal use that were considered and why those alternatives were unacceptable or contribution this research may have on the broad fields of biology or medicine.
 - **Describe in detail** how the animals will be utilized in the experiment. Include methods and procedures, such as experimental design and data analysis. Describe any experimental procedures in detail. Identify the species, strain, sex, age, weight, source and number of animals proposed for the project.
 - **Proposed methods of animal care** need to be described and demonstrate this compliance with California Education Code and ISEF Rules and Regulations regarding procurement, housing,

Revised- June, 2015

husbandry, experimental conditions, and disposition of

Live Vertebrate Summary

Students conducting experiments with Live Vertebrate Animals must submit the following ONLINE at our <u>Pre-approval Site</u>

- 1. Information entered from the downloadable <u>Vertebrate Animals Pre-approval template</u>
- 2. **SR projects** need to <u>also</u> complete the downloadable <u>2015 SrDiv Vertebrate CertForms</u> and keep them, with original signatures, for the judges.

Any proposed changes in the Research Plan and Attachment by the student <u>after</u> initial SRC approval must have subsequent SRC approval before such changes are made and before experimentation resumes. Contact Jennifer Moses (below) for any proposed changes.

Any project not conducted in conformity with these rules and regulations the humane laws of the California Education Code will be disqualified from competition and display. *If a project is disqualified because of animal suffering through mistreatment or neglect, the appropriate law enforcement authorities will be notified.*

For additional information concerning these rules, regulations and Certification Forms, contact:

Jennifer Moses, President

Los Angeles County Science & Engineering Fair 8504 Firestone Boulevard #247 Downey, CA 90241 Email: <u>jmoses@lascifair.org</u> Email: <u>certforms@lascifair.org</u> all animals expected to be used in the project.

Section V Rules and Regulations Regarding Hazardous Materials, Activities or Devices

ALL projects involving research with hazardous materials must be pre-approved by the LA County Science Review Committee (SRC) before experimentation is begun, with the following exceptions:

- Model rocket experimentation using a fully assembled rocket motor, reload kit or propellant modules,
- Commonly used laboratory devices, assuming that the student researcher has experience working with them, such as Bunsen burners, hot plates, scales, saws, drills, hammers, etc. with oversight by an adult.

DEFINITION: research that involves the use of hazardous materials, devices and activities (Includes DEA-controlled substances, prescription drugs, alcohol & tobacco, firearms and explosives, radiation, lasers, etc.). Rules for Hazardous Materials include substances and devices that are regulated by local, state, country, or international law, most often with restrictions of their use by minors such as DEA-controlled substances, prescription drugs, alcohol and tobacco and firearms and explosives. Hazardous activities are those that involve a level of risk *above and beyond that encountered in the student's everyday life*.

Before beginning research involving hazardous materials, activities or devices, *be sure to check with your school or District fair as more strict rules and guidelines may be in effect.*

Prohibited Research

Liquid Nitrogen

Students are **prohibited from handling** liquid nitrogen (LN2). <u>Pre-approval is needed</u> for a project involving liquid nitrogen, which must be handled by an Adult Supervisor or scientist trained in safety requirements See <u>Health and Safety</u> <u>Code section 25500-25519</u>. Liquid Nitrogen is so cold that it can literally kill your skin when it gets on you and can cause asphyxiation and death if inhaled. It is generally around -320 degrees Fahrenheit. A full-face mask and protective cryogenic gloves and a full-length apron must be worn when handling nitrogen.

Prohibited Chemicals

The <u>CA Science Safety Handbook</u> lists *chemicals never to be stored or used in CA K-12 schools*, including:

- Explosive Chemicals (Table 7.2), pages 113-114
- Extremely Hazardous Chemicals (Table 7.3), pages 126-127

Prescription Drugs

Prescription drugs are drugs regulated by federal or country laws and are available only through a pharmacy to protect against inappropriate or unsafe use. Therefore, special precautions must be taken in their use for a science project.

- 1. Students are **prohibited** from <u>administering</u> prescription drugs to human subjects.
- 2. Students are **prohibited** from administering prescription drugs to vertebrate animals. The only exception is: *If a student is working with a veterinarian searching for a cure for his/her personal animal.* Strict veterinary supervision is required.

<u>Alcohol and Tobacco</u> – *Prohibited* for middle and high school students per <u>Title IV, Part A – Safe and Drug-Free</u> <u>Schools and Communities</u>

Firearms and Explosives – *Prohibited* for middle and high school students per <u>California Education Code</u>, Section 48915. "Firearm" means any device designed to be used as a weapon from which a projectile is expelled through a barrel by the force of any explosion or other form of combustion. Examples of "dangerous object" include but are not limited to: air soft guns, paintball guns, B.B. guns, pellet guns, air rifles, brass knuckles, fist packs, nunchaku, sling shots, throwing stars, darts and any object likely to cause injury to persons or property that has no reasonable use at school. <u>Education Code</u> 48900(b)

Creating explosions or setting items on fire is **strictly prohibited**. **M-80's and Cherry Bombs are explosives**. *Exceptions:* using a fully assembled rocket motor, reload kit or propellant modules; burning food with a calorimeter.

Supervision Regulations

- 1. The student researcher <u>must</u> conduct a risk assessment *in collaboration with* a Designated Supervisor or Qualified Scientist prior to experimentation.
- 2. The use of hazardous materials and devices and involvement in hazardous activities require <u>direct</u> <u>supervision</u> by a Designated Supervisor, *except those involving* **DEA-controlled substances**, which require supervision by a Qualified Scientist who is licensed by the DEA for use of the controlled substance.
- 3. All studies using **DEA Schedule 1** substances must have the research protocol approved by DEA before research begins. <u>Schedule 2, 3 and 4 substances do not require</u> <u>protocol approval by DEA.</u>
- 4. For all chemicals, devices or activities requiring a **Federal** and/or State Permit, the student/supervisor will be expected to have the permit prior to the onset of experimentation. A copy of the permit should be available for review by adults supervising the project and/or the Scientific Review Committee in their review prior to competition.

Safety Precautions

The student researcher must design experiments to minimize the impact that an experiment has on the environment, for instance using minimal quantities of chemicals that must subsequently be disposed of in an environmentally safe manner in accordance with good laboratory practices. The <u>CA</u> <u>Science Safety Handbook</u> describes general lab safety precautions (page 26-31).

Examples <u>not</u> needing preapproval: Dry Ice - *Always* handle *dry ice* with insulated gloves and wear eye protection.

• **Burning solid substances** (such with a calorimeter) must be performed under a fume hood or outside the classroom.

The **2015 EPA list of chemicals** known to cause cancer or reproductive problems can be <u>downloaded here.</u>

DEA-Controlled Substances

The U.S. Drug Enforcement Administration (DEA) regulates a number of chemicals that can be diverted from their regular use to make illegal drugs. If a student is uncertain whether chemicals involved in a project are controlled by the DEA, he/she should consult the <u>listing of DEA-controlled substances</u> (Click here).

Waste Disposal

Experimentation must include **proper disposal methods** for the chemicals/materials used in an experiment. The <u>CA</u> <u>Science Safety Handbook</u> describes safe waste disposal for substances used in the lab (page 123-124). The <u>Flinn Scientific Catalog</u> provides good information for the proper disposal of chemicals. If applicable, the student researcher must incorporate in the research plan disposal procedure required by federal and state guidelines. Flinn <u>Scientific</u> has an excellent FREE online <u>School Laboratory</u> <u>Safety Course</u>.

Risk Assessments

The student researcher <u>must</u> conduct a risk assessment in collaboration with a Designated Supervisor or Qualified Scientist prior to experimentation. This risk assessment is documented on the <u>2015 SrDiv ISEF Hazard Material</u> CertForms **or** the Hazard Materials Pre-approval template.

Hazardous Materials

A proper risk assessment of chemicals should include review of factors such as the degree of toxicity, reactivity, flammability or corrosiveness.

- **Toxicity** the tendency of a chemical to be hazardous to health when inhaled, swallowed, injected or in contact with the skin.
- **Reactivity** the tendency of a chemical to undergo chemical change.
- Flammability the tendency of a chemical to give off vapors which readily ignite when used under normal working conditions
- **Corrosiveness** the tendency of a chemical, upon physical contact, to harm or destroy living tissues or physical equipment.

When doing a risk assessment, the type and amount of exposure to a chemical must be considered. For example, an

Page 10 Revised- June, 2015 individual's allergies and/or family history may have an influence on the overall effect of any chemical. The student researcher must refer to <u>Safety Data Sheets (SDS)</u> to ensure that proper safety precautions are taken. Some SDS sheets (e.g., Flinn) rank the degree of hazard associated with a chemical. This rating may assist students and adult sponsors in determining risk associated with the use of a chemical.

Hazardous Devices

The documentation of a risk assessment (Form 3) is required when a student researcher works with potentially hazardous/dangerous equipment and/or other devices, in or outside a laboratory setting, that require a **moderate to high level of expertise to be used safely.** See hazardous levels of sound production on hearing on our webpage.

Use of other potentially dangerous devices such as high vacuum equipment, heated oil baths, NMR equipment, and high temperature ovens **must have documentation** of a risk assessment. It is recommended that all student-designed inventions also have documentation of a risk assessment.

Radiation

A risk assessment must be conducted when a student uses **non-ionizing radiation** *beyond that normally encountered in everyday life*. Non-ionizing radiation includes the spectrum of ultraviolet (UV), visible light, infrared (IR), microwave (MW), radiofrequency (RF) and extremely low frequency (ELF). Lasers usually emit visible, ultraviolet or infrared radiation. Lasers are classified into four classes based upon their safety. Manufacturers are required to label Classes II – IV lasers. This classification system changes periodically. Manufacturers have been known to make errors on labeling. Therefore, you should never look directly into a laser or a laser reflection thinking it is safe. Follow standard laser safety protocols to avoid laser exposure to bystanders.

- Class I lasers are those found in CD players, laser printers, geological survey equipment and some laboratory equipment. There are no known risks associated with using a Class I laser. THIS IS THE ONLY TYPE OF LASER THAT MAY BE DISPLAYED AT THE FAIR.
- **Class II lasers** are found in laser pointers, aiming and range finding devices and pose a risk if the beam is directly viewed over a long period of time.
- **Class III lasers** are found in higher powered laser pointers, printers and spectrometers. They are to be considered hazardous devices, which can cause eye damage when the beam is directly viewed even for a short period of time.
- **Class IV lasers** are high-powered lasers used in surgery, research, and industrial settings. They are extremely hazardous and can cause eye and skin damage. The beam is also a fire hazard.

Projects involving radionuclides (radioisotopes) and X-rays must involve a careful examination of the risks associated with the study. Depending upon the level of exposure, radiation released from these sources can be a health hazard. Most research institutions have a **Radiation Safety Office**, which oversees the use of ionizing radiation and ensures compliance with state and federal regulations.

Hazardous Materials, Devices & Activities Summary

Students conducting experiments with hazardous materials, devices and activities must submit the following **ONLINE at our new Pre-approval Site.**

- 1. Information entered from the downloadable Hazard Materials Pre-approval template
- SR projects need to also complete the downloadable <u>2015 SrDiv ISEF Hazard Material CertForms</u> and keep them, with original signatures, for the judges.

For additional information concerning these rules, regulations and Certification Forms, contact:

Jennifer Moses, President Los Angeles County Science & Engineering Fair 8504 Firestone Boulevard #247 Downey, CA 90241 Email: <u>jmoses@lascifair.org</u> Email: <u>certforms@lascifair.org</u>

Section VI Regulations for Experiments with Microbes (Pathogenic or potentially pathogenic bacteria, viruses, viroids, prions, Rickettsia, fungi or parasites)

<u>ALL</u> projects involving research with microbes must be preapproved by the Los Angeles County Science Review Committee (SRC) before experimentation is begun. **EXCEPTION**: Studies of mold growth on food items if the experiment is terminated at the <u>first evidence</u> of mold.

Definition: Microbes are defined as pathogenic (diseasecausing) or potentially pathogenic agents including *bacteria*, *viruses*, *viroids*, *Rickettsia*, *molds and other fungi or parasites*.

Prohibited Research

- Studies involving pathogenic agents or potentially pathogenic agents are **prohibited from being conducted in a home environment**, except that specimens may be collected at home. Student research with potentially pathogenic agents may be performed only under the direct supervision of an experienced Biomedical Scientist or Designated Adult Supervisor in an institutional laboratory, including a school, if facilities are adequate and appropriate.
- Laboratory studies utilizing **MRSA** (Methicillin-resistant Staphylococcus aureus) and **VRE** (Vancomycin-Resistant Enterococcus) are **prohibited**. Bacteria KNOWN to be pathogenic are **not** to be cultured. *Pure cultures of nonpathogenic microorganisms should be used in experiments* (e.g. pure E. coli purchased from a Scientific Supply Company, singly or in a kit.)
- *Studies intended to produce bacteria with <u>multiple</u> antibiotic resistance <i>are prohibited*.
- Bacterial studies must be conducted in a properly equipped school or institutional laboratory under qualified adult supervision. No experimentation using existing antibiotic-resistant microorganisms may be conducted at home or at school unless strains are auxotrophic as well. Auxotrophic microbes cannot survive unless they're grown on special medium that contains essential amino acids that they are incapable of producing. They die anywhere outside the Petri dish. District-approved Scientific Supply Houses provide auxotrophic bacterial strains in Lab Kits for use in AP and IB Science labs. These are approved strains.
- Students may NOT be directly involved in the obtaining of microbes (exception: microbe collection in the <u>environment</u> using sterile swabs and appropriate collection techniques and supervision.

Safety Precautions

These safety precautions are intended for experimental activities involving any bacteria or fungi. Even nonpathogenic microbes may cause disease if they enter the body accidentally. *Autoclave or disinfect all waste material; disinfect work areas with 10% bleach, use gloves and goggles.*

- Research involving pathogenic or potentially pathogenic agents shall be conducted following standard microbiological practices as defined in pathogenic or potentially pathogenic agents as defined in Biosafety in Microbiological and Biomedical Laboratories (BMBL), http://www.lascifair.org/wp-content/uploads/2014/05/BMBL.pdf
- All projects must conform to the <u>CA Education Code Title</u> 2, Division 2, Part 28, Chapter 4, Article 5, 51540.
- Collection from Human Subjects: Student researchers who collect specimens of pathogenic or potentially pathogenic agents from human subjects are also required to fill out a downloadable sample Written Consent Form to be given to human participants in your project, to understand the project procedures, risks and confidentiality. Choose the appropriate form below.
 - o <u>Jr-Div-Human-Consent-Form</u>
 - Sr Human Informed Consent Form
 - Human-Subject-Consent-Form-EXAMPLE
- Environmental Sampling of unknown microorganisms from school grounds, household surfaces and field sites off campus. These studies present a challenge because the identity, concentration, and pathogenicity of the cultured agents are unknown. Unknown microorganisms should be collected with proper safety procedures, *samples sealed immediately and grown in a school or institutional laboratory, NOT at home.* When soil or water is used as a source of bacteria (or molds), it is important to collect samples unlikely to be contaminated by human pathogens and never from areas suspected to be or posted as polluted. Collection of soil samples in or around old building sites, animal burrows and/or areas in which valley fever is endemic should be avoided.

Supervision

The student and Designated Adult Supervisor may consult with the Biomedical Scientist (if required) for detailed guidance in the techniques to be used by the student under the direct continuous supervision of the Designated Adult Supervisor. The Biomedical Scientist or Designated Adult Supervisor must be in the same locality as the student for the length of the experimental work. A project started in one city may not be continued in another unless an alternate Designated Adult Supervisor, approved by the Biomedical Scientist prior to the continuation of the experimental work, agrees to supervise the project.

Any proposed changes in the Research Plan and Attachments by the student after initial Los Angeles County Science Review Committee approval must have subsequent SRC approval before such changes are made and before experimentation resumes.

Page 12 Revised- June, 2015

Culturing (Growing) Microbes

- All cultures in Petri dishes must be bound together with transparent tape, immediately after exposure/inoculation. Any Petri dish that contains fungus/mold should be *taped shut*. Examine through lids only.
- **Inoculating loops** must be used with care. Wire loops used for transferring bacteria cultures should be flamed until the *entire* wire is *red* hot before and after each transfer is made. Petri dishes that are inoculated with materials containing unknown microorganisms (i.e., the material might not be a pure non-pathogenic culture) must not contain blood agar or Brain Heart Infusion (BHI) Broth, *(unless used in a research facility)* but rather nutrient or trypticase soy agar.
- Experimentation with molds and other fungi *must take* place in a fume hood or open-air area (to prevent contamination of living areas with mold spores and allergic reactions). If anyone in the area has a damaged immune system or any allergies, experiments with molds and other fungi must be conducted in a laboratory. Containers must be <u>sealed airtight</u> with tape around the edges during observations and disposed of as possible pathogens.

Disposal Techniques

- Glass Petri dishes: to sterilize plates before cleaning or disposal, follow these steps: Autoclave the unopened plates in the usual manner. Usually, steaming at a pressure of 15 pounds per square inch for 15 to 20 minutes kills most microbes. However, to sterilize soil samples or large volumes of culture, continue with the procedure described below. Wait one day for any resistant spores to leave the resting stage and begin to grow, sterilize a second time. Wait one more day, sterilize a third time – discard sterilized cultures in the regular trash.
- All cultured materials must be autoclaved at the end of experimentation according to the recommended procedures in the Science Safety Handbook for California Public Schools (2012 edition). Exception: Cultures of pure, non-pathogenic bacteria grown in plastic Petri dishes (usually obtained through Science Supply Company kits) can be covered with a 10% bleach solution and allowed to soak for at least 1 to 2 hours. Discard in the regular trash.
- **Disposable plastic petri dishes**: place unopened, sealed dishes in Biohazard disposal bags (included in Science

Supply kits for *E.coli* and molds) and use District pick-up of bags as hazardous waste. Calls to nearby universities and hospitals can also yield a place to dispose of microbial waste.

- Sterilizing plates of <u>pure</u>, non-pathogenic bacterial cultures: the materials can be covered with a 10% bleach solution and allowed to soak for at least 1 to 2 hours. Discard sterilized cultures in the regular trash.
- Operation of Pressure Cooker (instead of an autoclave) for Sterilization
 - Before using a pressure cooker, the teacher should be familiar with directions for its operation.
 - The safety valve should be examined to make sure it is in working order.
 - The gauge pressure should be kept at or below a maximum of 20 pounds per square inch.
 - The pressure should be returned to zero before the cover can be safely removed.
 - The test stopcock should be opened before the clamp can be safely released.
 - An eye-protective device should be used when working with a pressure cooker.

Microbes Summary

Students conducting experiments with ANY microbes must submit the following **ONLINE at our new** <u>Pre-approval</u> <u>Site.</u>

- 1. Information entered from the downloadable <u>Microbes Pre-approval template</u>.
- SR projects need to <u>also</u> complete the downloadable <u>2015</u> <u>SrDiv ISEF Microbes CertForms</u> and keep them, with original signatures, for the judges.

For further information concerning these rules, regulations, and Certification Forms, contact:

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