HUMAN PARTICIPANT RULES

Rules involving human participants

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 human participants and the student researcher. Health and well-being is of the highest priority when students conduct research with human participants.

According to Code of Federal Regulation 45, CFR 46, a human participant is a living individual about whom an investigator conducting research obtains (1) data or samples through intervention or interaction with individuals(s) or (2) identifiable private information.

Examples of projects that are considered "human participant research" include:

- Participants in physical activities (e.g., physical exertion, ingestion of any substance, any medical procedure)
- Psychological, educational and opinion studies (e.g., surveys, questionnaires, tests)
- Studies in which the researcher is the subject of the research
- Testing of student designed invention, prototype or computer application by human participants other than student researcher
- Data/record review projects that include data that are not de-identified/anonymous (e.g., data set that includes name, birth date, phone number or other identifying variables)
- Behavioral observations that
  a. involve any interaction with the observed individual(s) or where the researcher has modified the environment (e.g., post a sign, place an object).
  b. occur in non-public or restricted access settings (e.g., day care setting, doctor's office)
  c. involve the recording of personally identifiable information.

RULES

1. Student researchers must complete ALL elements of the Human Participants portion of the Research Plan/Project Summary Instructions and evaluate and minimize the physical, psychological and privacy risks to their human participants. See Risk Assessment information on page 11 and the online Risk Assessment Guide (**https://sspcdn.blob.core.windows.net/files/Documents/SEP/ISEF/Resources/Risk-Assessment-Guide.pdf**) for additional guidance.
2. Student research involving human participants must be reviewed and approved by an Institutional Review Board (IRB) (See page 6) before any interaction (e.g., recruitment, data collection) with human participants may begin. It is the responsibility of the IRB to evaluate potential physical and/or psychological risks of the project and make a determination about whether the project is appropriate for student research and safe for the student researcher and participants.
   a. Projects that are conducted at school, at home or in the community that are not affiliated with a Regulated Research Institution (RRI) must be reviewed and approved by the School IRB before the student may begin recruiting and/or interacting with human participants. The School IRB must assess the risk and document its determination of risk on Form 4.
   b. Projects that are conducted at a Regulated Research Institution (RRI) (e.g., university, hospital, medical center, government lab) must have IRB approval from the RRI. A copy of the IRB approval for the project must be obtained. A letter from an adult mentor and/or Qualified Scientist is not sufficient documentation of the RRI IRB review and approval process.
3. The student must comply with all determinations made by the School or RRI IRB before beginning any interaction with human participants (e.g., recruitment, data collection).
   a. If the IRB requires a Qualified Scientist (QS), Form 2 must be completed by the QS before any interaction with human participants. The School IRB will review this completed form before approving the project.
   b. If the IRB requires a Direct Supervisor (DS), Form 3 must be completed before any interaction with human participants. The School IRB will review this completed form before approving the project.
   c. See rule #4 below regarding required procedures for obtaining informed consent/assent and/or parental permission.
4. Participation in research may begin only after research participants have voluntarily given informed consent/assent (in some cases with parental permission). Adult research participants may give their own consent. Research participants under 18 years of age and/or individuals not able to give consent (e.g. developmentally disabled individuals) give their assent, with the parent/guardian providing permission.

   The School IRB will determine whether the consent/assent/parental permission may be a) verbal or implicit or b) must be written. See the Risk Assessment information on page 11 and the online **Risk Assessment Guide** for further explanation of informed consent.
   a. Informed consent requires that the researcher provides complete information to the participant (and where applicable, parents or guardians) about the risks and benefits associated with participation in the research study, which then allows the participants and parents or guardians to make an informed decision about whether or not to participate.
   b. Participants must be informed that their participation is voluntary and that they are free to stop participating at any time (i.e., they may participate or decline to participate, with no adverse consequences of non-participation or aborted participation).
   c. Informed consent may not involve coercion.
   d. When written parental permission is required and the study includes a survey, the survey must be attached to the consent form.
   e. The student researcher may request that the IRB waive the requirement for written informed consent/parental permission in his/her research plan if the project meets specific requirements. See section on IRB waivers for more information about situations in which written parental permission and/or written informed consent can be waived by the IRB.

5. The research study must be in compliance with all privacy laws (e.g., U.S. Family Educational Rights and Privacy Act (FERPA) and the U.S. Health Insurance Portability and Accountability Act (HIPAA)) when they apply to the project (e.g. the project involves medical information).
6. Students are prohibited from independently diagnosing disease, administering medication, and/or performing medical procedures on human participants.
    a. A student may observe and collect data for analysis of medical procedures, medication/treatment efficacy, and diagnosis of illness, only under the direct supervision of a licensed health care provider/professional. Students are prohibited from drawing blood or conducting any other medical procedures on anyone except themselves.
    b. This Healthcare provider/professional must be named in the research plan/ protocol approved by the IRB. The IRB must also confirm that the student is not violating the appropriate practice act (medical, nursing, pharmacy, etc) of the state or country in which he/she is conducting the research.
    c. Students are prohibited from providing advice, diagnostic or medical information to participants without direct supervision and involvement of a medical professional. This includes publishing diagnostic apps on public websites or app stores without appropriate FDA approvals.
7. Student researchers may NOT publish or display information in a report that identifies the human participants directly or through identifiers linked to the participants (including photographs) without the written consent of the participant(s) (Public Health Service Act, 42, USC 241 (d)).
8. All published instruments that are not in the public domain must be administered, scored and interpreted by a Qualified Scientist as required by the instrument publisher. Any and all use and distribution of the test must be in accordance with the publisher's requirements, including procurement of legal copies of the instrument.
9. Studies that involve the collection of data via use of the internet (e.g., email, web-based surveys) are allowed, but researchers should be aware that they can pose challenges in collecting anonymous data, obtaining informed consent, and ensuring that participants are of the appropriate age to give informed consent.
    a. Studies that involve the use of minors in conducting online surveys must have Informed Consent and the parent/guardian of the minor must provide written parental permission before the survey may be given to the minor. The procedures used to obtain parental permission must be described in the Research Plan.
    b. In order to protect the confidentiality of the participants, it is extremely important that IP addresses, as well as the data provided, be safeguarded. Precautions must be delineated in the Research Plan.

    For suggestions as to how to comply with 9a and 9b above please see the **Online Survey Consent Procedures**.
10. After initial IRB approval, a student with any proposed changes in the Research Plan must repeat the approval process and regain approval before resuming interaction (recruitment, data collection) with human participants.
11. After experimentation and before competition, the Affiliated Fair SRC will review for compliance with all rules.
12. The following forms are required for studies involving human participants:
    a. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan/Project Summary, and Approval Form (1B)
    b. Human Participants Form (4) for projects reviewed by school IRB or IRB approval documentation from an RRI and all applicable informed consents and survey(s)
    c. Regulated Research Institution Form (1C), when applicable
    d. Qualified Scientist Form (2), when applicable
    e. Risk Assessment (3) when applicable

IRB WAIVER OF WRITTEN INFORMED CONSENT/PARENTAL PERMISSION

The IRB may waive the requirement for documentation of written informed consent/assent/parental permission if the research involves only minimal risk and anonymous data collection and if it is one of the following:

1. Research involving normal educational practices
2. Research on individual or group behavior or characteristics of individuals where the researcher does not manipulate the participants' behavior and the study does not involve more than minimal risk.
3. Surveys, questionnaires, or activities that are determined by the IRB to involve perception, cognition, or game theory, etc. and that do NOT involve gathering personal information, invasion of privacy or potential for emotional distress.
4. Studies involving physical activity where the IRB determines that no more than minimal risk exists and where the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in DAILY LIFE or during performance of routine physical activities.

If there is any uncertainty regarding the appropriateness of waiving written informed consent/assent/parental permission, it is strongly recommended that documentation of written informed consent/assent/parental permission be obtained.

HUMAN PARTICIPANT INVOLVEMENT IN STUDENT-DESIGNED INVENTION, PROTOTYPE, COMPUTER APPLICATION, ENGINEERING/DESIGN CONSUMER PROJECTS & PRODUCT TESTING

Student-designed invention, prototype, computer application, engineering/design projects and product testing that involve testing of the invention or consumer product by any human participant require attention to the potential risks to the individual(s) testing or trying out the invention/prototype.

1. IRB review and pre-approval is required when the student-designed invention, prototype, application, etc. is tested by human participants other than the student researcher(s) or single adult guardian/adult sponsor/QS/DS when the testing requires an adult tester. This includes surveys conducted regarding potential use or opinions of the invention or consumer product by the general public. This is not intended to apply to professional feedback from experts in the field of study.
2. Human participants testing of an invention, prototype or project that involves a medical diagnosis or intervention (as defined by the FDA or Medical Practices Act) must adhere to Rule 6 of the Human Participant Rules regarding prohibition of medical procedures and be supervised by a health care professional with appropriate credentials and specialization in the area of medical diagnosis or intervention being studied.
3. A Risk Assessment Form 3 is required for all projects that involve human participant testing of any project involving student- designed inventions, prototypes or consumer products.

EXEMPT STUDIES (DO NOT REQUIRE IRB PREAPPROVAL OR HUMAN PARTICIPANTS PAPERWORK)

Some studies involving humans are exempt from IRB pre-approval or additional human participant forms. Exempt projects for ISEF and affiliated fairs are:

1. Student-designed Invention, Prototype, Computer Applications, Engineering/Design Project or Consumer Product Testing in which the student researcher is the only person testing the invention, prototype, computer application or consumer product and the testing does not pose a health or safety hazard.
    a. The exemption can also apply when the human participant testing is a single adult guardian or Adult Sponsor/QS/DS when the testing requires an adult tester.
    b. It is required that a Risk Assessment Form (3) be completed for all such projects.
    c. IRB review and pre-approval is required if the project involves more than the student researcher or any introduction of a human variable or factor in the testing of a consumer product/invention/prototype/application (e.g., amount of sleep, strength or endurance of tester, etc.).
2. Data/record review studies (e.g., baseball statistics, crime statistics) in which the data are taken from preexisting data sets that are publicly available and/or published and do not involve any interaction with humans or the collection of any data from a human participant for the purpose of the student's research project.
3. Behavioral observations of unrestricted, public settings (e.g., shopping mall, public park) in which all of the following apply:
    a. the researcher has no interaction with the individuals being observed
    b. the researcher does not manipulate the environment in any way and
    c. the researcher does not record any personally identifiable data.
4. Projects in which the student receives pre-existing/ retrospective data in a **de-identified/anonymous** format which complies with both of the following conditions:
    a. the professional providing the data certifies in writing that the data have been appropriately de-identified before being given to the student researcher and are in compliance with all privacy and HIPAA laws, and
    b. the affiliated fair SRC ensures that the data were appropriately de-identified by review of the written documentation provided by the supervising adult(s).

HUMAN PARTICIPANT & IRB RESOURCES

Use this information to help determine the level of risk involved in a study involving human participants.

All human participant projects are considered to have some level of risk.

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 by a potential participant in everyday life or during performance of routine physical or psychological examinations or tests.

More than minimal risk exists when the possibility of physical or psychological harm or harm related to breach of confidentiality or invasion of privacy is greater than what is typically encountered in everyday life. Most of these studies require documented informed consent or minor assent with the permission of parent or guardian (as applicable).

1. **Examples of Greater than Minimal Physical Risk**
   a. Exercise other than ordinarily encountered in everyday life.
   b. Ingestion, tasting, smelling, or application of a substance. However, ingestion or tasting projects that involve commonly available food or drink will be evaluated by the IRB which determines risk level based upon the nature of the study and local norms.
   c. Exposure to any potentially hazardous material.

2. **Examples of Greater than Minimal Psychological Risk**

   A research activity (e.g. survey, questionnaire, viewing of stimuli) or experimental condition that could potentially result in emotional stress. Some examples include: answering questions related to personal experiences such as sexual or physical abuse, divorce, depression, anxiety; answering questions that could result in feelings of depression, anxiety, or low self esteem; or viewing violent or distressing visual images.

3. **Privacy Concerns**
   a. The student researcher and IRB must consider whether an activity could potentially result in negative consequences for the participant due to invasion of privacy or breach of confidentiality. Protecting confidentiality requires measures to ensure that identifiable research data are not disclosed to the public or unauthorized individuals.
   b. Risk level can be reduced by protecting confidentiality or collecting data that is strictly anonymous. This requires the collection of research in such a way that it is impossible to connect research data with the individual who provided the data.

4. **Risk Groups**

   If the research study includes participants from any of the following groups, the IRB and student research must consider whether the nature of the study requires special protections or accommodations:
   a. Any member of a group that is naturally at-risk (e.g. pregnant women, developmentally disabled persons, economically or educationally disadvantaged persons, individuals with diseases such as cancer, asthma, diabetes, AIDS, dyslexia, cardiac disorders, psychiatric disorders, learning disorders, etc.)
   b. Special groups that are protected by federal regulations or guidelines (e.g. children/minors, prisoners, pregnant women, students receiving services under the Individuals with Disabilities Education Act (IDEA).

   See the online **Risk Assessment Guide** and **Online Survey Consent Procedures** for more detailed information on risk assessment. If the risk is more than minimal, a Risk Assessment Form 3 is required.

VERTEBRATE ANIMAL RULES

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. Health and well-being is of high priority when students conduct research with animal subjects.

The Society for Science strongly endorses the use of non-animal research methods and encourages students to use alternatives to animal research, which 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":

- **Replace** vertebrate animals with invertebrates, lower life forms, tissue/cell cultures and/or computer simulations where possible.
- **Reduce** the number of animals without compromising statistical validity.
- **Refine** the experimental protocol to minimize pain or distress to the animals.
- **Respect** animals and their contribution to 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 for all vertebrate animal studies 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. (Use of tissues obtained from research conducted at a Regulated Research Institution requires a copy of an IACUC certification with the name of the research institution, the title of the study, the IACUC approval number and date of IACUC approval.) 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.

Vertebrate animals, as covered by these rules, are defined as:

1. All nonhuman vertebrates (including fish) at hatching or birth.
2. Live nonhuman vertebrate mammalian embryos or fetuses
3. Tadpoles
4. Bird and reptile eggs starting three days (72 hours) prior to hatching

Exception: Because of their delayed cognitive neural development, zebrafish embryos may be used up to seven days (168 hours) post-fertilization and not be considered a vertebrate. However, regardless of time of treatment, survival past the 7 days must be considered a vertebrate animal and the entire study is subject to all of the rules below.

RULES FOR ALL VERTEBRATE ANIMAL STUDIES

1. 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.
2. 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 local or affiliated fair SRC serves in this capacity for vertebrate animals studies performed in a school, home or field. Any SRC serving in this capacity must include a veterinarian or an animal care provider with training and/or experience in the species being studied.
3. 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.
4. 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 or Direct Supervisor, who is qualified to determine the illness, or by a veterinarian. If the illness or distress is caused by the study, the experiment must be terminated immediately.
5. 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 Direct 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.
6. All animals must be monitored for signs of distress. Because significant weight loss is one sign of stress, weight must be recorded at least weekly with 15% being the maximum permissible weight loss or growth retardation (compared to controls) of any experimental or control animal. If weighing of animals cannot be done in a fashion that is safe for both the researcher and the animal, then an explanation and approval by an SRC or IACUC needs to be included in the research plan, as well as an alternative method(s) to address signs of distress. Additionally, body conditioning scoring (BCS) systems are available for most species of animals utilized in research and

agriculture and are an objective method for assessing the overall health status of the research subject, with or without weight loss. A BCS system should be included in the design of any study utilizing live vertebrate animals and results regularly recorded.

7. 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 or studies with the intent to study toxic effects of a substance on a vertebrate animal.
   b. Behavioral experiments using conditioning with aversive stimuli, mother/infant separation or induced helplessness.
   c. Studies of pain.
   d. Predator/vertebrate prey experiments.
8. 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 (RRI).
9. Animals may not be captured from or released into the wild without approval of authorized wildlife or other regulatory officials. All appropriate methods and precautions 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.
10. A Qualified Scientist or Direct Supervisor must directly supervise all research involving vertebrate animals, except for observational studies.
11. After initial SRC approval, a student with any proposed changes in the Research Plan/Project Summary of the project must repeat the approval process before laboratory experimentation/data collection resumes.

A. 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:

1. Studies of animals in their natural environment.
2. Studies of animals in zoological parks.
3. Studies of livestock that use standard agricultural practices.
4. 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 criteria in Section A. must be conducted in a Regulated Research Institution (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 Direct 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 and Teaching (Ag-Guide)
   - Quality Assurance Manuals (for the appropriate species)
3. The local or affiliated fair Scientific Review Committee must determine if a veterinarian's certification of the research and animal husbandry plan is required. This certification, as well as SRC approval, is required before experimentation 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 conducted in a responsible and ethical manner, and 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.
7. Livestock or fish raised for food using standard agricultural/ aquacultural production practices may be euthanized by a qualified adult for carcass evaluation.
8. The following forms are required:
   a. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan/Project Summary, and Approval Form (1B)
   b. Vertebrate Animal Form (5A)
   c. 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 that are otherwise permissible under 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 (IACUC) and are in compliance with U.S. federal laws are included in this definition. For projects 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 Regulated Research Institution are not permitted for participation in 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 affiliated fair SRCs must also review the project to certify that the research project complies with 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 Veterinary Medical Association (AVMA) Guidelines.
3. Research projects that cause more than momentary or slight pain or distress to vertebrate animals are prohibited unless mitigated by IACUC-approved anesthetics, analgesics and/or tranquilizers.
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. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan/Project Summary, and Approval Form (1B)
    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 are available as a separate section at the end of the document.

EXEMPT STUDIES (DO NOT REQUIRE SRC PREAPPROVAL)

1. 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
    c. The study meets all federal and state agriculture, fish, game and wildlife laws and regulations.

POTENTIALLY HAZARDOUS BIOLOGICAL AGENTS (PHBA) RULES

Potentially Hazardous Biological Agents Rules for use of microorganisms (including bacteria, viruses, viroids, rickettsia, fungi and parasites), recombinant DNA technologies or human or animal fresh/frozen tissues, blood, or body fluids.

Students are permitted to do research projects with potentially hazardous biological agents meeting the conditions and rules described below which were designed to protect students and to ensure adherence to federal and international biosafety regulations and guidelines.

When dealing with potentially hazardous biological agents, it is the responsibility of the student and all of the adults involved in a research project to conduct and document a risk assessment on Form (6A) to define the potential level of harm, injury or disease to plants, animals and humans that may occur when working with biological agents. The risk assessment determines a biosafety level which in turn determines if the project can proceed, and if so, the proposed laboratory facility is properly equipped and all personnel are trained and appropriate supervision is planned.

All projects involving microorganisms, recombinant DNA technologies and human or animal fresh/frozen tissues, blood or body fluids must adhere to the rules below AND, depending on the study, to the additional rules in Section A, B or C.

RULES FOR ALL PROJECTS WITH POTENTIALLY HAZARDOUS BIOLOGICAL AGENTS (PHBA)

1. Prior review and approval is required for the use of potentially hazardous microorganisms (including bacteria, viruses, viroids, rickettsia, fungi, and parasites), recombinant DNA (rDNA) technologies or human or animal fresh/frozen tissues, blood, or body fluids.
2. An affiliated fair SRC, an IBC or an IACUC must approve all research before experimentation begins. The initial risk assessment determined by the student researcher and adults supervising the project must be confirmed by the SRC, IBC or IACUC.
3. Experimentation involving the culturing of potentially hazardous biological agents, even BSL-1 organisms, is prohibited in a home environment. However, specimens may be collected at home as long as they are immediately transported to a laboratory with the BSL containment determined by the affiliated fair SRC.
4. Research determined to be at Biosafety Level 1 (BSL-1) must be conducted in a BSL-1 or higher laboratory. The research must be supervised by a trained Direct Supervisor or a Qualified Scientist. The student must be properly trained in standard microbiological practices.
5. Research determined to be a Biosafety Level 2 (BSL-2) must be conducted in a laboratory rated BSL-2 or above (commonly limited to a Regulated Research Institution). The research must be reviewed and approved by the Institutional Biosafety Committee (IBC) if the Regulated Research Institution requires the review. For a high school BSL-2 laboratory, the SRC must review and approve. The research must be supervised by a Qualified Scientist.
6. Students are prohibited from designing or participating in BSL-3 or BSL-4 Research.
7. Laboratory studies designed to culture known clinically significant multidrug resistant organisms (MDROs) must have a written justification for usage and be conducted at a Regulated Research Institution laboratory with a minimum of BSL-2 containment and documented IBC review and approval. Representative examples include, but are not limited to the following known agents: MRSA (Methicillin-Resistant *Staphylococcus aureus*), VISA/VRSA (Vancomycin Intermediate or Resistant *Staphylococcus aureus*), VRE (Vancomycin-Resistant *Enterococci*), CRE (Carbapenem Resistant *Enterobacteriacae*), ESBLs (Extended Spectrum Beta-Lactamase producing gram negative organisms), and fungi (yeasts or molds) with known resistance to antifungal agents.
8. Insertion of antibiotic resistance markers for the clonal selection of bioengineered organisms is permitted, with the following exceptions:
   a. Students are prohibited from the insertion of antibiotic-resistance traits or selection of organisms expressing traits that may affect the ability to provide effective treatment of infections acquired by humans, animals, or plants.
   b. Students are prohibited from designing or selecting for multiple drug resistant organisms (MDROs) to investigate the pathology, development, or treatment of antibiotic-resistant infections.
9. Extreme caution must be exercised when selecting and sub-culturing antibiotic-resistant organisms. Studies using such organisms, including BSL-1 organisms that may have originally been exempt from prior SRC approval, require at least BSL-2 containment.
10. All studies involving the use of prions or prion-like proteins are prohibited.
11. The culturing of human or animal waste, including sewage sludge, is considered a BSL-2 study.
12. Naturally-occurring plant pathogens may be studied (not cultured) at home, but may not be introduced into a home/garden environment.
13. All local, state and national laws and permit requirements must be followed regarding the transport and use of microorganisms such as, but not limited to citrus greening or tobacco mossaic, etc.
14. All potentially hazardous biological agents must be properly disposed at the end of experimentation in accordance with their biosafety level. For BSL 1 or BSL 2 organisms: Autoclave at 121 degrees Celsius for 20 minutes, use of a 10% bleach solution (1:10 dilution of domestic bleach), incineration, alkaline hydrolysis, biosafety pick-up and other manufacturer recommendations are acceptable.
15. Any proposed changes in the Research Plan/Project Summary by the student after initial local or affiliated fair SRC approval must undergo subsequent SRC or IBC review and approval before such changes are made and before experimentation resumes.
16. The following forms are required:
   a. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan/Project Summary, and Approval Form (1B)
   b. Regulated Research Institution Form (1C)—when applicable

c. Qualified Scientist (2), when applicable
d. Risk Assessment (3), when applicable
e. PHBA Risk Assessment Form (6A), when applicable
f. Human and Vertebrate Animal Tissue Form (6B)—for all studies involving tissues and body fluids.

A. Additional Rules for Projects Involving Unknown Microorganisms

Studies involving unknown microorganisms present a challenge because the presence, concentration and pathogenicity of possible agents are unknown. In science fair projects, these studies typically involve the collection and culturing of microorganisms from the environment (e.g. soil, household surfaces, skin.)

1. Research with unknown microorganisms can be treated as a BSL-1 study under the following conditions:
   a. Organism is cultured in a plastic petri dish (or other standard sterile non-breakable container) and sealed.
   b. Experiment involves only procedures in which the petri dish remains sealed throughout the experiment (e.g., counting presence of organisms or colonies).
   c. The sealed petri dish is disposed of via autoclaving or disinfection under the supervision of the Direct Supervisor.
2. If a culture container with unknown microorganisms is opened for any purpose, (except for disinfection/disposal), it must be treated as a BSL-2 study and involve BSL-2 laboratory precautions.

B. Additional Rules for Projects Involving Recombinant DNA (rDNA) Technologies

Studies involving rDNA technologies in which microorganisms, plants and/or animals have been genetically modified require close review to assess the risk level assignment. Some rDNA studies can be safely conducted in a BSL-1 high school laboratory with prior review by a SRC.

1. All rDNA technology studies involving BSL-1 organisms and BSL-1 host vector systems, including commercially available kits, must be conducted in at least a BSL-1 laboratory under the supervision of a Qualified Scientist or Direct Supervisor and must be approved by the SRC prior to experimentation. Examples include cloning of DNA in *E. coli K–12, S. cerevesiae,* and *B. subtilis* host-vector systems.
2. An rDNA technology study using BSL-1 agents that may convert to BSL-2 agents during the course of experimentation must be conducted entirely in a BSL-2 facility.
3. All rDNA technology studies involving BSL-2 organisms and/or BSL-2 host vector systems must be conducted in a Regulated Research Institution and approved by the IBC prior to experimentation, where applicable.
4. Propagation of recombinants containing DNA coding for human, plant or animal toxins (including viruses) is prohibited. All genome editing studies that include alteration of germline cells, insertion of gene drives, use of rapid trait development systems (RTDS®), etc., should be categorized as a BSL-2 study and must be conducted at an RRI and approved by the IBC from the institution. Qualified scientists are expected to ensure that student research protocols address appropriate intrinsic and extrinsic containment precautions.
5. Introduction or disposal of non-native, genetically-altered, and/or invasive species (e.g. insects or other invertebrates, plants, vertebrates), pathogens, toxic chemicals or foreign substances into the environment is prohibited. Students and adult sponsors should reference their local, state and national regulations and quarantine lists.

C. Additional Rules for Projects with Tissues and Body Fluids, including Blood and Blood Products

Studies involving fresh/frozen tissue, blood or body fluids obtained from humans and/or vertebrates may contain microorganisms and have the potential of causing disease. Therefore, a proper risk assessment is required.

1. Research involving human and/or non-human primate established cell lines and tissue culture collections (e.g., obtained from the American Type Culture Collection) must be considered a BSL-1 or BSL-2 level organism as indicated by source information and treated accordingly. The source and/or catalog number of the cultures must be identified in the Research Plan/Project Summary.
2. If tissues are obtained from an animal that was euthanized for a purpose other than the student's project, it may be considered a tissue study.
   a. Use of tissues obtained from research conducted at a Regulated Research Institution requires a copy of the IACUC certification with the name of the research institution, the title of the study, the IACUC approval number and date of IACUC approval.
   b. Use of tissues obtained from agricultural/aquacultural studies require prior SRC approval.
3. If the animal was euthanized solely for the student's project, the study must be considered a vertebrate animal project and is subject to the vertebrate animal rules. (See vertebrate animal rules.)
4. The collection and examination of fresh/frozen tissue and/or body fluids, (not including blood or blood products; see rule 7) from a non-infectious source with little likelihood of microorganisms present must be considered biosafety Level 1 studies and must be conducted in a BSL-1 laboratory or higher and must be supervised by a Qualified Scientist or trained Direct Supervisor.
5. The collection and examination of fresh/frozen tissues or body fluids or meat and meat by-products NOT obtained from food stores, restaurants, or packing houses may contain microorganisms. Because of the increased risk from unknown potentially hazardous agents, these studies must be considered biosafety level 2 studies conducted in a BSL-2 laboratory under the supervision of a Qualified Scientist.
6. Human breast milk of unknown origin, unless certified free of HIV and Hepatitis C, and domestic unpasteurized animal milk are considered BSL-2.
7. All studies involving human or wild animal blood or blood products should be considered at a minimum a biosafety level 2 study and must be conducted in a BSL-2 laboratory under the supervision of a Qualified Scientist. Known BSL-3 or BSL-4 blood is prohibited. Studies involving domestic animal blood may be considered a BSL-1 level study. All blood must be handled in accordance with standards and guidelines set forth in the OSHA, 29CFR, Subpart Z. Any tissue or instruments with the potential of containing blood-borne pathogens (e.g. blood, blood products, tissues that release blood when compressed, blood contaminated instruments) must be properly disposed after experimentation.

8. Studies of human body fluids, where the sample can be identified with a specific person, must have IRB review and approval, and informed consent.
9. Any study involving the collection and examination of body fluids that may contain biological agents belonging to BSL-3 or BSL-4 is prohibited.
10. A project involving a student researcher using their own body fluids (if not cultured)
    a. can be considered a BSL-1 study
    b. may be conducted in a home setting
    c. must have IRB review if the body fluid is serving as a measure of an effect of an experimental procedure on the student researcher (e.g. student manipulates diet and takes a blood or urine sample). An example of a project not needing IRB review would be collecting urine to serve as a deer repellent.
    d. must receive prior SRC review and approval prior to experimentation
11. Studies involving embryonic human stem cells must be conducted in a Registered Research Institution and reviewed and approved by the ESCRO (Embryonic Stem Cell Research Oversight) Committee.

EXEMPT STUDIES (NO SRC PRE-APPROVAL REQUIRED)

The following types of studies are exempt from requiring SRC pre-approval as listed below, but may be subject to additional rules dependent upon the design of the project. Student researchers and adult sponsors are required to refer to sections A, B, and C of this section to review additional rules for projects that involve unknown organisms, recombinant DNA (rDNA) technologies, tissues, fluids, blood, or blood products before deciding upon a final biosafety level (BSL) designation for projects.

1. The following types of studies are exempt from prior SRC review, but require a Risk Assessment Form 3:
    a. Studies involving protists and archaea
    b. Research using manure for composting, fuel production, or other non-culturing experiment
    c. Commercially available color change coliform detection test kits; these kits must remain sealed and must be properly disposed
    d. Studies involving decomposition of vertebrate organisms (such as in forensic projects)
    e. Studies with microbial fuel cells in which the device is sealed during experimentation and disposed of properly at the conclusion of the study
2. The following types of studies involve BSL-1 organisms and are exempt from prior SRC review and require no additional forms:
    a. Studies involving fermentation of baker's yeast and brewer's yeast, except in rDNA studies
    b. Studies involving *Lactobacillus*, *Bacillus thuringiensis*, nitrogen-fixing, oil-eating, and algae-eating bacteria introduced into their natural environment (not exempt if cultured in a petri dish environment)
    c. Studies involving water or soil microbes not concentrated in media conducive to their microbial growth
    d. Studies of mold growth on food items if the experiment is terminated at the first evidence of mold
    e. Studies of slime molds and edible mushrooms
    f. Studies involving *E. coli* K-12 that are performed at school and are not subject to additional rules for recombinant DNA studies or use of antibiotic resistant organisms.
    g. Studies involving *E. coli* OP-50 and other strains of *E. coli* that are used solely as a food source for *C. elegans* and are performed at school and are not subject to additional rules for recombinant DNA studies or use of antibiotic resistant organisms.

EXEMPT TISSUES (NO SRC PRE-APPROVAL REQUIRED)

1. The following types of tissue do not need to be treated as potentially hazardous biological agents:
    a. Plant tissue (except those known to be toxic or hazardous)
    b. Plant and non-primate established cell lines and tissue culture collections (e.g., obtained from the American Type Culture Collection). The source and/or catalog number of the cultures must be identified in the Research Plan/Project Summary
    c. Human capillary/blood collection (i.e. finger stick) of the student researcher to themself; blood collection from any other human participants must be reviewed and approved by an IRB
    d. Fresh or frozen meat, meat by-products obtained from food stores, restaurants, or packing houses and eggs or pasteurized milk
    e. Hair, hooves, nails and feathers
    f. Teeth that have been sterilized to kill any blood-borne pathogen that may be present
    g. Fossilized tissue or archeological specimens.
    h. Prepared fixed tissue

Sources of Information are available as a separate section at the end of the document.

POTENTIALLY HAZARDOUS BIOLOGICAL AGENTS RISK ASSESSMENT

Use this information to complete PHBA Risk Assessment Form (6A)

Risk assessment defines the potential level of harm, injury or disease to plants, animals and humans that may occur when working with biological agents. The end result of a risk assessment is the assignment of a biosafety level which then determines the laboratory facilities, equipment, training, and supervision required.

Risk assessment involves:

1. Assignment of the biological agent to a risk group.
2. Studies involving a known microorganism must begin with an initial assignment of the microorganism to a biosafety level risk group based on information available through a literature search.
3. The study of unknown microorganisms and the use of fresh tissues relies on the expertise of the supervising adult(s).
4. Determination of the level of biological containment available to the student researcher to conduct the experimentation. (See "Levels of Biological Containment" for details.)
5. Assessment of the experience and expertise of the adult(s) supervising the student.
6. Assignment of a biosafety level for the study based on risk group of biological agent, level of biological containment available and the expertise of the Qualified Scientist or Direct Supervisor who will be supervising the project.
7. Documentation of review and approval of study prior to experimentation:
   a. If a study is conducted at a non-regulated site (e.g. school), the SRC reviews the Research Plan/Project Summary.
   b. If the study was conducted at a Regulated Research Institution, and was approved by the appropriate institutional board (e.g. IBC, IACUC), the SRC reviews the institutional forms provided and documents SRC approval (Form(6A)).
   c. If a PHBA study was conducted at a Regulated Research Institution but the institution does not require review for this type of study, the SRC must review the study and document approval on Form 6A that the student received appropriate training and the project complies with ISEF rules.

Classification of Biological Agents

Risk Groups

Biological agents are classified according to biosafety level risk groups. These classifications presume ordinary circumstances in the research laboratory, or growth of agents in small volumes for diagnostic and experimental purposes.

BSL-1 risk group contains biological agents that pose low risk to personnel and the environment. These agents are highly unlikely to cause disease in healthy laboratory workers, animals or plants. The agents require Biosafety Level 1 containment. Examples of BSL-1 organisms are: Agrobacterium tumefaciens, Micrococcus leuteus, Neurospora crassa, Bacillus subtilis.

BSL-2 risk group contains biological agents that pose moderate risk to personnel and the environment. If exposure occurs in a laboratory situation, the risk of spread is limited and it rarely would cause infection that would lead to serious disease. Effective treatment and preventive measures are available in the event that an infection occurs. The agents require Biosafety Level 2 containment. Examples of BSL-2 organisms are: Mycobacterium, Streptococcus pneumoniae, Salmonella choleraesuis.

BSL-3 risk group contains biological agents that usually cause serious disease (human, animal or plant) or that can result in serious economic consequences. Projects in the BSL-3 group are prohibited.

BSL-4 risk group contains biological agents that usually produce very serious disease (human, animal or plant) that is often untreatable. Projects in the BSL-4 group are prohibited.

Levels of Biological Containment

There are four levels of biological containment (Biosafety Level 1–4). Each level has guidelines for laboratory facilities, safety equipment and laboratory practices and techniques.

BSL-1 containment is normally found in water-testing laboratories, in high schools, and in colleges teaching introductory microbiology classes. Work is done on an open bench or in an appropriate biosafety hood. Standard microbiological practices are used when working in the laboratory. Decontamination can be achieved by treating with chemical disinfectants or by steam autoclaving. Lab coats and gloves are required. The laboratory work is supervised by an individual with general training in microbiology or a related science.

BSL-2 containment is designed to maximize safety when working with agents of moderate risk to humans and the environment. Access to the laboratory is restricted. Biological safety cabinets (Class 2, type A, BSC) must be available. An autoclave should be readily available for decontaminating waste materials. Lab coats and gloves are required; eye protection and face shields must also be worn as needed. The laboratory work must be supervised by a scientist who understands the risk associated with working with the agents involved.

BSL-3 containment is required for infectious agents that may cause serious or potentially lethal diseases as a result of exposure by inhalation. Projects in the BSL-3 group are prohibited.

BSL-4 containment is required for dangerous/exotic agents that pose high risk of life-threatening disease. Projects in the BSL-4 group are prohibited.

HAZARDOUS CHEMICALS, ACTIVITIES OR DEVICES RULES

Includes DEA-controlled substances, prescription drugs, alcohol & tobacco, firearms and explosives, radiation, lasers, etc.

The following rules apply to research using hazardous chemicals, devices and activities. These 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, tobacco, firearms and explosives. Hazardous activities are those that involve a level of risk above and beyond that encountered in the student's everyday life.

These rules are intended to protect the student researcher by ensuring proper supervision and the consideration of all potential risks so that the appropriate safety precautions are taken. Students are required to meet all standards imposed by ISEF, school, local, and/or regional fair(s).

RULES FOR ALL PROJECTS INVOLVING HAZARDOUS CHEMICALS, ACTIVITIES OR DEVICES

1. The student researcher must conduct a risk assessment in collaboration with a Direct Supervisor or Qualified Scientist prior to experimentation. This risk assessment should be documented in the research plan to include the risk assessment process, supervision, safety precautions and appropriate methods of disposal. This risk assessment is also documented on Risk Assessment Form 3.
2. The use of hazardous chemicals and devices and involvement in hazardous activities require direct supervision by a Direct Supervisor, except those involving DEA-controlled substances, which require supervision by a Qualified Scientist.
3. Student researchers must acquire and use regulated substances in accordance with all local, state, U.S. federal and country laws. For further information or classification for these laws and regulations, contact the appropriate regulatory agencies.
4. For all chemicals, devices or activities requiring a federal and/or state permit, the student/supervisor must obtain the permit prior to the onset of experimentation. A copy of the permit must be available for review by adults supervising the project and the local, affiliated, and ISEF SRCs in their review prior to competition.
5. The student researcher must minimize the impact of an experiment on the environment. Examples include using minimal quantities of chemicals that will require subsequent disposal; ensuring that all disposal is done in an environmentally safe manner and in accordance with good laboratory practices. (Proper chemical, sharps and other hazardous materials disposal must follow local, state, federal guidelines.)
6. The following forms are required:
    a. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan/Project Summary and Approval Form (1B)
    b. Regulated Research Institution Form (1C), when applicable
    c. Qualified Scientist Form (2), when applicable
    d. Risk Assessment Form (3)

ADDITIONAL RULES FOR SPECIFIC REGULATED AREAS

There are additional rules for the following regulated areas:

A. DEA-controlled Substances
B. Prescription Drugs
C. Alcohol & Tobacco
D. Firearms and Explosives
E. Regulated Drones
F. Radiation

A. DEA-Controlled Substances

The U.S. Drug Enforcement Administration (DEA) regulates chemicals that can be diverted from their intended use to make illegal drugs. Other countries may have similar regulatory bodies; students outside of the U.S. must adhere to their own country's drug regulatory agency requirements in addition to U.S. DEA regulations. DEA-controlled substances and their schedule number are at the DEA website under Sources of Information. It is the responsibility of the student to consult this list if there is a possibility that substances used in experimentation could be regulated.

a. All studies using DEA-controlled substances must be supervised by a Qualified Scientist at a RRI (and must be conducted at a Regulated Research Institution) who is licensed by the DEA (or other international regulatory body) for use of the controlled substance.

b. All studies using DEA Schedule 1 substances (including marijuana) must have the research protocol approved by DEA before research begins. Schedule 2, 3 and 4 substances do not require protocol approval by DEA.

B. Prescription Drugs

In the United States, the Food and Drug Administration (FDA) tightly regulates the issuance of prescription drugs including non-controlled medications. State laws further regulate the use of prescription drugs, and it is unlawful for any person to knowingly or intentionally possess a non-controlled medication unless it was obtained directly from a valid prescription or order of a practitioner while acting in the course of their professional practice. It is also unlawful to use a prescription for persons or purposes outside of the original intent of the prescription or for the person it was originally prescribed for. All applicable federal, state, and country laws must be followed.

1. Students are prohibited from the use of prescription drugs in their study outside the authority of a practitioner or researcher that has obtained the non-controlled medication with appropriate approvals and is using the medication for the purpose for which it was prescribed.
2. Exemptions include research and educational products purchased that are considered research grade and not pharmaceutical grade, therefore not for human consumption.
3. In the case of prescription drugs administered to verterbrate animals, this may ony be done under a veterinarian's supervision and with prescriptions provided for this specified purpose.

C. Alcohol and Tobacco

The U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) regulates the production of alcohol and distribution of alcohol and tobacco products. Many such products are restricted by age for purchase, possession and consumption.

1. Fermentation studies in which minute quantities of ethyl alcohol are produced are permitted.
2. The Direct Supervisor is responsible for the acquisition, usage and appropriate disposal of the alcohol or tobacco used in the study.
3. Production of wine or beer by adults is allowable in the home and must meet TTB home production regulations. Students are allowed to design and conduct a research project, under direct parental supervision, involving the legal production of the wine or beer.
4. Students are prohibited from conducting experiments where consumable ethyl alcohol is produced by distillation. However, students are allowed to distill alcohol for fuel or other non-consumable products. To do so, the work must be conducted at school or a Regulated Research Institution and follow all local and country laws. See Alcohol and Tobacco Tax and Trade Bureau (TTB) website for details.

D. Firearms and Explosives

The U.S. Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), along with state agencies, regulates the purchase and use of firearms and explosives. A firearm is defined as a small arms weapon from which a projectile is fired by gunpowder. An explosive is any chemical compound, mixture or device, the primary purpose of which is to function by explosion. Explosives include, but are not limited to, dynamite, black powder, pellet powder, detonators, and igniters.

The purchase of a firearm by a minor is generally unlawful. The use of a firearm, without proper state certification, is illegal. Students should check the training and certification requirements of individual states and countries.

1. Projects involving firearms and explosives are allowable when conducted with the direct supervision of a Direct Supervisor and when in compliance with all federal, state and local laws.
2. A fully assembled rocket motor, reload kit or propellant modules containing more than 62.5 grams of propellant are subject to the permitting, storage and other requirements of federal explosive laws and regulations.
3. Potato guns and paintball guns are not considered firearms unless they are intended to be used as weapons. However, they must be treated as hazardous devices.

E. Regulated Drones

Projects involving unmanned aircraft systems (UAS)/drones must follow all state, federal and country laws. See the Federal Aviation Administration (FAA) for more details **(https://www.faa.gov/uas/)**.

Current U.S. law requires all forms of drones to be registered with the FAA.

F. Radiation

Projects involving radionuclides (radioisotopes) and X-rays must involve a careful examination of the risks associated with the study and appropriate safety precautions must be taken. Depending upon the level of exposure, radiation released from these sources can be a health hazard.

1. All studies may not exceed the dose limits set by the Nuclear Regulatory Commission of 0.5 mrem/hr or 100 mrem/year of exposure.
2. If the voltage needed in the study is <10 kvolts, a risk assessment must be conducted. The study may be done at home or school, and SRC preapproval is not required.
3. A study using 10–25 kvolts must have a risk assessment conducted and must be preapproved by the SRC to assess safety. Such a study must be conducted in a metal-lined chamber using a camera only, not direct view through glass. A dosimeter or radiation survey meter is required to measure radiation exposure.
4. All studies using > 25 kvolts must be conducted at an institution with a Licensed Radiation Program and must be preapproved by the Institutions' Radiation Safety Officer or the Committee which oversees the use of ionizing radiation to ensure compliance with state and federal regulations.

GUIDANCE FOR RISK ASSESSMENT

PLEASE FIND BELOW GUIDANCE ON CONDUCTING RISK ASSESSMENT WHEN USING THE FOLLOWING: HAZARDOUS CHEMICALS, HAZARDOUS DEVICES, RADIATION

1. Hazardous Chemicals

A proper risk assessment of chemicals must include review of the following factors:

a. Toxicity—the tendency of a chemical to be hazardous to human or environmental health
   - Human health toxicity includes acute and chronic hazards when inhaled, swallowed, injected or in contact with the skin.
   - Environmental health includes aquatic toxicity (both acute and chronic), toxicity to mammals and birds, and impact on ecosystems.

b. Reactivity—the tendency of a chemical to undergo chemical change, including instability and reactivity with other substances or conditions (i.e., reaction with water, air, temperature, pressure).

Environmentally Responsible Chemistry

The mission of environmentally responsible (green) chemistry is to avoid the use or production of hazardous substances during chemical process. The principles of green chemistry are described on the EPA website in the Sources of Information section. Whenever possible the following principles should be incorporated into the research plan.

- Waste prevention
- Use of the safest possible chemicals and products
- Design of the least possible hazardous chemical syntheses
- Use of renewable materials
- Use of catalysts in order to minimize chemical usage
- Use of solvents and reaction conditions that are safe as possible
- Maximization of energy efficiency
- Minimization of accident potential and avoiding the use of reactive substances

c. Flammability—the tendency for a chemical substance to be ignited at ambient temperatures. Combustible substances can include:
   - Chemical solvents that produce vapors which readily ignite when used under normal working conditions.
   - Combustible solids (small particles, powders, or substances easily ignited by fire or an ignition source)

d. Corrosiveness—the tendency of a chemical, upon physical contact, to harm or destroy living tissues or physical equipment.

When assessing risk, the type and amount of exposure to a chemical must be considered. For example, an individual's allergic and genetic disposition may have an influence on the overall effect of the chemical. The student researcher must refer to Safety Data Sheets provided by the vendor (SDS) 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.

A risk assessment (documented on Form 3) must include proper disposal methods for the chemicals used in an experiment. The Flinn Catalog (referenced in the Sources of Information section) provides 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.

2. Hazardous Devices

The documentation of 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 ensure their safe usage. Some commonly used devices (Bunsen burners, hot plates, saws, drills, etc.) may not require a documented risk assessment, assuming that the student researcher has experience working with the device. 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.

3. Radiation

A risk assessment (documented on Form 3) must be conducted when a student's project involves radiation beyond that normally encountered in everyday life. Non-ionizing radiation includes the spectrum of ultraviolet (UV), visible light, infrared (IR), microwave (NW), radiofrequency (RF) and extremely low frequency (ELF).

ENGINEERING AND INVENTION PROJECTS GUIDE

USE THIS INFORMATION TO HELP DETERMINE THE REQUIREMENTS OF ENGINEERING PROJECTS AND POTENTIAL AREAS THAT WILL REQUIRE PRE-APPROVAL AND/OR EXTRA SAFETY PRECAUTIONS.

A GUIDE FOR ENGINEERING & INVENTION PROJECTS HAS BEEN DEVELOPED AS AN ADDITIONAL RESOURCE AND PROVIDES A SERIES OF QUESTIONS TO CONSIDER AS YOU BEGIN AND DESIGN AN ENGINEERING OR INVENTION PROJECT.

ENGINEERING AND INVENTION PROJECT CHECKLIST

Consider the answers to the questions below. If the response is yes, then the project may fall under more specific rules and those sections of the International Rules & Guidelines should be consulted.

Hazardous Chemicals, Activities and Devices

Will your project involve any of the following:

- ☐ DEA-controlled Substances
- ☐ Firearms and Explosives
- ☐ Prescription Drugs
- ☐ Alcohol & Tobacco
- ☐ Regulated Drones
- ☐ Radiation

If any are checked, see Hazardous Rules, page 19.

Device Testing with Human Participants

- ☐ Are you going to test your project (device, app, invention, prototype, etc.)? If yes, does it require persons to interact with it other than yourself or adult sponsor/supervisor?
- ☐ Do you intend to gather background knowledge through a survey or interviews to understand the potential use and needs for your project design?
- ☐ Are you going to ask for opinions or suggestions on your project design at any point of the project?
- ☐ Does your project intend to gather personal data/have a health benefit to the user?

If any are checked, see Human Participant Rules, page 8.

Vertebrate Animals

- ☐ Does your project include any interaction with vertebrate animals in any phase of the project?

If any are checked, see Vertebrate Animal Rules, page 12.

Potentially Hazardous Biological Agents

- ☐ Does your project include any collection, examination or handling of microorganisms, and/or fresh or frozen tissue, primary cell cultures, blood, blood products or body fluids?
- ☐ Are you going to culture or isolate any substance, known or unknown?

If any are checked, see Potentially Hazardous Biological Agents Rules, page 15.

SOURCES OF INFORMATION FOR ALL PROJECTS

1. United States Patent and Trade Office
   Customer Service: 1-800-786-9199 (toll-free); 571-272-1000 (local); 571-272-9950 (TTY)
   uspto.gov
   uspto.gov/patents/process/index.jsp

   Conducting a Patent Search:

   - **https://patents.google.com/**
   - **http://www.freepatentsonline.com/**
   - **https://worldwide.espacenet.com/**

2. USPTO Resources
   - 7 Step Search Strategy Guide and Video Tutorial
     https://www.uspto.gov/learning-resources
   - Pro Bono Program
     https://www.uspto.gov/patents-getting-started/using-legal-services/pro-bono/patent-pro-bono-program
   - Law School Clinic Certification Program
     uspto.gov/learning-and-resources/ip-policy/public-information-about-practitioners/law-school-clinic-1
   - USPTO Pro Se Assistance Program
     https://www.uspto.gov/learning-and-resources/newsletter/inventors-eye/pro-se-assistance-program
3. European Patent Office
   www.epo.org
   www.epo.org/applying/basics.html
4. Plagiarism and Ethics
   https://resourcecenter.cis.ieee.org/
   https://www.scribbr.com/plagiarism-checker/
5. Aquatic Nuisance Species (ANS) Task Force
   www.anstaskforce.gov
   https://www.fws.gov/program/aquatic-nuisance-species-task-force/documents
6. APHIS
   https://www.aphis.usda.gov/aphis/ourfocus/wildlifedamage/operational-activities/SA_Invasive/CT_Invasive_species1
   Animal and Plant Health Inspection Service
   Invasive Species List
   https://www.aphis.usda.gov/aphis/resources/pests-diseases
   Agricultural Pests and Diseases
7. Invasive Species Specialist Group
   http://www.iucngisd.org/gisd/
   The Global Invasive Species database contains invasive species information supplied by experts from around the world.
8. Invasive Species Information
   www.invasivespeciesinfo.gov/resources/lists.shtml
   Provides information for species declared invasive, noxious, prohibited, or harmful or potentially harmful.

HUMAN PARTICIPANTS

1. Code of Federal Regulation (CFR), Title 45 (Public Welfare), Part 46-Protection of Human Subjects (45CFR46)
   https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46
2. NIH tutorial, "Protecting Human Research Participants"
   http://phrp.nihtraining.com/files/PHRP.pdf
3. Belmont Report, April 18, 1979
   https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf
4. Standards for Educational and Psychological Testing. (1999). Washington, DC: AERA, APA, NCME.
   https://www.apa.org/science/programs/testing/standards
5. American Psychological Association
   750 First Street, NE Washington, DC 20002-4242
   phone: 202-336-5500; 800-374-2721
   www.apa.org

   Information for students:
   https://www.apa.org/about/students

   Information regarding publications:
   www.apa.org/pubs/index.aspx
6. Educational and Psychological Testing
   Testing Office for the APA Science Directorate
   phone: 202-336-6000
   email: **testing@apa.org**
   https://www.apa.org/science/programs/testing/
7. The Children's Online Privacy Protection Act of 1998 (COPPA) (15 U.S.C. §§ 6501–6506)
   https://www.ftc.gov/enforcement/rules/rulemaking-regulatory-reform-proceedings/childrens-online-privacy-protection-rule

VERTEBRATE ANIMALS

Animal Care and Use

1. Laboratory Animals, Institute of Laboratory Animal Research (ILAR), Commission on Life Sciences, National Research
   https://www.nationalacademies.org/ilar/institute-for-laboratory-animal-research
2. Guide for the Care and Use of Laboratory Animals, 8th Edition (2011)
   http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf
3. Guidelines for the Care and Use of Mammals in Neuroscience and Behavioral Research (2003), Board on Animal Health Sciences, Conservation, and Research (BAHSCR)
   https://www.nap.edu/catalog/10732/guidelines-for-the-care-and-use-of-mammals-in-neuroscience-and-behavioral-research
   To order these BAHSCR publications contact:
   National Academies Press
   500 Fifth Street, NW
   Washington, DC 20055
   phone: 888-624-8373 or 202-334-3313; fax: 202-334-2451
   https://www.nap.edu/content/help-with-ordering
4. Federal Animal Welfare Act (AWA)
   7 U.S.C. 2131-2157
   Subchapter A - Animal Welfare (Parts I, II, III)
   https://www.nal.usda.gov/animal-health-and-welfare/animal-welfare-act

Document is available from:
USDA/APHIS/AC
4700 River Road, Unit 84
Riverdale, MD 20737-1234
email: **ace@aphis.usda.gov**
phone: 301-734-7833; fax: 301-734-4978
https://www.nal.usda.gov/awic

5. Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching (Agri-Guide)
Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International)
https://www.aaalac.org/
https://www.aaalac.org/about/Ag_Guide_3rd_ed.pdf

6. *Guidelines for the Use of Fish in Research* (2014), American Fisheries Society.
www.fisheries.org

https://fisheries.org/policy-media/science-guidelines/guidelines-for-the-use-of-fishes-in-research/

7. Euthanasia Guidelines

AVMA Guidelines on Euthanasia (2020)
American Veterinary Medical Association
https://www.avma.org/resources-tools/avma-policies/avma-guidelines-euthanasia-animals

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
https://pubmed.ncbi.nlm.nih.gov/

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@ars.usda.gov**
www.nal.usda.gov/awic

3. Board on Animal Health Sciences, Conservation, and Research (BAHSCR) provides a variety of information on animal sources, housing and handling standards, and alternatives to animal use through annotated bibliographies published quarterly in BAHSCRJ ournal.
BAHSCR—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: **BAHSCR@nas.edu**
https://www.nationalacademies.org/bahscr/board-on-animal-health-sciences-conservation-and-research

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
email: **tehip@teh.nlm.nih.gov**
https://www.nlm.nih.gov/

5. Johns 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@jhu.edu**
https://caat.jhsph.edu/

6. Quality Assurance Manuals (for appropriate species)
Such as:
Poultry: **https://www.poultryimprovement.org/documents/BestManagementPracticesHatcheries.pdf**
Beef: **https://www.bqa.org/Media/BQA/Docs/nationalmanual.pdf**
Pork: **https://porkgateway.org/wp-content/uploads/2015/07/pork-quality-assurance1.pdf**

POTENTIALLY HAZARDOUS BIOLOGICAL AGENTS

1. American Biological Safety Association: ABSA Risk Group Classification—list of organisms
www.absa.org

2. American Type Culture Collection (ATCC)
www.atcc.org

3. Bergey's Manual of Systematic Bacteriology website—follow the links for resources and microbial databases for a collection of international websites of microorganisms and cell cultures.
https://www.bergeys.org

4. Biosafety in Microbiological and Biomedical Laboratories (BMBL)—4th Edition. Published by CDC-NIH
https://www.cdc.gov/labs/BMBL.html

5. World Health Organization Publications
https://www.who.int/publications
World Health Organization Laboratory Safety Manual
https://www.who.int/publications/i/item/9789240011311

6. Canada—Agency of Public Health—list of non-pathogenic organisms
https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html

- American Society for Microbiology
https://www.asm.org

- Microbiology Society
14-16 Meredith Street
London
ECIR 0AB

UK
info@microbiologysociety.org
microbiologysociety.org

7. *NIH Guidelines for Research Involving Recombinant DNA Molecules. Published by National Institutes of Health.*
https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf
8. OSHA—Occupational Health and Safety Administration
osha.gov

HAZARDOUS CHEMICALS, ACTIVITIES OR DEVICES

GENERAL LAB/CHEMICAL SAFETY

1. *Safety in Academic Chemistry Laboratories, Volumes 1 and 2, 2003.* Washington, DC: American Chemical Society.
Order from (first copy free of charge):
American Chemical Society
Publications Support Services
1155 16th Street, NW
Washington, DC 20036
phone: 202-872-4000 or 800-227-5558
email: **help@acs.org**
https://www.acs.org/content/acs/en/education.html
2. Environmental Protection Agency (EPA) website for green chemistry
www.epa.gov/greenchemistry
3. Safety and Data Sheets (SDS)
https://www.flinnsci.com/safety/
A directory of SDS sheets from Flinn Scientific Inc. that includes a ranking of hazard level and disposal methods.

www.ilpi.com/msds/index.html - A listing of numerous sites that have free downloads of SDS sheets.

NFPA (National Fire Protection Association) 704 Standard for guidance on Chemical Reactivity and Instability:
https://en.wikipedia.org/wiki/NFPA_704
4. Pesticides
National Pesticide Information Center
http://npic.orst.edu/ingred/ptype/natbio.html
Describes the various types of pesticides and the legal requirements for labelling. Provides links and phone numbers to get additional information.

Environmental Protection Agency
http://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1
A database of product labels. Enter the product name or company name to view the approved label information of pesticides which are registered with the agency.
5. DEA Controlled Substances
Drug Enforcement Agency website:
https://www.dea.gov
Controlled Substance Schedules – a list of controlled substances:
https://www.deadiversion.usdoj.gov/schedules/schedules.html
6. Alcohol, Tobacco, Firearms, and Explosives
Alcohol and Tobacco Tax and Trade Bureau
https://www.ttb.gov
Bureau of Alcohol, Tobacco, Firearms and Explosives
https://www.atf.gov/
7. Radiation
Radiation Studies Information (CDC)
www.cdc.gov/nceh/radiation/default.htm
8. CDC Laboratory Safety Manuals
https://www.cdc.gov/labs/BMBL.html
9. Occupational Safety and Health Administration
www.osha.gov
Safety and Health Topics:
www.osha.gov/safety-management
www.osha.gov/SLTC/reactivechemicals/index.html
www.osha.gov/SLTC/laserhazards/index.html
www.osha.gov/SLTC/radiationionizing/index.html
10. U.S. Nuclear Regulatory Commission
Material Safety and Inspection Branch
One White Flint North
11555 Rockville Pike
Rockville, MD 20852
phone: 301-415-8200; 800-368-5642
www.nrc.gov