

# INTERNATIONAL RULES FOR PRE-COLLEGE SCIENCE RESEARCH

**GUIDELINES FOR SCIENCE AND ENGINEERING FAIRS 2025–2026** 

# INTERNATIONAL RULES FOR PRE-COLLEGE SCIENCE RESEARCH: GUIDELINES FOR SCIENCE AND ENGINEERING FAIRS 2025–2026

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Participating in an affiliated science fair and the Regeneron ISEF carries moral and ethical responsibilities for every participant. Society for Science expects students to act with honor and integrity when conducting scientific research and in interacting within their peer community.

This 2026 edition of the International Rules & Guidelines has been reorganized from previous editions to emphasize the rules and to format the information similarly in each section. Each section has been organized to address 1) key definitions of the section, 2) prohibited studies, 3) rules, 4) documentation and approval, and 5) exempt studies.

In addition to the rules contained within this document, there are several resources and guides that have been created to support students, educators, parents and all involved in supporting student research in understanding the rules and guidance on how to appropriately assess risk prior to experimentation. We encourage you to visit the Society for Science website to access these materials.

- SOCIETY FOR SCIENCE WEBSITE INTERNATIONAL RULES AND GUIDELINES: the full text of the international rules and forms in html and as a downloadable pdf.
- **ISEF RULES WIZARD**: an interactive tool which asks questions about your intended project and provides a list of forms required.
- **ISEF RULES FAQS**: answers to questions that are commonly received in the email account src@societyforscience.org. We encourage you to submit suggestions.
- GUIDELINES FOR CONDUCTING A RISK ASSESSMENT

#### THESE RULES ARE APPLICABLE FOR:

Society for Science affiliated science fairs and the Regeneron International Science and Engineering Fair 2026.

The purpose of these rules is to:

- Protect the rights and welfare of the student researcher
- Protect the rights and welfare of human participants
- Protect the health and welfare of vertebrate animal subjects
- Protect and promote good stewardship of the environment
- Ensure adherence to federal regulations
- Ensure use of safe laboratory practices
- Determine eligibility for competition at Regeneron ISEF

For pre-review and approval of your project, find your fair:

https://findafair.societyforscience.org

For rules questions, contact the ISEF Scientific Review Committee:

SRC@societyforscience.org

For general questions, contact:
Society for Science
Science Education Programs
1719 N Street, NW, Washington, DC 20036
office: 202-785-2255, fax: 202-785-1243

email: isef@societyforscience.org

### **ALL PROJECTS**

#### **ETHICS STATEMENT**

Student researchers, as well as adults who have a role in their projects, are expected to maintain the highest ethical standards. These standards include, but are not limited to:

- Integrity. Honesty, objectivity, and avoidance of conflicts of interest are expected during every phase of the project. The project should reflect independent research done by the student(s) and presented in their own words with proper citation. The presentation of fraudulent data, the evidence of plagiarism or the inappropriate use of AI are prohibited and grounds for the project to fail to qualify.
- Legality. Compliance with all federal, state and local laws and regulations is essential. In addition, projects conducted outside the U.S. must also adhere to the laws of the country and jurisdiction in which the project was performed. All projects must be approved by a Scientific Review Committee (SRC), and when necessary must also be approved by an Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), and/or Institutional Biosafety Committee (IBC). It is recommended that students reference their local, state or national laws and regulations.
- Respect for Confidentiality and Intellectual Property.
   Confidential communications, as well as patents, copyrights, and other forms of intellectual property must be honored. Unpublished data, methods, or results may not be used without permission, and credit must be given for all contributions to the research.
- Stewardship of the Environment. It is the responsibility of the researcher and the adults involved to protect the environment from harm. Introduction or disposal of native, genetically-altered, and/or invasive species, (e.g. insects, plants, invertebrates, vertebrates), pathogens, toxic chemicals or foreign substances into the environment is prohibited. It is recommended that students reference their local, state or national regulations and quarantine lists.
- Acknowledgment of Risks. All projects involve some amount of risk. Everyone is expected to recognize the hazards, assess the risks, minimize the risks, and prepare for emergencies.
- Animal Care. Proper care and respect must be given to all animals. The use of non-animal research methods and alternatives to animal research are strongly encouraged and must be explored before conducting a vertebrate animal project. The guiding principles for the use of animals in research includes the following "Four R's:' Replace, Reduce, Refine, Respect.
- Human Participant Protection. The highest priority is the health and well-being of the student researcher(s) and human participants.

 Potentially Hazardous Biological Agents (PHBAs). It is the responsibility of the student and adults involved in the project to conduct and document a risk assessment, and to safely handle and dispose of organisms and materials.

Scientific fraud and misconduct are not condoned at any level of research or competition. This includes plagiarism, forgery, use or presentation of other researcher's work as one's own and fabrication of data. A violation of this ethics statement may result in disqualification from participating in ISEF and ISEF-affiliated fairs, and forfeiture of any awards, prizes, and acknowledgment received.

#### **ELIGIBILITY/LIMITATIONS**

- Each ISEF-affiliated fair may send to ISEF the number of projects allocated and committed to within their affiliation agreement.
- 2. A student must be selected by an ISEF-affiliated fair, and meet both of the following:
  - a. be in grades 9-12 or equivalent; and
  - b. not have reached age 20 on or before May 1 preceding ISEF.
- 3. English is the official language of ISEF. Student project boards and abstracts must be in English.
- Each student is only allowed to enter one project.
   That project may include no more than 12 months of continuous research and may not include research performed before January 2025.
- 5. Team projects must have no more than three members. Teams competing at ISEF must be composed of the original members who competed at the ISEF-affiliated fair and must all meet ISEF eligibility.
- 6. Students may compete in only one ISEF affiliated fair, except when proceeding to a state/national fair affiliated with ISEF from an affiliated regional fair.
- Projects that are demonstrations, literature reviews, 'library' research, informational projects, and/ or 'explanation' models are not recommended or appropriate for ISEF.
- Artificial Intelligence may be used as a project resource but must be cited and given proper acknowledgements. All materials presented must be in the researcher's own words.
- All sciences and engineering disciplines are represented at ISEF and projects compete in one of the 22 categories. Review a complete list of categories and sub-categories with definitions.
- 10. A research project may be a part of a larger study performed by professional scientists, but the project presented by the student must be only their own portion of the complete study.

#### REQUIREMENTS

#### **GENERAL**

- 1. All domestic and international students competing in an ISEF-affiliated fair must adhere to all rules as set forth in this document.
- 2. All projects must adhere to all of the tenets of the Ethics Statement.
- It is the responsibility of the student and the Adult Sponsor to evaluate the study to determine which forms are required and whether approval by a committee must be obtained prior to experimentation.
- 4. Projects competing at ISEF must have an exhibit that adheres to ISEF Display & Safety requirements and is visible during all operable hours of the exhibit hall without reliance on electricity or internet connections.
- 5. All projects must adhere to the requirements of the affiliated fair(s) in which it competes to qualify for participation in ISEF. Affiliated fairs may have additional restrictions or requirements. Knowledge of these requirements is the responsibility of the student and Adult Sponsor.

#### CONTINUATION/RESEARCH PROGRESSION OF PROJECTS

- As in the professional world, research projects typically build on work performed previously. A valid continuation project is a sound scientific endeavor and demonstrates the student's commitment to the field.
- 2. Any project based on the student's prior research could be considered a continuation/research progression project. These projects must document that the additional research is a substantive expansion from prior work (e.g. testing a new variable or new line of investigation). Repetition of previous experimentation with the same methodology and research question, even with an increased sample size, is an example of an unacceptable continuation.
- 3. Students will be judged only on laboratory experiment/data collection performed over 12 continuous months beginning no earlier than January 2025 and ending May 2026.
- 4. The display board and abstract must reflect the current year's work only. The project title displayed in the finalist's booth may mention years (for example, "Year Two of an Ongoing Study"). Previous year's databooks, research papers and supporting documents may be at the booth if properly labeled as such.
- 5. Longitudinal studies are permitted as acceptable continuations under the following conditions:
  - a. The study is a multi-year study testing or documenting the same variables in which time is a critical variable. (Examples: Effect of high rain or drought on soil in a given basin, return of flora and fauna in a burned area over time.)
  - b. Each consecutive year must demonstrate timebased change.

- c. The display board must be based on collective past conclusionary data and its comparison to the current year data set. No raw data from previous years may be displayed.
- 6. All projects must be reviewed and approved each year and forms must be completed for the new year.

#### **TEAM PROJECTS**

- 1. Team projects compete and are judged in the category of their research at ISEF. All team members must meet the eligibility requirements for ISEF.
- 2. Teams must have no more than three members.
- 3. A team with members from different geographic regions may compete at an affiliated fair of one of its members, but not at multiple fairs.
  - Each affiliated fair holds the authority to determine whether teams with members outside of a fair's geographic territory are eligible to compete
  - b. If the team wins the right to attend ISEF, all team members' expenses must be supported.
- 4. Team membership cannot be changed during a given research year unless there are extenuating circumstances and the local SRC reviews and approves the change, including converting a team project to an individual project or vice versa. Such conversions must address rationale for the change and include a clear delineation between research preceding the change and that which will follow. A memorandum documenting this review and approval should be attached to Form 1A.
  - a. Once a project has competed in a science fair at any level, team membership cannot change and the project cannot be converted from an individual project to a team project or vice versa.
  - b. In a future research year, any project may be converted from an individual to a team project, from a team to an individual project and/or have a change in team membership.
- 5. Each team is encouraged to appoint a team leader to coordinate the work and act as spokesperson. However, each member of the team should be able to serve as spokesperson, be fully involved with the project, and be familiar with all aspects of the project. The final work should reflect the coordinated efforts of all team members and will be evaluated using the same judging criteria as individual projects.
- Each team member must submit an Approval Form (1B). Team members must jointly submit the Checklist for Adult Sponsor (1), one abstract, a Student Checklist (1A), a Research Plan/ Project Summary and other required forms.
- 7. Full names of all team members must appear on the abstract and forms.

#### **DOCUMENTATION AND APPROVAL**

- Project documentation should begin with the development of a research plan to detail the rationale, research question(s), materials, methodology and procedures, risk assessment and a bibliography for the proposed research.
- 2. This research plan should be completed before experimentation and will inform the forms required for your research.
- 3. If a mentor was involved in the project, the research plan should delineate what parts of the project were done by the student and which parts of the project were done by the mentor.
- 4. Projects involving human participants, vertebrate animals, potentially hazardous biological agents and/or tissue must be reviewed and approved by a local or regional Institutional Review Board (IRB) or Scientific Review Committee (SRC) prior to the start of experimentation.
- 5. Every project must have the following forms:
  - Checklist for Adult Sponsor (1). In coordination with completion by the Adult Sponsor
  - Student Checklist (1A)
  - · Research Plan/Project Summary
  - Approval Form (1B)
- A Qualified Scientist is required for all studies involving Biosafety Level 2 (BSL-2) potentially hazardous biological agents and DEA-controlled substances and is also required for many human participant studies and many vertebrate animal studies.
- 7. After initial IRB/SRC approval (if required), any proposed changes in the Student Checklist (1A) and Research Plan/ Project Summary must be re-approved before laboratory experimentation/data collection resumes.
- 8. After competing in an Affiliated Fair, projects may not be changed or amended. The approved research plan must include any and all phases of the project to be conducted. Additional data may be collected using the same methodology that was previously approved for the affiliated fair.
- Continuation projects require annual review and approval from the IRB/SRC as applicable. Any continuation project must document that the additional research is new and different by completing Continuation/Research Progression Projects Form (7). At ISEF, this form must be displayed at the project booth.
- Any continuing project must document that the additional research is new and different by completing Continuation/ Research Progression Projects Form (7). At ISEF, this form must be displayed at the project booth.

- 11. If work was conducted or mentored either virtually or on site at a regulated research institution, industrial setting, or any work site other than home, school or field at any time during the current ISEF project year, the Regulated Research Institutional/Industrial Setting Form (1C) must be completed and displayed at the project booth.
- 12. After experimentation, each student or team must submit a (maximum) 250-word, one-page abstract which summarizes the current year's work. The abstract must describe research conducted by the student(s), not by the supervising adult(s).
- 13. A project data book and research paper are not required, but are strongly recommended for judging purposes. Regional or local fairs may require a project data book and/ or a research paper.
- 14. All signed forms, certifications, and permits must be available for review by all regional, state, national and international affiliated fair SRCs in which the student(s) participate. This review must occur after experimentation and before competition.

#### **DIGITAL PAPERWORK AND SIGNATURES**

- 1. Submission of forms generated by a digital system are allowable under the following conditions:
  - a. The forms must have the same content and order as ISEF forms.
  - b. Digital signatures should have a verification system via login and have a time and date stamp to indicate this authentication or be otherwise verified by the affiliated fair personnel.
  - Paperwork submitted to Society for Science for ISEF must be scanned and submitted via the online portal.

### **HUMAN PARTICIPANT RULES**

#### Rules involving human participants

The following rules were developed 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.

#### WHAT IS CONSIDERED A HUMAN PARTICIPANT STUDY?

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.

A few examples of human participant studies include:

- Studies in which the researcher interacts with another human for purposes of their study
- · Participants in physical activities
- Studies collecting surveys, questionnaires, tests of any kind
- 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 studies that include data that are not de-identified/ anonymous
- 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.

All human participant studies must be reviewed and approved by an Institutional Review Board (IRB) prior to experimentation. An IRB must consist of a minimum of three members including the following:

- An educator (not the teacher that is serving as the Adult Sponsor)
- A school administrator (preferably principal or vice principal)
- A medical or mental health professional. (More details about the composition and duties of an IRB can be found in the Glossary of Terms).

#### **PROHIBITED STUDIES**

 Students are prohibited from independently diagnosing any human condition, illness or disease, administering medication, and/or performing medical procedures on human participants.

- a. Students are prohibited from drawing blood or conducting any other medical procedures on anyone except themselves.
- Students are prohibited from providing advice, diagnostic or medical information to participants without direct supervision and involvement of a medical professional.
- c. Students are prohibited from publishing diagnostic apps on public websites or app stores without appropriate FDA approvals.
- d. Students are prohibited from disclosing results or data from their study to the human participants.
- 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)).

#### **RULES**

- Student research involving human participants must be reviewed and approved by an Institutional Review Board (IRB) before any interaction (e.g., recruitment, data collection) with human participants may begin. An IRB will determine any additional supervision required, make any adjustments to the research plan and designate the risk and consent processes required.
- 2. A consent process is required. Participation in research may begin only after participants have voluntarily given informed consent/assent (and in many cases received parental permission).
  - Adult research participants may give their own consent.
  - All human participant studies involving minors (students under 18 years of age) must receive assent from the student participant and written parental permission from a legal guardian.
  - c. For studies involving minors, if the study includes a survey, the survey must be attached to the consent form as part of the written parental permission process.
  - d. 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.
  - e. 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).
- f. Informed consent may not involve coercion.
- g. A student researcher may request that the IRB waive the requirement for written informed consent from adult participants (over the age of 18) if the research involves only minimal risk and anonymous data collection.
- 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).
- 4. 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. 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.
- 5. 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.
- 6. Studies that involve recruitment and interaction with human participants online or via the internet are allowed if they adhere to all of the human participant rules above regarding consent processes and restrictions, including obtaining written parental permission for studies involving minors. In order to protect the confidentiality of the participants, it is extremely important that IP addresses, as well as the data provided, be safeguarded.
- 7. 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.
  - a. 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 a single adult guardian/ adult sponsor/QS/DS when the testing requires an adult tester (such as driving or other age-restricted activities). 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 receiving professional feedback from experts in the field of study prior to experimentation.

b. 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 the prohibition of medical procedures (see Prohibited Studies) and be supervised by a health care professional with appropriate credentials and specialization in the area of medical diagnosis or intervention being studied.

#### **DOCUMENTATION AND APPROVAL**

1. Student researchers must have a Research Plan that includes all of the standard elements as well as the following areas specific to human participant research:

#### a. Participants:

- Describe age range, gender, racial/ethnic composition of participants.
- Identify vulnerable populations (minors, pregnant women, prisoners, mentally disabled or economically disadvantaged).

#### b. Recruitment:

- Where will you find your participants?
- · How will they be invited to participate?

#### c. Methods:

- What will participants be asked to do?
- Will you use any surveys, questionnaires or tests?
   If yes and not your own, how did you obtain? Did it require permissions? If so, explain.
- What is the frequency and length of time involved for each subject?

#### d. Risk Assessment:

- What are the risks or potential discomforts (physical, psychological, time involved, social, legal, etc.) to participants?
- · How will you minimize risks?
- · List any benefits to society or participants.

#### e. Protection of Privacy:

- Will identifiable information (e.g., names, telephone numbers, birth dates, email addresses) be collected?
- Will data be confidential/anonymous?
- If anonymous, describe how the data will be collected.
- If not anonymous, what procedures are in place for safeguarding confidentiality?
- Where will data be stored? Who will have access to the data?
- What will you do with the data after the study?

#### f. Informed Consent Process:

- Describe how you will inform participants about the purpose of the study what they will be asked to do, that their participation is voluntary and they have the right to stop at any time.
- If participants are minors, explain the process by which written parental permission will be received and a parent will have access to the survey instrument prior to providing permission.

- 2. Student research involving human participants must be reviewed and approved by an IRB 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.
  - b. The School IRB (or SRC/IRB from your affiliate fair) must assess the risk and document its determination of risk on Form 4.
  - c. Projects that are conducted at an 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.
  - d. A letter from an adult mentor and/or Qualified Scientist is not sufficient documentation of the RRI IRB review and approval process.
- 3. When working with a facility for protected groups where participants live or attend programming (e.g. retirement home, daycare, prison, etc.) written approval from the facility must be obtained prior to experimentation, as well as informed consents for the individual participants.
- 4. 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.
- 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.
- After experimentation and before competition, the Affiliated Fair SRC will review for compliance with all rules.
- 7. The following forms are required for studies involving human participants:
  - » Checklist for Adult Sponsor (1)
  - » Student Checklist (1A)
  - » Research Plan/Project Summary
  - » Approval Form (1B)

- » Human Participants Form (4) for projects reviewed by school IRB or IRB approval documentation from an RRI
- » Informed Consents/Parental Permission, when applicable
- » Copies of any surveys, when applicable
- » Regulated Research Institution Form (1C), when applicable
- » Qualified Scientist Form (2), when applicable
- » Risk Assessment (3) when applicable
- 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 PRE-APPROVAL OR HUMAN PARTICIPANTS PAPERWORK)

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

- 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. (This is instead of the student researcher; not to supplement.)
  - b. IRB review and pre-approval is required if the project involves more than the student researcher (or single adult guardian serving as the sole tester) 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.).
- 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.
- 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)

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.

#### WHAT ARE CONSIDERED VERTEBRATE ANIMALS?:

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

 All nonhuman vertebrates (including fish) at hatching or birth.

### **VERTEBRATE ANIMAL RULES**

Rules involving vertebrate animals

- Live nonhuman vertebrate mammalian embryos or fetuses
- 3. Tadpoles
- 4. Bird and reptile eggs starting three days (72 hours) prior to hatching
- Zebrafish past 7 days (168 hours) post-fertilization due to delayed cognitive neural development
- Cephalopods are to be treated as vertebrate animals
   NOTE: A project is not considered a vertebrate animal
   study if tissue is obtained from an animal that was
   euthanized for a purpose other than the student's
   project. (See Tissue & Body Fluid Rules)

#### **PROHIBITED STUDIES:**

- Research projects which cause more than momentary or slight pain or distress to any vertebrate animals are prohibited.
- 2. Studies that are designed or anticipated to cause vertebrate animal death are prohibited.
- 3. No vertebrate animal deaths due to the experimental procedures are permitted in any group or subgroup.
- 4. Student researchers are prohibited from performing euthanasia.
  - a. Projects conducted in a school/home/field location are prohibited from performing euthanasia for tissue removal and/or pathological analysis. (Such projects must be conducted at a Regulated Research Institution (RRI) with qualified personnel performing euthanasia.)
- 5. 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.
  - Behavioral experiments using conditioning with aversive stimuli, mother/infant separation or induced helplessness.
  - c. Studies of pain.
  - d. Predator/vertebrate prey experiments.
- 6. Students are prohibited from fishing with barbed hooks, live bait or from performing electrofishing.

#### RULES:

- 1. All vertebrate animal studies must be reviewed and approved before experimentation begins.
  - a. If a study is performed in a school, home or field, the local or affiliated fair SRC serves in this approval

- capacity for vertebrate animal studies. 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.
- b. If a study is being conducted at an RRI, the Institutional Animal Care and Use Committee (IACUC) approval must be obtained. An IACUC is the institutional animal oversight review and approval body for all animal studies at an RRI.
- 2. The health and well-being of the vertebrate animal must be considered at all phases of the study.
- Throughout the study, 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 and must be continually monitored for signs of distress.
  - a. Animals must be treated kindly and cared for properly.
  - Animals must be housed in a clean, ventilated, comfortable environment appropriate for the species.
  - c. They must be given a continuous, clean (uncontaminated) water and food supply.
  - d. Cages, pens and fish tanks must be cleaned frequently
- 4. A vertebrate animal project must be designed to ensure no more than momentary or slight pain or distress is experienced.
  - a. If conducted at an RRI under an IACUC protocol, more than momentary or slight pain or distress to vertebrate animals must be relieved by IACUC-approved anesthetics, analgesics and/or tranquilizers.
- A veterinarian must be consulted and 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.
- 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 an RRI.
- 7. Research conducted in an RRI 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.
- 8. Any illness or unexpected weight loss must be investigated and a veterinarian consulted to receive required medical care.

- a. This investigation must be documented by the Qualified Scientist or Direct Supervisor, who must be qualified to determine the illness, or by a veterinarian.
- b. If the illness or distress is caused by the study, the experiment must be terminated immediately.
- 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.
  - a. 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.
  - b. Additionally, body conditioning scoring (BCS) systems 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.
- 10. If an illness or emergency occurs, the affected animal(s) must receive proper medical or nursing care that is directed by a veterinarian.
- 11. A student researcher must stop experimentation if there is unexpected weight loss or death in the experimental subjects.
  - a. 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.
  - b. If death is the result of the experimental procedure, the study must be terminated, and the study will not qualify for competition.
- 12. 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.
- 13. 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.
- 14. 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.
- 15. Vertebrate animal projects may be conducted at a home, school, farm, ranch, in the field, etc. including:
  - · Studies of animals in their natural environment
  - · Studies of animals in zoological parks
  - · Studies of livestock that use standard agricultural

- practices
- Studies of fish that use standard aquaculture practices

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.
- 16. 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.

#### AFTER EXPERIMENTATION/ EUTHANASIA

- Projects conducted at school/home/field site must plan for the final disposition of the animals in the study.
  - a. The final disposition of the animals must be conducted in a responsible and ethical manner.
  - b. Euthanasia for tissue removal and/or pathological analysis is not permitted for a project conducted in a school/home/field site.
  - Livestock or fish raised for food using standard agricultural/ aquacultural production practices may be euthanized by a qualified adult for carcass evaluation.
- Euthanasia at the end of experimentation for tissue removal and/or pathological analysis is permitted at an RRI by qualified personnel, not by the student researcher. All methods of euthanasia must adhere to current American Veterinary Medical Association (AVMA) Guidelines.

#### **DEATH VERIFICATION:**

- Any unexpected 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.
  - a. The project must be suspended until the cause is determined and then the results must be documented in writing.
  - b. If death was the result of the experimental procedure, the study must be terminated, and the study will not qualify for competition.

#### DOCUMENTATION AND APPROVAL

- Student researchers must have a Research Plan that includes all of the standard elements as well as the following areas specific to vertebrate animal research:
  - a. Justification why animals must be use.
    - 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 with 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 animals proposed for use, to include:
    - » species
    - » strain
    - » sex
    - » age
    - » weight
    - » source
    - » number of animals
- 2. All vertebrate animal studies must be reviewed and approved before experimentation begins.
  - a. The local or affiliated fair Scientific Review Committee serves in this capacity for vertebrate animal 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.
  - b. The local or affiliated fair SRC 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.
  - c. 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.
  - d. When working at an RRI, the 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.
  - e. A Qualified Scientist or Direct Supervisor must directly supervise all research involving vertebrate

- animals, except for observational studies under the exempt guidelines below.
- f. 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.
- g. The following forms are required:
  - » Checklist for Adult Sponsor (1),
  - » Student Checklist (1A),
  - » Research Plan/Project Summary,
  - » Approval Form (1B)
  - » Vertebrate Animal Form (5A) if conducted at home/school/field OR Vertebrate Animal Form (5B) if conducted at an RRI
  - » Qualified Scientist Form (2), when applicable
  - » Regulated Research Institution Form (1C), when applicable

#### EXEMPT STUDIES (DO NOT REQUIRE SRC PRE-APPROVAL)

- 1. Studies involving behavioral observations of animals are exempt from prior SRC review if ALL of the following apply:
  - There is no interaction with the animals being observed,
  - 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.

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.

#### **PROHIBITED STUDIES:**

- 1. Experimentation involving the culturing of potentially hazardous biological agents, even BSL-1 organisms and *C. elegans*, is prohibited in a home environment.
  - a. 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.
- 2. Students are prohibited from designing or participating in any research involving biosafety levels above BSL-2. (This includes BSL-2+, BSL-3 and BSL-4.)
- 3. Any study involving the collection and examination of body fluids that may contain biological agents belonging to a biosafety level over 2 is prohibited. (Please see Tissue & Body Fluid Rules)
- Students are prohibited from the insertion of antibioticresistance traits or selection of organisms expressing traits that may affect the ability to provide effective treatment of infections acquired by humans, animals, or plants.
  - a. Students are prohibited from designing or selecting for multiple drug resistant organisms (MDROs) to investigate the pathology, development, or treatment of antibiotic- resistant infections.
- All studies involving the use of prions or purified prion-like proteins are prohibited. This includes studies working with amyloid-b (Ab), tau, a-synuclein, transactive response DNA-binding protein of 43 kDa, and amyloid fibrils.
- Propagation of recombinants containing DNA coding for human, plant or animal toxins (including viruses) is prohibited.
- 7. 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.

#### **RULES**

 Prior review and approval is required for the use of potentially hazardous microorganisms (including bacteria, viruses, viroids, rickettsia, fungi, cyanobacteria, and parasites) and recombinant DNA (rDNA) technologies.

- 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.
- 3. Research determined to be a Biosafety Level 2 (BSL-2) must be conducted in a laboratory rated BSL-2 or above and follow BSL-2 safety conditions throughout the study. (Commonly limited to a Regulated Research Institution (RRI). The research must be reviewed and approved by the Institutional Biosafety Committee (IBC) if the RRI 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.
- 4. Laboratory studies involving the culturing of clinically significant multidrug resistant organisms (MDROs) must have a written justification for usage and be conducted at an RRI laboratory with a minimum of BSL-2 containment and documented IBC review and approval.
  - a. 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.
  - 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.
  - c. Insertion of antibiotic resistance markers for the clonal selection of bioengineered organisms is permitted, with the exceptions outlined in prohibited studies item #4.
- 5. The culturing of human or animal waste, including sewage sludge, is considered a BSL-2 study.
- 6. Naturally-occurring plant pathogens may be studied (not cultured) at home, but may not be introduced into a home/ garden environment.
- 7. Projects involving water samples collected from active Harmful Algal Blooms are considered BSL-2 studies.
- 8. Insect and arthropod vector-borne pathogens such as Malaria, Lyme, etc. are considered BSL-2 studies.

- 9. Studies involving animals or animal tissues that have been bred to express prion-like proteins (such as C. elegans and Drosophila) are permissible if conducted in a BSL-2 laboratory, under BSL-2 conditions.
- 10. 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.
- 11. All potentially hazardous biological agents must be properly disposed of 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.

#### PROJECTS INVOLVING UNKNOWN MICROORGANISMS

Studies involving unknown microorganisms must adhere to the following rules:

- Research with unknown microorganisms can be treated as a BSL-1 study under the following conditions:
  - 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.
- 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.

#### PROJECTS INVOLVING RECOMBINANT DNA (RDNA) TECHNOLOGIES

- 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.
  - a. 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.
  - All rDNA technology studies involving BSL-2 organisms and/or BSL-2 host vector systems must be conducted in an RRI and approved by the IBC prior to experimentation, where applicable.
  - c. 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.

#### DOCUMENTATION AND APPROVAL

- 1. The student and all of the adults involved in a research project must 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.:
  - a. Give source of the organism and describe BSL assessment process and BSL determination.
  - b. Detail safety precautions and discuss methods of disposal.
- Prior review and approval is required for the use of potentially hazardous microorganisms (including bacteria, viruses, viroids, rickettsia, fungi, and parasites) and recombinant DNA (rDNA) technologies.
  - a. 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. Any proposed changes in the Research Plan/Project Summary by the student after initial local or affiliated fair SRC approval must undergo subsequent SRC, IBC or IACUC review and approval before such changes are made and before experimentation resumes.
- 4. The following forms are required:
  - » Checklist for Adult Sponsor (1)
  - » Student Checklist (1A)
  - » Research Plan/Project Summary
  - » Approval Form (1B)
  - » Regulated Research Institution Form (1C) when applicable
  - » Qualified Scientist (2), when applicable
  - » Risk Assessment (3), when applicable
  - » PHBA Risk Assessment Form (6A), when applicable
  - » The BSL-2 Checklist when a BSL-2 facility is used that is not at a Regulated Research Institution.

#### EXEMPT STUDIES (NO SRC PRE-APPROVAL REQUIRED)

The following types of studies are exempt from prior SRC review, but require a Risk Assessment Form 3:

- · Studies involving protists and archaea
- Research using manure for composting, fuel production, or other non-culturing experiment
- Commercially available color change coliform detection test kits; these kits must remain sealed and must be properly disposed
- Studies involving decomposition of vertebrate organisms (such as in forensic projects)
- Studies with microbial fuel cells in which the device is sealed during experimentation and disposed of properly at the conclusion of the study
- Studies involving fermentation of baker's yeast and brewer's yeast, except in rDNA studies
- 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)
- Studies involving water or soil microbes not concentrated in media conducive to their microbial growth
- Studies of mold growth on food items if the experiment is terminated at the first evidence of mold
- · Studies of slime molds and edible mushrooms
- 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.
- 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.

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 and must receive the same considerations as potentially hazardous biological agents.

### TISSUE & BODY FLUID RULES

Fresh/frozen tissue (including primary vertebrate cell lines, human and other primate established cell lines and tissue cultures), blood, blood products and body fluids.

#### **PROHIBITED STUDIES**

1. Any study involving the collection and examination of body fluids, including blood, that may contain biological agents belonging to BSL-2+, BSL-3, BSL-4 is prohibited.

#### **RULES**

- 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.
- 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 (RRI) requires a copy of the Institutional Animal Care and Use Committee (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 culturing of samples from fresh/frozen tissues or body fluids or meat and meat by-products obtained from food stores, restaurants, or packing houses must be considered biosafety Level 1 studies and must be conducted in a BSL-1 laboratory or higher.
- 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.
- Human breast milk of unknown origin, unless certified free of HIV and Hepatitis C, and domestic unpasteurized animal milk are considered BSL-2. All other breast milk is considered BSL-1.
- 7. All studies involving human or wild animal blood or blood products, except those that only involve blood from student researcher(s) should be at a minimum a BSL-2 study done under the supervision of a Qualified Scientist. 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 of 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. A project involving a student researcher using their own body fluids (if not cultured)
  - a. must receive prior SRC review and approval prior to experimentation
  - b. can be considered a BSL-1 study
  - c. may be conducted in a home setting
  - d. must have Institutional Review Board (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.
- Studies involving embryonic human stem cells must be conducted in an RRI and reviewed and approved by the ESCRO (Embryonic Stem Cell Research Oversight) Committee.

#### DOCUMENTATION AND APPROVAL

- 1. Student researchers must have a Research Plan that includes all of the standard elements as well as the following areas specific to tissue research:
  - a. Give source of the organism and describe BSL assessment process and BSL determination.
  - b. Detail safety precautions and discuss methods of disposal.
- The source and/or catalog number of the cultures must be identified in the Research Plan/Project Summary, and on forms 6A and 6B, even if the project is exempt from IRB approval. If catalog number is unavailable, student can provide a receipt and/or letter from mentor regarding the origin of the items.
  - a. If the tissue is obtained from a private/noncommercial source (public or private laboratory, museum, etc.), documentation from the supplier must be uploaded in the application, including IACUC approvals for the original study. This includes samples from blood banks or human breast milk.
  - b. If obtained from mentor's study or another lab's study, upload original study's IACUC approval OR reference to the original study's publication.

- 3. Prior review and approval is required for the use of human or vertebrate fresh/frozen tissues, blood, or body fluids.
  - a. 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, IACUC, or Institutional Biosafety Committee (IBC).
- 4. 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.
- 5. The following forms are required:
  - » Checklist for Adult Sponsor (1)
  - » Student Checklist (1A)
  - » Research Plan/Project Summary
  - » Approval Form (1B)
  - » Regulated Research Institution Form (1C) when applicable
  - » Qualified Scientist (2), when applicable
  - » Risk Assessment (3), when applicable
  - » PHBA Risk Assessment Form (6A)
  - » Human and Vertebrate Animal Tissue Form (6B)
  - » The BSL-2 Checklist when a BSL-2 facility is used that is not at a Regulated Research Institution.

#### 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)
  - 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 and on forms 6A and 6B
  - 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 bloodborne pathogen that may be present
  - g. Fossilized tissue or archeological specimens.
- Projects utilizing only data or images are exempt from IACUC pre-approval ONLY if the originating study is published in a peer-reviewed journal or the data is available in a publicly available database. In this case, the student must provide a reference to the original study OR link to the database.

 If the data or images were obtained from another scientist (mentor or not a mentor) or source AND the research is not yet published (not publicly available), then IACUC approval of the original study must be provided by the ISEF participant.

The following rules apply to projects using hazardous chemicals, devices and activities. These include substances and devices that are regulated by local, state, country, or international law. Hazardous activities are those that involve a level of risk above and beyond that encountered in the student's everyday life. The student researcher must minimize the impact of an experiment on the environment.

### HAZARDOUS CHEMICALS, ACTIVITIES OR DEVICES RULES

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

#### **PROHIBITED STUDIES**

- 1. A study using prescription drugs is prohibited when the prescription is being used outside of the purpose for which it was prescribed.
- Students are prohibited from conducting experiments where consumable ethyl alcohol is produced by distillation.
- 3. Any study using DEA controlled substances is prohibited in a school or home setting.
- 4. Any study using > 25 kvolts of radiation is prohibited in a school or home setting.
- 5. All radiation studies may not exceed the dose limits set by the Nuclear Regulatory Commission of 0.5 mrem/hr or 100 mrem/year of exposure.
- 6. Underage researchers are prohibited from the following:
  - a. Purchasing alcohol, tobacco, and vape products
  - Purchasing firearms or ammunition, including black powder
  - c. Purchasing explosives

#### **RULES**

- The student researcher must conduct a risk assessment in collaboration with a Direct Supervisor or Qualified Scientist prior to experimentation. The research must be supervised as appropriate for the hazardous substance, activity or device being used.
- 2. Students are required to meet all standards and rules imposed by ISEF, school, local, and/or regional fair(s).
- 3. Student researchers must acquire and use regulated substances in accordance with all local, state, U.S. federal and country laws. This includes:
  - a. Regulations regarding DEA-controlled substances,
  - b. FDA and state laws regarding prescription drugs,
  - c. TTB and state laws regarding alcohol and tobacco,
  - d. ATF and state laws regarding firearms and explosives and
  - e. FAA and state laws regarding drones.
    - 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. All transportation and acquisition of materials must comply with all Federal and State laws and regulations.
- 5. Disposal procedures shall be described in sufficient

detail to ensure compliance with EPA Guidelines as outlined in the appropriate Safety Data Sheets. Examples include minimal quantities of chemicals that will require subsequent disposal; ensuring that all disposal is done in an environmentally safe manner. Proper chemical, sharps and other hazardous materials disposal must follow local, state, and federal guidelines.

#### **CHEMICALS**

- All projects using chemicals in a home, school, or lab setting must be conducted under the following conditions:
  - a. Obtain and read the Safety Data Sheets (SDS) for each chemical being used. \*
  - b. Follow standard lab practices for chemical handling, safety, ventilation, and specific disposal procedures as outlined in the Safety Data Sheets (SDS).
  - c. Cannot reuse any cookware, utensils, and/or equipment used during the experimentation for regular household use.
  - d. Be conducted with a Direct Supervisor with proper training and knowledge of the chemicals being used.

\*NOTE: Safety Data Sheets can be found online and provide Globally Harmonized System (GHS) ratings for chemicals. These ratings use different categories to define a chemical's physical, health, and environmental hazards. The GHS rating should be factored into a student's risk assessment and safety precautions. Chemicals may also be rated on the National Fire Protection Association (NFPA) scale. This scale runs from 0-4, with 4 being the most hazardous. A GHS rating of 1 is equivalent to an NFPA of 4.

#### **DEA-CONTROLLED SUBSTANCES**

The U.S. Drug Enforcement Administration (DEA) regulates chemicals that can be diverted from their intended use to make illegal drugs.

- All studies using DEA-controlled substances must be supervised by a Qualified Scientist at a Regulated Research Institution (RRI) and must be conducted at an RRI who is licensed by the DEA (or other international regulatory body) for use of the controlled substance.
- 2. 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.

#### PRESCRIPTION DRUGS

In the United States, the Food and Drug Administration (FDA) tightly regulates the issuance of prescription drugs

including non-controlled medications. It is 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.

- A study involving prescription drugs must obtain the prescription drug through the authority of a practitioner or researcher that has obtained the noncontrolled medication with appropriate approvals or be using a prescription drug that is a research or education research-grade product and therefore not for human consumption.
- Research involving prescription drugs being administered to vertebrate animals, may only be done under a veterinarian's supervision and with prescriptions provided for this specified purpose.

#### **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, tobacco, or vape products used in the study.
- 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 may distill alcohol for fuel or other nonconsumable products, but the work must be conducted at school or a Regulated Research Institution and follow all local and country laws.

#### 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. 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.

- 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. Any use of a firearm must be conducted with the proper state certification and training.
- 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, transportation, and other requirements of federal explosive laws and regulations.
- 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.

#### 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/).
- 2. Current U.S. law requires all forms of drones to be registered with the FAA.

#### 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.

- 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 pre-approval is not required.
- 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.
- 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.

#### **DOCUMENTATION AND APPROVAL**

- 1. Student researchers must have a Research Plan that includes all of the standard elements as well as a thorough risk assessment that discusses:
  - · process,
  - · supervision,
  - usage,
  - · safety precautions and
  - · methods of disposal
- The student researcher must conduct a risk assessment in collaboration with a Direct Supervisor or Qualified Scientist prior to experimentation. The result of this review is also documented on Risk Assessment Form 3.
- 3. Any permits and/or licenses collected as a requirement of the project must be included with the project

paperwork and must be available for review by adults supervising the project and the local, affiliated, and ISEF SRCs in their review prior to competition.

- 4. The following forms are required:
  - » Checklist for Adult Sponsor (1)
  - » Student Checklist (1A)
  - » Research Plan/Project Summary
  - » Approval Form (1B)
  - » Regulated Research Institution Form (1C), when applicable
  - » Qualified Scientist (2), when applicable
  - » Risk Assessment (3)

The International Rules & Guidelines use several terms to describe individuals involved in the research and the review committees that support the pre-approval and competition review to ensure the safety of the student researchers and all involved in the research.

#### **ROLES AND RESPONSIBILITIES OF STUDENTS AND ADULTS**

### **GLOSSARY OF TERMS**

#### THE STUDENT RESEARCHER(S)

The student researcher is responsible for all aspects of the research project:

- Enlisting the aid of any required supervisory adults (Adult Sponsor, Qualified Scientist, etc.)
- Following the International Rules & Guidelines, obtaining all necessary approvals (SRC, IRB, etc.) and completing all appropriate documentation
- Performing the project (which may include, but is not limited to) experimentation, data collection, engineering, data analysis, and any other process or procedures related to the project
- Understanding and abiding by the Ethics Statement and attesting to this understanding on Approval Form 1B.

To avoid conflict of interest, no Adult Sponsor, parent or other relative of the student, the Qualified Scientist, or Direct Supervisor who oversees the project, may serve on the SRC or IRB reviewing that project.

#### THE ADULT SPONSOR

#### Qualifications:

- An Adult Sponsor may be a teacher, parent, professor, and/or other professional scientist
- Should be knowledgeable in the area of student research, be familiar with the regulations around procedures and materials that apply to the student project, particularly when involving human participants, vertebrate animals, potentially hazardous biological agents or hazardous chemicals, devices or activities.
- Should have close contact with the student throughout the timeline of the project.

#### Responsibilities:

- Working with the student to evaluate any possible risks involved in order to ensure the health and safety of the student conducting the research and the humans and/or animals involved in the study.
- Reviewing the student's Student Checklist (1A) and Research Plan/Project Summary to ensure that:
- experimentation follows local, state, and federal laws and ISEF rules
- · forms are completed by other required adults
- any required Qualified Scientist meets the criteria as set forth in the ISEF Rules and Guidelines
- the student's research is eligible for entry in ISEF

#### THE QUALIFIED SCIENTIST (QS)

#### Qualifications:

 Earned a doctoral/professional degree in a scientific discipline related to student's area of research

#### AND/OF

- Individual with extensive experience and expertise in the student's area of research
- Must be thoroughly familiar with the following regulations that govern the student's area of research including all local, state, Federal and if applicable, non-U.S. national regulations and laws.
- Can also serve as the Adult Sponsor, if that person meets those qualifications
- May live elsewhere and not be local to the student, in which case, a Direct Supervisor must be appointed and trained to serve as the onsite supervision as necessary for the specific student project.

#### Responsibilities:

- Reviewing the ISEF rules relevant to the project and approving the student's research plan or engineering design prior to the start of experimentation
- Providing direct supervision throughout the timeline of the project or coordinating with a Direct Supervisor to serve in this capacity
- Ensuring the proper training of the Student Researcher and/or Direct Supervisor in the necessary procedures
- Completing the required documentation which may include the Regulated Research Institutional Setting Form (1C), the Qualified Scientist Form (2) and the Risk Assessment Form (3), when applicable.

#### THE DIRECT SUPERVISOR (DS)

#### Qualifications:

- · Does not need an advanced degree
- Must be familiar with the student's project and agree to any training necessary
- May also serve as the Adult Sponsor for the project
- If the project involves the use of Vertebrate Animals (where behavior/habitat is influenced by humans), must be knowledgeable about the humane care and handling of the animals

#### Responsibilities:

- Providing direct supervision of the student experimentation
- Completing the required documentation the Direct Supervisor box on the Qualified Scientist Form (2) when applicable
- Reviewing and completing the Risk Assessment Form (3)

when needed

#### **REVIEW COMMITTEES**

To avoid conflict of interest, no Adult Sponsor, parent or other relative of the student, the Qualified Scientist, or Direct Supervisor who oversees the project, may serve on the IRB, SRC, or any other committee reviewing that project. A project reviewed by a committee with a conflict of interest may fail to qualify. Additional members are recommended to help avoid a potential conflict of interest and to increase the expertise of the committee.

#### AFFILIATED FAIR SCIENTIFIC REVIEW COMMITTEE (SRC)

A Scientific Review Committee (SRC) is a group of qualified individuals that is responsible for evaluation of student research, certifications, research plans and exhibits for compliance with the rules, applicable laws and regulations at each level of science fair competition. Affiliated Fairs may authorize local SRCs to serve in this prior review capacity. The operation and composition of the local and Affiliated Fair SRCs must fully comply with the International Rules. Directions for obtaining pre-approval are available from the affiliated fair. A list of fairs can be found at <a href="https://findafair.societyforscience.org">https://findafair.societyforscience.org</a>.

Most proposed research projects involving human participants, vertebrate animals and/or potentially hazardous biological agents must be reviewed and approved BEFORE experimentation. Local or regional SRC prior review is not required for human studies previously reviewed and approved by a properly constituted IRB.

ALL projects, including those at an RRI, must be reviewed and approved by the SRC after experimentation and before competition in an Affiliated Fair.

An SRC must consist of a minimum of three persons, including the following:

- a biomedical scientist with an earned graduate degree
- · an educator
- at least one additional member

Additional Expertise: Many project evaluations require additional expertise (e.g., on biosafety and/or of human risk groups). If the SRC needs an expert as one of its members and one is not in the immediate area, all documented contact with an external expert must be submitted. If animal research is involved, at least one member must be familiar with proper animal care procedures. Depending on the nature of the study, this person can be a veterinarian or animal care provider with training and/or experience in the species being studied.

A Scientific Review Committee (SRC) examines projects for the following:

- Evidence of proper supervision
- Completed forms, signatures, research dates, and preapproval dates (when required)
- · Evidence of proper team composition

- Compliance with rules and laws governing human and/ or animal research and research involving potentially hazardous biological agents and/or hazardous chemicals, activities or devices
- · Compliance with ISEF ethics statement
- · Use of accepted and appropriate research techniques
- · Evidence that risks have been properly assessed
- Evidence of search for alternatives to animal use
- · Humane treatment of animals
- Documentation of substantial expansion for continuation projects
- Evidence of appropriate literature search and attribution

#### THE INSTITUTIONAL REVIEW BOARD (IRB ) — FOR HUMAN PARTICIPANT REVIEW

An Institutional Review Board (IRB), is a committee that, according to federal regulations (45-CFR-46), must evaluate the potential physical and/or psychological risk of research involving humans. All proposed human research must be reviewed and approved by an IRB before experimentation begins. This includes review of any surveys or questionnaires to be used in a project.

Federal regulations require local community involvement. Therefore, it is advisable that an IRB be established at the school level to evaluate human research projects. If necessary, the local or ISEF-affiliated SRC can serve as an IRB as long as it has the required membership. An IRB must consist of a minimum of three members including the following:

- An educator (not the teacher that is serving as the Adult Sponsor)
- A school administrator (preferably principal or vice principal)
- A medical or mental health professional. The medical or mental health professional may be a medical doctor, nurse practitioner, physician's assistant, doctor of pharmacy, registered nurse, psychologist, licensed social worker or licensed clinical professional counselor. The medical or mental health professional on the IRB may change depending on the nature of the study. This person must be knowledgeable about and capable of evaluating the physical and/or psychological risk involved in a given study.

**Additional Expertise:** If an expert is not available in the immediate area, documented contact with an external expert is recommended. A copy of all correspondence with the expert (e.g. emails) must be attached to Form 4 and can be used in lieu of the signature of that expert.

IRBs exist at federally Regulated Research Institutions (e.g., universities, medical centers, NIH, correctional facilities). Prisoner advocates must be included on the IRB when research participants are incarcerated. The institutional IRB must initially review and approve all proposed research conducted at or sponsored by that institution. The Adult Sponsor and the local IRB are responsible for ensuring that

the project is appropriate for a pre-college student and adheres to ISEF rules.

It is the responsibility of the members of the IRB to thoroughly review the Research Plan and collectively decide whether to approve the project, request revisions to the methodology/ require more oversight (e.g., QS) to reduce risk to participants, or to determine that the project is not appropriate for student research. An IRB documents the determination of risk level on Human Participant Form 4.

In reviewing projects just prior to a fair, if the SRC serving at that level of competition judges an IRB's decision as inappropriate, thereby placing human participants in jeopardy, they may override the IRB's decision and the project may fail to qualify for competition. It is advised that IRBs consult with the local or affiliated fair SRCs and/or with ISEF SRC in questionable cases.

#### **COMBINED SRC/IRB COMMITTEE**

A combined committee is allowed as long as the membership meets both the SRC and IRB requirements listed previously.

#### REGULATED RESEARCH INSTITUTIONS (RRI) REVIEW COMMITTEES

Regulated Research Institution: An RRI within the U.S. is defined as a professional research/ teaching institution that is regularly inspected by the USDA and is licensed to use animals covered by the Animal Welfare Act and may also be subject to U.S. Public Health Service Policy.

Also included are all federal laboratories such as National Institutes of Health, Veteran's Affairs Medical Centers and the Centers for Disease Control. In addition, pharmaceutical and biotechnology companies and research institutions that utilize research animals that are not covered by the Animal Welfare Act but have an operational Institutional Animal Care and Use Committee and are in compliance with U.S. federal laws are included in this definition. For 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.

Certain areas of research conducted in a regulated research institution or an industrial setting require review and approval by federally mandated committees that have been established at that institution. These committees include:

- Institutional Animal Care and Use Committee (IACUC);
   Animal Care and Use Committee (ACUC); Animal Ethics
   Committee
- Institutional Review Board (IRB); Human Subjects Participant Program (HSPP)
- Institutional Biosafety Committee (IBC)
- Embryonic Stem Cell Research Oversight Committee (ESCRO)
- · Safety Review Committee

Independent or private laboratories, such as those

established to support student researchers do not meet the requirements of oversight or committee infrastructure to be considered RRIs. Therefore, such laboratories should be considered the same as high school laboratories as it pertains to the International Rules and the types of projects able to be conducted in this setting. For purposes of documentation, such facilities may complete the Regulated Research Institution/Industrial Setting Form 1C to address the adult supervision and conditions of research.

#### THE ISEF SCIENTIFIC REVIEW COMMITTEE (ISEF SRC)

All projects are reviewed by ISEF Scientific Review Committee prior to competition. ISEF SRC is the final arbiter of the qualification of students to participate in ISEF. Before the fair, committee members review research plans and all required forms to confirm that applicable ISEF rules have been followed. ISEF SRC may request additional information from students prior to ISEF or may interview potential ISEF participants at the fair to ensure that they qualify to compete.

ISEF SRC, like an Affiliated Fair SRC, is made up of adults knowledgeable about research regulations. In addition to the review of all projects at ISEF, committee members answer questions about the rules throughout the year from students and teachers. The ISEF SRC can be contacted at SRC@societyforscience.org.

#### **Members of ISEF Scientific Review Committee 2025**

Ms. Susan Appel
Mr. Henry Disston
Dr. Paula Johnson
Dr. Timothy Martin
Mrs. Evelyn Montalvo
Mr. Joseph Scott
Mrs. Lisa Scott
Mrs. Andrea Spencer
Mrs. Jeanne Waggener

#### **Consultants**

Dr. Jennifer Green Dr. Ellen Murphy Dr. Jason Shuffitt

### **ISEF DISPLAY & SAFETY REGULATIONS**

Please address any questions regarding ISEF Display & Safety Regulations to displayandsafety@societyforscience.org

#### **DISPLAY & SAFETY COMMITTEE MISSION**

The mission of this committee is to ensure that all competitors qualify for competition according to the rules established in conjunction with the Scientific Review Committee and Society for Science.

The ISEF Display & Safety inspection process can be initiated only when all items are present at the display. The Display & Safety Committee will offer guidance on Display & Safety issues for projects approved by the SRC to compete in ISEF. Occasionally, the ISEF Display & Safety Committee may require students to make revisions to conform to Display & Safety regulations. Persistent issues will be directed to a committee of individuals which may include Society for Science (the Society) personnel, Display & Safety

(D&S) and/or Scientific Review Committee (SRC) executive committee members.

The following regulations must be adhered to when a finalist exhibits a project at ISEF. All projects must adhere to the Display & Safety requirements of the affiliated fair(s) in which they compete to qualify for participation in ISEF. Affiliated fairs may have additional restrictions or requirements. Knowledge of these requirements is the responsibility of the Finalist, Adult Sponsor, and Fair Director.

#### DISPLAY REGULATIONS

Maximum Size of Project
Depth (front to back): 76 cm
Width (side to side): 122 cm
Height (floor to top): 240 cm

Please be aware when ordering posters that the mechanism that supports the poster should conform to the maximum size limitations stated above.

- All project materials and support mechanisms must fit within the project dimensions (including table covers).
- Fair-provided tables at ISEF will not exceed a height of 36 inches (91 centimeters).
- If a table is used it becomes part of the project and must not exceed the allowed dimensions.
- Nothing can be attached to the rear curtain.
- All demonstrations must be done within the confines of the finalist's booth space. When not being demonstrated, all project components must be returned to the project display and must fit within allowable dimensions as defined above.
- Projects can be continued under the table BUT this area is not to be used for storage.

#### **POSITION OF PROJECT**

The fair provided table or freestanding display must be parallel to, and positioned at, the back curtain of the booth. Projects may NOT lean against the back curtain.

### FORMS REQUIRED TO BE VISIBLE AND VERTICALLY DISPLAYED AT THE PROJECT BOOTH

The placement of the required forms may include the front edge of the table, the display board, or in a free-standing acrylic frame placed on the table top.

#### FORMS REQUIRED TO BE VERTICALLY DISPLAYED AT ALL PROJECTS:

- An original Official Abstract and Certification as approved (stamped/embossed) by the ISEF Scientific Review Committee.
  - a. Upon SRC approval, the stamped/embossed Official Abstract and Certification will be provided.
    - No other format or version of an abstract will be allowed for any purpose at ISEF, including display at your project." Judges are provided the official Abstract and Certification digitally; no handouts are permitted.
  - b. The term "abstract" may NOT be used as a title or reference for any information on a finalist's display or materials at the project except as part of displaying the official stamped/embossed abstract.
    - It is the recommendation of the Display & Safety Committee to NOT include the word "abstract" nor the abstract itself when preparing backboards or posters prior to the fair. However, it is reasonable to leave a blank space (8½" x 11") on the backboard/poster so as to facilitate the addition of the official abstract. Keep in mind this document can also be displayed vertically on the front edge of the table or in a free-standing acrylic frame.
- 2. ISEF Project Set-up Approval Form (received on-site at the Fair)
  - a. This form documents the project as approved by the Scientific Review Committee and is used to document the Display & Safety Committee's review process and final approval.
  - b. This form must be signed by the finalist and the Display & Safety Committee member at the time of inspection.

#### Additional Forms required (only when applicable):

- Regulated Research Institutional/Industrial Setting Form (1C)
  - a. If work was conducted in a regulated research institution, industrial setting or any work site other than home, school or field at any time during the current ISEF project year, the **Regulated Research Institutional/Industrial Setting Form (1C)** must be completed and vertically displayed at the project booth.
  - b. The information provided by the mentor on Form 1C may be referenced to confirm that the information provided on the project board is that of the finalist. Only minimal reference to a mentor's or another researcher's work is allowable and must only reflect background information or be used to clarify differences between finalist's and others' work.
- 2. Continuation/Research Progression Projects Form (7)
  - a. If a study is a continuation/research progression, the Continuation/Research Progression Projects Form (7) must be completed and vertically displayed at the project booth.
  - b. The display board and abstract must reflect only the current year's work. The project title displayed in the finalist's booth may mention years of continuing research (for example, "Year Two of an Ongoing Study").
  - c. Reference to past work on the display board must be limited to summative past conclusory data and its comparison to the current year data set. No raw data from previous years may be publicly displayed; however, it may be included in the student research notebooks and/or logbooks if properly labeled.

#### Forms Required at Project but not Displayed

- Forms, excluding those listed above, that were required for the Scientific Review Committee approval should not be vertically displayed, but must be available in the booth in case asked for by a judge or other ISEF official. These forms include, but are not limited to, Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan, Approval Form (1B), and a photograph/video release form.
- 2. A photograph/video release form signed by the subject is required for visual images of humans (other than the finalist) displayed as part of the project.

### Forms NOT to be at the Project Display Booth or in the Exhibit Hall

Completed informed consent/assent forms for a human participant study are NOT to be displayed and should NOT be present at the project display. The Finalist may include a sample (incomplete) form in their logbook or research notebook but under NO CIRCUMSTANCE should the completed informed consent/assent forms for a human participant be in the Exhibit Hall.

### Photograph/Visual Image/Graph/Chart/Data Table Requirements

- 1. ALL graphics that are created by the Finalist MUST BE properly cited individually and include the program or software utilized to create the graphic using statements such as "Photo taken by Finalist," "Image created by Finalist using . . ."; Graph created by Finalist using . . ."; or "Data Table created by Finalist using . . ."
- 2. ALL graphics not created by the finalist(s) MUST BE properly cited individually (APA format is preferred). If the graphic was obtained via the Internet, then a URL must be provided (digital object identifiers are acceptable in place of long URLs). This applies even if the license under which the graphic was obtained does not require credit or citation. For more information and examples please see our D&S Graphic Credit Guidance.
- 3. Citations must be provided alongside the graphic or in a vertically displayed reference list.
- 4. Photographs may not be offensive or inappropriate in nature. This includes, but is not limited to, images/ photographs showing invertebrates, vertebrates or humans in surgical, necrotizing dissection or distressing situations.
- 5. Photographs or images of people other than the Finalist need to have a signed photo/video release form from those individuals in a notebook. These signed release forms must be available upon request during the set-up and inspection process, but may not be displayed.
- Sample release text: "I consent to the use of visual images (photos, videos, etc.) involving my participation/my child's participation in this research."
- 7. Finalists using any digital display/device outside of a project board must be prepared to show these materials in their entirety. All aforementioned rules regarding photos, images, data tables, graphs and charts apply to these materials. These materials may not be altered in any way after the Display & Safety inspection has been completed. Examples include, but are not limited to, PowerPoint, Prezi, Canva, BioRender, computer code, Keynote, software program/simulation and other image and/or graphics displayed on a screen.

#### Items/Materials Not Allowed on Display or at Project Booth

- Personal items or packaging materials stored in or around the booth, including under the table.
- 2. Any information on the project display or items that are self-promotions or external endorsements are not allowed in the project booth
  - a. The use of commercial logos including known brands, institutional crests or trademarks, and flags unless unless integral or incidental to the project and approved by the ISEF D&S Committee.

- Any reference to an institution or mentor that supported the finalist's research except as provided in an acknowledgement section of the poster and wtihin official ISEF paperwork, most notably Form 1C.
- c. Published research papers may only be present within a lab notebook. Lab notebooks must be closed when a finalist is not present at their booth.
- d. Plans for additional/future work that includes any reference to a mentor, institution, conference, or pending publication.
- e. Any reference to patent status of the project.
- f. Any items intended for distribution such as disks, CDs, flash drives, brochures, booklets, endorsements, give-away items, business cards, printed materials or food items designed to be distributed to judges or the public.
- 3. Any awards or medals, except for past or present ISEF medals that may be worn by the finalist.
- 4. Postal addresses, World Wide Web, email and/or social media addresses, QR codes, telephone and/or fax numbers of a project or finalist. Note: The only personal information that is permissible to include on the display is the finalist name, school, city, state, country, age and grade.
- 5. Exceptions will only be made if requested by email to displayandsafety@societyforscience.org and approved in advance by the Display & Safety Committee.
- Any changes, modifications, or additions to projects including any attempt to uncover, replenish or return removed language or items after the approval by the Display & Safety Committee and the Scientific Review Committee has been received is prohibited.
  - a. Display & Safety inspections will include recording photographic evidence of the approved Project Display and Project booth.
  - Finalists who do not adhere to this signed agreement on the ISEF Project Set-up Approval Form regarding this regulation may fail to qualify for competition.

I/we understand that the initial Display & Safety
Inspection has been completed, but that additional
reviews occur and that I/we should check back
regularly. I/we will vertically display this signed form
at our project at all times. I/we have not and will not
store packing material under the booth. I/we further
understand that returning items that have been
removed by the SRC or D&S and/or adding items that
are not permitted after final clearance are grounds
for failing to qualify for competition and/or forfeiture
of all awards received.

#### SAFETY REGULATIONS

#### Not Allowed at Project or Booth

Note: In the case in which a Finalist's Project includes an item that is prohibited from display, please consider taking photographs and/or documenting the significance of the prohibited item through video.

- Biological materials (living, dead, or preserved) other than those commercially available. This includes but is not limited to:
  - Living organisms, including plants
  - · Taxidermy specimens or parts
  - Preserved vertebrate or invertebrate animals
  - · Human or animal food
  - Human/animal parts or body fluids (for example, blood, urine)
- 2. All chemicals including water. Absolutely no liquids can be utilized in the Project Display
- All other hazardous substances or devices included but not limited to:
  - Soil, sand, rock, cement and/or waste samples
  - Poisons
  - Drugs
  - Firearms, weapons, ammunition, reloading devices
  - Granules or powders
  - Grease/oil and sublimating solids such as dry ice
  - Sharp items (for example, syringes, needles, pipettes, knives)
  - Glass
  - Flames and highly flammable materials
  - Batteries with open-top cells or wet cells or battery packs over 100 watt-hour capacity
  - Drones or any flight-capable apparatus unless the propulsion power source removed
  - Inadequately insulated apparatus capable of producing dangerous temperatures are not permitted
  - Any apparatus with belts, pulleys, chains, or moving parts with tension or pinch points that are not appropriately shielded
- 4. Items that may have contained or been in contact with hazardous substances (Exception: Item may be permitted if professionally cleaned and documentation for such cleaning is available, and is approved by Display & Safety)
- Any display items that are deemed distracting including but not limited to:
  - Sounds
  - Lights
  - Odors
- 6. Any apparatus or project material deemed unsafe by the Scientific Review Committee, the Display & Safety Committee, or the Society

#### **Electrical Regulations**

- 1. Electrical power supplied to the project is 120 or 220 Volt, AC, single phase, 60 Hz. No multi-phase will be available or shall be used. Maximum circuit amperage/wattage available is determined by the electrical circuit capacities of the exhibit hall and may be adjusted on-site by the Display & Safety Committee. For all electrical regulations, "120 Volt AC" or "220 Volt AC" is intended to encompass the corresponding range of voltage as supplied by the facility in which ISEF is being held.
- 2. Electrical devices must be protectively enclosed. Any enclosure must be non-combustible. All external non-current carrying metal parts must be grounded.
- 3. Energized wiring, switches, and metal parts must have adequate insulation and over-current safety devices (such as fuses) and must be inaccessible to anyone other than the finalist. Exposed electrical equipment or metal that may be energized must be shielded with a non-conducting material or with a grounded metal box to prevent accidental contact.
- 4. Decorative lighting or illumination is discouraged. If used, lighting must be as low a voltage as possible and must be LED lighting that does not generate heat. Incandescent and fluorescent light bulbs are prohibited. When student is not at the exhibit, all electrical power must be disconnected, or power bars must be switched off (Exception: during pre-judging audio visual displays may be available).
- 1. An insulating grommet is required at the point where any wire or cable enters any enclosure.
- 2. No exposed live circuits over 36 volts are allowed.
- 3. There must be an accessible, clearly visible on/off switch or other means of quickly disconnecting from the 120 or 220 Volt power source.

#### **Laser/Laser Pointer Regulations**

Any Class 1, Class 2, Class 3A, or Class 3R lasers are allowed to be used responsibly. No other lasers may be used or displayed.

- 1. Laser beams may not pass through magnifying optics such as microscopes and telescopes.
- 2. Lasers must be labeled by the manufacturer so that power output can be inspected. Lasers without labels will NOT be permitted.
- 3. Handheld lasers are NOT permitted.
- 4. Lasers will be confiscated with no warning if not used in a safe manner.

### **ISEF CATEGORIES AND SUBCATEGORIES**

The categories have been established with the goal of better aligning judges and student projects for the judging at ISEF. Local, regional, state and country fairs may or may not choose to use these categories, dependent on the needs of their area. Please check with your affiliated fair(s) for the appropriate category listings at that level of competition.

Please visit our website at https://www.societyforscience.org/isef/categories-and-subcategories for a full description and definition of ISEF categories:

#### **ANIMAL SCIENCES (ANIM)**

**Animal Behavior** 

Cellular Studies
Development
Ecology
Genetics
Nutrition and Growth
Physiology
Systematics and Evolution
Other

### BEHAVIORAL AND SOCIAL SCIENCES (BEHA)

Behavioral Neuroscience Development Cognitive Psychology Sociology and Anthropology Other

#### **BIOCHEMISTRY (BCHM)**

Analytical Biochemistry General Biochemistry Medical Biochemistry Structural Biochemistry Other

### BIOMEDICAL AND HEALTH SCIENCES (BMED)

Cell, Organ, and Systems Physiology Genetics and Molecular Biology of Disease Immunology Nutrition and Natural Products Pathophysiology Other

### BIOMEDICAL ENGINEERING (ENBM)

Biomaterials and Regen Medicine Biomechanics Biomedical Devices Biomedical Imaging Cell and Tissue Engineering Synthetic Biology Other

### CELLULAR AND MOLECULAR BIOLOGY (CELL)

Cell Physiology
Cellular Immunology
Genetics
Molecular Biology
Neurobiology
Other

#### **CHEMISTRY (CHEM)**

Analytical Chemistry Computational Chemistry Environmental Chemistry Inorganic Chemistry Materials Chemistry Organic Chemistry Physical Chemistry Other

### COMPUTATIONAL BIOLOGY AND BIOINFORMATICS (CBIO)

Computational Biomodeling Computational Epidemiology Computational Evolutionary Biology Computational Neuroscience Computational Pharmacology Genomics Other

### EARTH AND ENVIRONMENTAL SCIENCES (EAEV)

Atmospheric Science Climate Science Environmental Effects on Ecosystems Geosciences Water Science Other

#### **EMBEDDED SYSTEMS (EBED)**

Circuits
Internet of Things
Microcontrollers
Networking and Data
Communications
Optics
Sensors
Signal Processing
Other

## ENERGY: SUSTAINABLE MATERIALS AND DESIGN (EGSD)

Biological Process and Design
Energy Storage
Hydrogen Generation and Storage
OtherThermal Power
Solar Process, Materials, and Design
Thermal Generation and Design
Triboelectricity and Electrolysis
Wind
Wind and Water Movement Power
Generation

#### ENGINEERING TECHNOLOGY: STATICS AND DYNAMICS (ETSD)

Aerospace and Aeronautical Engineering Civil Engineering Computational Mechanics Control Theory

Other

Ground Vehicle Systems Industrial Engineering-Processing Mechanical Engineering Naval Systems Other

### ENVIRONMENTAL ENGINEERING (ENEV)

Bioremediation Land Reclamation Pollution Control Recycling and Waste Management Water Resources Management Other

#### **MATERIALS SCIENCE (MATS)**

Biomaterials
Ceramic and Glasses
Composite Materials
Computation and Theory
Electronic, Optical and Magnetic
Materials
Nanomaterials
Polymers
Other

#### **MATHEMATICS (MATH)**

Analysis
Combinatorics, Graph Theory and
Game Theory
Geometry and Topology
Number Theory
Probability and Statistics
Other

#### **MICROBIOLOGY (MCRO)**

Antimicrobials and Antibiotics Applied Microbiology Bacteriology Environmental Microbiology Microbial Genetics Virology Other

### PHYSICS AND ASTRONOMY (PHYS)

Astronomy and Cosmology Atomic, Molecular and Optical Physics Biological Physics Condensed Matter and Materials Mechanics Nuclear and Particle Physics Theoretical, Computational and Quantum Physics Other

#### PLANT SCIENCES (PLNT)

Agriculture and Agronomy Ecology Genetics/Breeding Growth and Development Pathology Plant Physiology Systematics and Evolution Other

# ROBOTICS AND INTELLIGENT MACHINES (ROBO)

Biomechanics Cognitive Systems Control Theory Machine Learning Robot Kinematics Other

#### SYSTEMS SOFTWARE (SOFT)

Algorithms
Cybersecurity
Databases
Human/Machine Interface
Languages and Operating
Systems
Mobile Apps
Online Learning
Other

### TECHNOLOGY ENHANCES THE ARTS (TECA)

Display Technology
Human Information Exchange
Music and Image Manipulation
Games
3D Modeling
Engineering Effects
Other

### TRANSLATIONAL MEDICAL SCIENCES (TMED)

Disease Detection and Diagnosis Disease Prevention Disease Treatment and Therapies Drug Identification and Testing Pre-Clinical Studies Other

### INFORMATION ON REQUIRED ABSTRACT & CERTIFICATION FOR ALL PROJECTS AT ISEF

\* This form may not be relevant for your regional or state fair; please refer to instructions from your affiliated fair.\*

IN ADDITION TO THE BASIC FORM REQUIREMENTS FOR ALL PROJECTS AND ANY OTHER REQUIREMENTS DUE TO SPECIFIC AREAS OF RESEARCH, AN ABSTRACT & CERTIFICATION IS REQUIRED AT THE CONCLUSION OF RESEARCH. DETAILS ON THIS REQUIREMENT FOLLOW.

#### **Completing the Abstract**

After finishing research and experimentation, you are required to write a (maximum) 250 word, one-page abstract. For ISEF, this abstract is written in the online Finalist Questionnaire portal and submitted electronically. This abstract must be written in your own words and will be run through a plagiarism checker.

### It is recommended that it **include the following:**

- a. purpose of the experiment
- b. procedure/methodology used
- c. most important/significant results you found
- d. conclusions/research applications

Only minimal reference to previous work may be included.

### An abstract **must not include the following**:

- a. acknowledgments (including naming the research institution and/or mentor with which you were working), or selfpromotions and external endorsements
- b. logos or proper names of commercial products
- c. work or procedures done by the mentor

#### **Completing the Certification**

At the bottom of the Abstract & Certification form there are six questions. Please read each carefully and answer appropriately. The ISEF Scientific Research Committee will review and approve the abstract and answers to the questions.

Revisions are permitted via the online portal through late April (please reference the system for current year deadlines.)

Once approved, two copies of the ISEF Abstract & Certification will be provided with a gold embossed seal; only this version of the abstract may be displayed or distributed.

**NOTE:** Your abstract must be on the International Science and Engineering Fair Abstract & Certification form and have the ISEF Scientific Review Committee approval seal before it is displayed or handed out. No other format or version of your approved Abstract will be allowed for any purpose at the ISEF.

**ISEF Sample Abstract & Certification** 

| F           | PROJECT TITLE   | PROJECT ID  |
|-------------|---|---|
| F           | INALIST NAME(S)   |   |
| F           | FINALIST SCHOOL, CITY, STATE/PROVINCE, COUNTRY  | Category<br>Pick one only—mark an "X"<br>in box at right  |
|             | ABSTRACT BODY  As a part of this research project, the student direct   | Animal Sciences   Behavioral and Social Sciences   Biochemistry   Biomedical and Health Sciences   Biomedical Engineering   Cellular & Molecular Biology   Chemistry   Computational Biology and   Bioinformatics   Earth & Environmental Sciences   Embedded Systems   Earth & Environmental Sciences   Embedded Systems   Energy: Sustainable   Materials and Design   Engineering Technology:   Statics and Dynamics   Environmental Engineering   Materials Science   Mathematics   Microbiology   Physics and Astronomy   Plant Sciences   Robotics & Intelligent   Machines   Systems Software   Technology Enhances the Arts   Translational Medical Science |
| 1. <i>F</i> | or interacted with (check all that apply):  | у папагеа, татригасеа,  |
|             | <ul><li>☐ human participants</li><li>☐ vertebrate animals</li><li>☐ potentially haza</li><li>☐ microorganisms</li></ul> | rdous biological agents   |
| 2.          | This abstract describes only procedures performed our own independent research, and represents or up yes up no          |   |
| 3.          | I/We worked or used equipment in a regulated resindustrial setting.  ☐ yes ☐ no   | search institution or   |
| 4.          | This project is a continuation of previous research  ☐ yes ☐ no   |   |
| 5.          | My display board includes non-published photogr<br>humans (other than myself):<br>☐ yes ☐ no                            | aphs/visual depictions o  |
| 6.          | I/We hereby certify that the abstract and response ments are correct and properly reflect my/our ow yes no              |   |
|             |   |   |

### **Checklist for Adult Sponsor (1)**

This completed form is required for ALL projects.

To be completed by the Adult Sponsor in collaboration with the student researcher(s): Student's Name(s): Project Title: 1. 

I have reviewed the ISEF Rules and Guidelines, including the science fair ethics statement. ☐ I have reviewed the student's completed Student Checklist (1A) and Research Plan/Project Summary. ☐ I have worked with the student and we have discussed the possible risks involved in the project. The project involves one or more of the following and requires prior approval by an SRC, IRB, IACUC or IBC: ☐ Humans Potentially Hazardous Biological Agents ☐ Vertebrate Animals ☐ Microorganisms ☐ rDNA ☐ Items to be completed for **ALL PROJECTS** ☐ Adult Sponsor Checklist (1) ☐ Research Plan/Project Summary ☐ Student Checklist (1A) ☐ Approval Form (1B) Regulated Research Institutional/Industrial Setting Form (1C) (when applicable; after completed experiment) ☐ Continuation/Research Progression Form (7) (when applicable) Additional forms required if the project includes the use of one or more of the following (check all that apply): Humans, including student designed inventions/prototypes. (Requires prior approval by an Institutional Review Board (IRB); see full text of the rules.) Human Participants Form (4) or appropriate Institutional IRB documentation ☐ Sample of Informed Consent Form (when applicable and/or required by the IRB) Qualified Scientist Form (2) (when applicable and/or required by the IRB) Vertebrate Animals (Requires prior approval, see full text of the rules.) ☐ Vertebrate Animal Form (5A)-for projects conducted in a school/home/field research site (SRC prior approval required Uvertebrate Animal Form (5B)-for projects conducted at a Regulated Research Institution. (Institutional Animal Care and Use Committee (IACUC) approval required prior experimentation.) Qualified Scientist Form (2) (Required for all vertebrate animal projects at a regulated research site or when applicable) Potentially Hazardous Biological Agents (Requires prior approval by SRC, IACUC or IBC, see full text of the rules.) ☐ Potentially Hazardous Biological Agents Risk Assessment Form (6A) Human and Vertebrate Animal Tissue Form (6B)-to be completed in addition to Form 6A when project involves the use of fresh or frozen tissue, primary cell cultures, blood, blood products and body fluids. Qualified Scientist Form (2) (when applicable) The following are exempt from prior review but require a Risk Assessment Form 3: projects involving protists, archae and similar microorganisms, for projects using manure for composting, fuel production or other non-culturing experiments, projects using color change coliform water test kits, microbial fuel cells, and projects involving decomposing vertebrate organisms. Hazardous Chemicals, Activities and Devices (No SRC prior approval required, see full text of the rules.) Risk Assessment Form (3) Qualified Scientist Form (2) (required for projects involving DEA-controlled substances or when applicable) ☐ Other Risk Assessment Form (3) ☐ I attest to the information checked above and that I have read and agree to abide by the science fair ethics statement. Adult Sponsor's Printed Name Date of Review (mm/dd/yy) Signature

Email

Phone

### **Student Checklist (1A)**

#### This form is required for ALL projects.

| 1. | a. Student/Team Leader:   | Grade:   |  |  |
|----|---|--|--|--|
|    | Email:  | Phone:   |  |  |
|    | b. Team Member:   | c. Team Member:                                |  |  |
| 2. | Title of Project:   |  |  |  |
|    |   |  |  |  |
| 3. | School: (if multiple schools, list of the team leader or list all schools).   | School Phone:                                  |  |  |
| Sc | hool Address:   |  |  |  |
|    |   |  |  |  |
| 4. | Adult Sponsor:  | Phone/Email:                                   |  |  |
| 5. | Does this project need SRC/IRB/IACUC or other pre-  | approval? ☐ Yes ☐ No Tentative start date:     |  |  |
| 6. | 6. Is this a continuation/progression from a previous year? ☐ Yes ☐ No a. If yes, attach the previous year's ☐ Abstract <b>and</b> ☐ Research Plan/Project Summary b. Explain how this project is new and different from previous years on ☐ Continuation/Research Progression Form (7); include forms for all previous years |  |  |  |
| 7. | This year's experimentation/data collection (include  | forms for all previous years):                 |  |  |
|    | Actual Start Date: (mm/dd/yy)   | End Date: (mm/dd/yy)                           |  |  |
| 8. | Where will you conduct your experimentation? (chec  |  |  |  |
|    | ☐ Research Institution ☐ School ☐ Field   | ☐ Home ☐ Other:                                |  |  |
| 9. | Source of Data:  ☐ Collected self/mentor ☐ Other List all URL(  | s) in Research Plan:                           |  |  |
| 10 | List the name and address of all non-home and non virtually or on-site:   | -school work site(s), whether you worked there |  |  |
| Na | me  |  |  |  |
| Ad | dress:  |  |  |  |
| Ph | one/email   |  |  |  |

- 11. Complete a Research Plan/Project Summary following the Research Plan/Project Summary instructions and attach to this form.
- 12. An abstract is required for all projects after experimentation.

### **Research Plan/Project Summary Instructions**

### A complete Research Plan/Project Summary is required for ALL projects and must accompany Student Checklist (1A).

- 1. The Research Plan is to be written prior to experimentation following the instructions below to detail the rationale, research question(s), methodology, and risk assessment of the proposed research.
- 2. If changes are made during the research prior to competing in an affiliated fair, such changes can be added to the original research plan as an addendum, recognizing that some changes may require returning to the IRB or SRC for appropriate review and approvals. If no additional approvals are required, this addendum serves as a project summary to explain research that was conducted.
- 3. If no changes are made from the original research plan, no project summary is required.
  - Some studies, such as an engineering design or mathematics projects, will be less detailed in the initial project plan and will change through the course of research. If such changes occur, a project summary that explains what was done is required and can be appended to the original research plan.
  - The Research Plan/Project Summary should include the following:
    - a. **RATIONALE:** Include a brief synopsis of the background that supports your research problem and explain why this research is important and if applicable, explain any societal impact of your research.
    - b. **RESEARCH QUESTION(S), HYPOTHESIS(ES), ENGINEERING GOAL(S), EXPECTED OUTCOMES:** How is this based on the rationale described above?
    - c. Describe the following in detail:
      - · List of materials:
      - **Procedures:** Detail all procedures and experimental design including list of materials, methods for data collection, and when applicable, the source of data used. Describe your project delineating what you will do and what will be done by your mentor.
      - Risk and Safety: Identify any potential risks and safety precautions needed.
      - Data Analysis: Describe the procedures you will use to analyze the data/results.
    - d. **BIBLIOGRAPHY:** List major references (e.g. science journal articles, books, internet sites) from your literature review. If you plan to use vertebrate animals, one of these references must be an animal care reference.

### Items 1-4 below are subject-specific guidelines for additional items to be included in your research plan/project summary as applicable.

#### 1. Human participants research:

- a. **Participants:** Describe age range, gender, racial/ethnic composition of participants. Identify vulnerable populations (minors, pregnant women, prisoners, mentally disabled or economically disadvantaged).
- b. Recruitment: Where will you find your participants? How will they be invited to participate?
- c. **Methods:** What will participants be asked to do? Will you use any surveys, questionnaires or tests? If yes and not your own, how did you obtain? Did it require permissions? If so, explain. What is the frequency and length of time involved for each subject?
- d. **Risk Assessment:** What are the risks or potential discomforts (physical, psychological, time involved, social, legal, etc.) to participants? How will you minimize risks? List any benefits to society or participants.
- e. **Protection of Privacy:** Will identifiable information (e.g., names, telephone numbers, birth dates, email addresses) be collected? Will data be confidential/anonymous? If anonymous, describe how the data will be collected. If not anonymous, what procedures are in place for safeguarding confidentiality? Where will data be stored? Who will have access to the data? What will you do with the data after the study?
- f. **Informed Consent Process:** Describe how you will inform participants about the purpose of the study, what they will be asked to do, that their participation is voluntary and they have the right to stop at any time.

#### 2. Vertebrate animal research:

- $a. \ \ Discuss\ potential\ ALTERNATIVES\ to\ vertebrate\ animal\ use\ and\ present\ justification\ for\ use\ of\ vertebrates.$
- b. Explain potential impact or contribution of this research.
- c. Detail all procedures to be used, including methods used to minimize potential discomfort, distress, pain and injury to the animals and detailed chemical concentrations and drug dosages.
- d. Detail animal numbers, species, strain, sex, age, source, etc., include justification of the numbers planned.
- e. Describe housing and oversight of daily care.
- f. Discuss disposition of the animals at the end of the study.

#### 3. Potentially hazardous biological agents research:

- a. Give source of the organism and describe BSL assessment process and BSL determination.
- b. Detail safety precautions and discuss methods of disposal.

#### 4. Hazardous chemicals, activities & devices:

- a. Describe Risk Assessment process, supervision, safety precautions and specific methods of disposal.
- b. Safety Data Sheets are not necessary to submit with paperwork.

### **Approval Form (1B)**

A completed form is required for each student, including all team members.

| 1. To Be Completed by Student a. Student Acknowledgment:   | and Parent                                   |  |   |  |  |  |
|--|--|--|---|--|--|--|
| <ul> <li>I understand the risks and possible dangers to me of the proposed research plan.</li> <li>I have read the ISEF Rules and Guidelines and will adhere to all International Rules when conducting this research.</li> <li>I have read and agree to uphold all aspects of the student researcher ethics statement.</li> </ul>   |  |  |   |  |  |  |
| Student researchers are expected to maintain the highest standards of honesty and integrity. Scientific fraud and misconduct are not condoned at any level of research or competition. Such practices include but are not limited to plagiarism, forgery, use or presentation of other researcher's work as one's own, and fabrication of data. Fraudulent projects will fail to qualify for competition in affiliated fairs and ISEF. |  |  |   |  |  |  |
| b. Parent/Guardian Approval: I have a Research Plan/Project Summary. I   |  |  |   |  |  |  |
| Parent/Guardian's Printed Name   | Signature                                    |  | Date Acknowledged (mm/dd/yy) (Must be prior to experimentation.)  |  |  |  |
| 2. To be completed by the local o (Required for projects requiring prior   |  |  | es appropriate.)  |  |  |  |
| a. Required for projects that need prior SRC/IF BEFORE experimentation (humans, vertebra potentially hazardous biological agents).  The SRC/IRB has carefully studied this project's Reproject Summary and all the required forms are insignature indicates approval of the Research Plan Summary before the student begins experimental Summary before the student begins experimental states.  | tes or  Research Plan/ ncluded. My n/Project | Research Inst<br>approval. This project was co<br>(not home or high<br>by the proper insti-<br>complies with the | research conducted at all Regulated itutions with no prior fair SRC/IRB onducted at a regulated research institution school, etc.), was reviewed and approved tutional board before experimentation and ISEF Rules. Attach (1C) and any required ovals (e.g. IACUC, IRB). |  |  |  |
| SRC/IRB Chair's Printed Name   |  | SRC Chair's Printed  | d Name  |  |  |  |

### 3. Final ISEF Affiliated Fair SRC Approval (Required for ALL Projects)

Date of Approval (mm/dd/yy)
(Must be prior to experimentation.)

| SRC Approval After Experimentation and Before Competition at Regional/State/National Fair I certify that this project adheres to the approved Research Plan/Project Summary and complies with all ISEF Rules. |           |                             |  |  |
|---|-----------|-----------------------------|--|--|
| Regional SRC Chair's Printed Name   | Signature | Date of Approval (mm/dd/yy) |  |  |
| State/National SRC Chair's Printed Name (where applicable)  | Signature | Date of Approval (mm/dd/yy) |  |  |

Signature

Signature

Date of Signature (mm/dd/yy) (May be after experimentation)

### Regulated Research Institutional/Industrial Setting Form (1C)

This form must be completed AFTER experimentation by the adult supervising the student research either virtually or on site, conducted in a regulated research institution, industrial setting or any work site other than home, school or field.

| Student's Name(s)  |  |
|--|--|
| Title of Project   |  |
| To be completed by the Supervising Adult in the Setting (NOT the S<br>(Responses must be on the form as it is required to be displayed at student's  | •  |
| Research was supported at my work site:  1. The student experience at your work site included:  • Used equipment and/or received data  • Minimal interaction with our group  • Mentored by me or someone else from our group  • Worked as a sub-set of our ongoing research  • Had an independent project from our group | <ul> <li>□ Yes</li> <li>□ No</li> <li>□ Yes</li> <li>□ No</li> <li>□ Yes</li> <li>□ No</li> <li>□ Yes</li> <li>□ No</li> </ul> |
| <ol> <li>Please describe the independent and/or creative work done by the<br/>but particularly in developing the hypotheses or engineering goat</li> </ol>   |  |
| <ol> <li>Detail the student's role in conducting the research (e.g. data col<br/>Differentiate what the student observed and the student actually</li> </ol>   |  |
| 4. Provide details regarding data provided to the student:   |  |
| <ol> <li>Did the student(s) work on the project as part of a group?</li> <li>Were there other high school students present? If yes, please list was related or different from the work of this projecct.</li> </ol>  | ☐ Yes ☐ No<br>the students names and describe how their work   |
| 6. If this project is under a grant and needs to be acknolwedged, pl   | ease list the grant statement here.  |
| I attest that the student has conducted the work as indicated above and regulatory board (IRB/IACUC/IBC) has been obtained. Copies are attache student will be presenting this work publicly in competition and I have corequirements for my review and/or restrictions of what is publicized.                           | ed if applicable. I further acknowledge that the   |
| Direct Supervisor's Printed Name Signature   | Title  |
| Institution  | Date Signed (must be after experimentation) (mm/dd/yy)   |
|  | Fmail/Phone  |

### **Qualified Scientist Form (2)**

May be required for research involving human participants, vertebrate animals, potentially hazardous biological agents, and hazardous substances and devices. Must be completed and signed before the start of student experimentation.

| Student's Name(s)   |   |   |   |  |  |
|---|---|---|---|--|--|
| Title of Project  |   |   |   |  |  |
| To be completed by the Qualified So   |   |   |   |  |  |
| Scientist Name:Educational Background:  | D ()  |   |   |  |  |
| Experience/Training as relates to the stu   |   |   |   |  |  |
| Position/Institution:   | Email/Phone:  |   |   |  |  |
| <ol> <li>Have you reviewed the ISEF rules relative thics statement relevant to this</li> <li>Will any of the following be used?         <ul> <li>Human participants</li> <li>Animals</li> <li>Potentially hazardous biological at tissues, including blood and blood.</li> <li>Hazardous substances and devices</li> </ul> </li> <li>Will this study be a sub-set of a large.</li> <li>Will you directly supervise the studers</li> <li>Did you provide any data; if yes, please</li> </ol> | agents (microorganisms, rDNA and products) es er study? | ☐ Yes | □ No |  |  |

#### To be completed by the Qualified Scientist:

I certify that I have reviewed and approved the Research Plan/Project Summary prior to the start of the experimentation. If the student or Direct Supervisor is not trained in the necessary procedures, I will ensure her/his training. I will provide advice and supervision during the research. I have a working knowledge of the techniques to be used by the student in the Research Plan/Project Summary.

| Qualified Scientist's Printed Name |  |
|------------------------------------|--|
|                                    |  |

Signature

# To be completed by the Direct Supervisor when the Qualified Scientist cannot directly supervise.

I certify that I have reviewed the Research Plan/Project Summary and have been trained in the techniques to be used by this student, and I will provide direct supervision.

Direct Supervisor's Printed Name

Experience/Training of Designated Supervisor

Signature Date of Approval (mm/dd/yy)

Phone email

Date of Approval (mm/dd/yy)

### **Risk Assessment Form (3)**

Must be completed before experimentation; recommended for all projects. May be required for projects involving Human Participants, Hazardous Chemicals, Materials or Devices or Potentially Hazardous Biological Agents.

| Student's Name(s) |  |                          |                    |  |   |
|-------------------|--|--------------------------|--------------------|--|---|
|                   | Title of Project   |                          |                    |  |   |
|                   | o be completed by the Student Rescientist: (All questions must be answe  |                          |                    | · · · · · · · · · · · · · · · · · · ·        |   |
| 1.                | Identify and assess the risks and hazard   | ls involved in this proj | ject.              |  |   |
| 2.                | a) List all hazardous chemicals, activiti<br>are exempt from pre-approval (see Pot   |                          |                    |  | t |
| 3.                | Describe the safety precautions and princlude permits received and safety plants   |                          | e used to reduce t | the risks. If you conducted field work,      |   |
| 4.                | Describe the specific disposal procedu   | ures that will be used   | (when applicable   | e).  |   |
| 5.                | List the source(s) of safety information   |                          |                    |  |   |
| <br> <br>         | To be completed and signed by the lagree with the risk assessment and safet Research Plan/Project Summary and the Idirect supervision. | y precautions and pro    | ocedures describe  | ed above. I certify that I have reviewed the | • |
| ī                 | Direct Supervisor's Printed Name   | Signature                |                    | Date of Review (mm/dd/yy)                    | _ |
| -                 | Experience/Training as relates to the student's are  | ea of research           |                    |  | _ |
| -                 | Position/Institution   |                          | Phone or e         | email contact information                    | _ |

### **Human Participants Form (4)**

Required for all research involving human participants not at a Regulated Research Institution. If at a Regulated Research Institution, use institutional approval forms for documentation of prior review and approval. (IRB approval required before recruitment or data collection.)

| Student's Name(s)   | Title of Project                           |                                |  |  |  |
|---|--|--------------------------------|--|--|--|
| Adult Sponsor  MUST BE COMPLETED BY STUDENT RESEARCHER(S) IN COLLABO  | Phone/Email  PRATION WITH THE ADULT SPONSO | DR/DIRECT SUPERVISOR/QUALIFIED |  |  |  |
| SCIENTIST:  1.  |  |                                |  |  |  |
| BELOW   | - IRB USE ONLY                             |                                |  |  |  |
| MUST be completed by Institutional Review Board (IRB) after review of the research plan. All questions must be answered for the approval to be valid. (If not approved, return paperwork to the student with instructions for modifications.)    Approved with Full Committee Review (3 signatures required) and the following conditions: (All 6 must be answered)   Risk Level (check one): |  |                                |  |  |  |
| physician's assistant, doctor of pharmacy, or registered nurse) wit Print Name below  | Degree/Professional License                |                                |  |  |  |
| Signature   | Date (prior to experimentation)            | Email                          |  |  |  |
| Educator Print Name below Degree/Professional License   |  |                                |  |  |  |
| Signature   | Date (prior to experimentation)            | Email                          |  |  |  |
| School Administrator  |  |                                |  |  |  |
| Print Name below  | Degree/Professional License                |                                |  |  |  |
| Signature   | Date (prior to experimentation)            | Email                          |  |  |  |

### **Human Informed Consent Form**

**Instructions to the Student Researcher(s):** An informed consent/assent/permission form should be developed in consultation with the Adult Sponsor, Direct Supervisor or Qualified Scientist.

This form is used to provide information to the research participant (or parent/guardian) and to document written informed consent, minor assent, and/or parental permission.

- When written documentation is required, the researcher keeps the original, signed form.
- · Students may use this sample form or may copy ALL elements of it into a new document.

| the form is serving to document parental permission, a copy of any survey or questionnaire must be attached.        |  |  |  |
|---|--|--|--|
| Student Researcher(s):  |  |  |  |
| Title of Project:   |  |  |  |
| I am asking for your voluntary participation in my sci<br>project. If you would like to participate, please sign in | ence fair project. Please read the following information about the n the appropriate area below.                         |  |  |
| Purpose of the project:   |  |  |  |
| If you participate, you will be asked to:   |  |  |  |
| Time required for participation:  |  |  |  |
| Potential Risks of Study:   |  |  |  |
| Benefits:   |  |  |  |
| How confidentiality will be maintained:   |  |  |  |
| If you have any questions about this study, feel free t   | o contact:   |  |  |
| Adult Sponsor/QS/DS:  | _ Phone/email:   |  |  |
|   | you decide not to participate there will not be negative participate, you may stop participating at any time and you may |  |  |
| By signing this form I am attesting that I have read ar assent to participate or permission for my child to pa      | nd understand the information above and I freely give my consent/articipate.   |  |  |
| Adult Informed Consent or Minor Assent  | Date Reviewed & Signed:(mm/dd/yy)  |  |  |
| Research Participant Printed Name:  | Signature:   |  |  |
| Parental/Guardian Permission (if applicable)  | Date Reviewed & Signed:(mm/dd/yy)  |  |  |
|   |  |  |  |

Signature:

Parent/Guardian Printed Name:

### **Vertebrate Animal Form (5A)**

Required for all research involving vertebrate animals that is conducted in a school/home/field research site. (SRC approval required before experimentation.)

| Student's Name(s)  |   |   |   |  |  |
|--|---|---|---|--|--|
| Title of Project   |   |   |   |  |  |
|  |   |   |   |  |  |
| To be completed by S   | tudent Researcher:  |   |   |  |  |
| 1. Common name (or G   | enus, species) and number of a  | nimals used.  |   |  |  |
| per cage, environme  | 2. Describe completely the housing and husbandry to be provided. Include the cage/pen size, number of animals per cage, environment, bedding, type of food, frequency of food and water, how often animal is observed, etc. Add an additional page as necessary.  |   |   |  |  |
| 3. What will happen to t   | he animals after experimentation  | on?   |   |  |  |
| 4. Attach a copy of wild   | life licenses or approval forms,  | as applicable                                       |   |  |  |
| documented by a let  |   | direct supervisor or a ve                           | ed weight loss be investigated and terinarian. If applicable, attach this mpetition.                                    |  |  |
| Level of Supervision Rolling Direct Supervisor Rolling Veterinarian and Dilling Veterinarian, Direct the Qualified Scien The SRC has carefully review  | To be completed by Local or Affiliate Fair Scientific Review Committee (SRC) BEFORE experimentation.  Level of Supervision Required for agricultural, behavioral or nutritional studies (select one):  Direct Supervisor REQUIRED. Please have applicable person sign below.  Veterinarian and Direct Supervisor REQUIRED. Please have applicable persons sign below.  Veterinarian, Direct Supervisor and Qualified Scientist REQUIRED. Please have applicable persons sign below and have the Qualified Scientist complete Form (2).  The SRC has carefully reviewed this study and finds it is an appropriate study that may be conducted in a non-regulated research site.  Local or affiliate fair SRC pre-approval signature: |   |   |  |  |
| SRC Chair Printed Name   | Signature   |   | of Approval (must be prior to imentation) (mm/dd/yy)  |  |  |
| To be completed by V   | eterinarian:  |   | by Direct Supervisor or Qualified   |  |  |
| <ul> <li>□ I have reviewed this research and animal husbandry with the student before the start of experimentation.</li> <li>□ I have approved the use and dosages of prescription drugs and/or nutritional supplements.</li> <li>□ I will provide veterinary medical and nursing care in case of illness or emergency. (Fees may apply.)</li> </ul> |   | the student before accept primary of the animals in | this research and animal husbandry with ore the start of experimentation and I responsibility for the care and handling |  |  |
| Printed Name   | Email/Phone   | Printed Name  | Email/Phone   |  |  |
| Signature  | Date of Approval (mm/dd/vv)   | Signature   | Date of Approval (mm/dd/yy)   |  |  |

### **Vertebrate Animal Form (5B)**

Required for all research involving vertebrate animals that is conducted in at a Regulated Research Institution. (IACUC approval required before experimentation. Form must be completed and signed after experimentation.)

| St | Student's Name(s)  |  |  |  |  |  |
|----|--|--|--|--|--|--|
| Ti | itle of Project  |  |  |  |  |  |
|    | Title and Protocol Number of IACUC Approved Project  |  |  |  |  |  |
|    | o be completed by Qualified Scientist or Principal Investigator:  Species of animals used: Number of animals used:   |  |  |  |  |  |
|    |  |  |  |  |  |  |
| 2. | Describe, in detail, the role of the student in this project: animal procedures and related equipment that were involved, oversight provided and safety precautions employed. (Attach extra pages if necessary.)       |  |  |  |  |  |
| 3. | . Was there any weight loss or death of any animal? If yes, attach a letter obtained from the qualified scientist, direct supervisor or a veterinarian documenting the situation and the results of the investigation. |  |  |  |  |  |
| 4. | . Did the student's project also involve the use of tissues? □ No □ Yes; complete Forms 6A and 6B  |  |  |  |  |  |
| 5. | What laboratory training, including dates, was provided to the student?  |  |  |  |  |  |
| 6. | . Attach a copy of the Regulated Research Institution IACUC Approval. A letter from the Qualified Scientist or Principal Investigator is not sufficient.   |  |  |  |  |  |
|    | Qualified Scientist/Principal Investigator   |  |  |  |  |  |
| -  | Printed Name   |  |  |  |  |  |
| -  | Signature Date (mm/dd/yy)  |  |  |  |  |  |

### Potentially Hazardous Biological Agents Risk Assessment Form (6A)

Required for research involving microorganisms, rDNA, fresh/frozen tissue (including primary cell lines, human and other primate established cell lines and tissue cultures), blood, blood products and body fluids.

SRC/IACUC/IBC approval required before experimentation.

| Studer   | nt's Name(s)   |  |  |
|----------|--|--|--|
| Title of | Project  |  |  |
|          |  |  | CT SUPERVISOR in collaboration with the student researcher(s). additional page(s) may be attached.   |
| 1. Ider  |  |  | e used in this experiment. Include the strain, source, quantity<br>nism.   |
| 2. Des   | cribe the biosafety lev  | vel of the experimentation :   | site.  |
| 3. Des   | cribe the procedures   | that will be used to minimi  | ze risk (personal protective equipment, safety cabinet type, etc.).  |
|          |  | lisposal of all cultured mate<br>an RRI, include the <u>BSL-2</u> o  | erials and other potentially hazardous biological agents.  Checklist   |
|          | N 2: TRAINING at training will the stud                              | dent receive for this projec   | :?   |
| 2. Exp   | erience/training of Di   | ect Supervisor as it relates   | to the student's area of research (if applicable).   |
| SECTION  | ON 3: For ALL CELL L   | <br>INES, MICROORGANISMS   | AND TISSUES – To be completed by the QUALIFIED SCIENTIST   |
| or Dire  | ct Supervisor - Chec<br>Experimentation on t<br>Regulated Research I | k the appropriate box(es) I<br>he microorganisms/cell lines<br>institution, but will be condu<br>SL-2. [This study has been re   |  |
|          | or higher lab at a Reg   |  | esistant Organisms (MDROs). It has been conducted in a BSL-2 and the required IBC pre-approval is attached.  |
|          | Research Institution a approval forms are at                         | and was approved by the approv | r/tissues to be used in this study will be conducted at a Regulated propriate institutional board prior to experimentation; institutional                  |
|          | Origin of cell lines:  |  | Date of IBC/IACUC approval   |
|          |  | he microorganisms/cell lines<br>re IACUC or IBC approval for   | /tissues to be used will be conducted at a Regulated Research Institution, this type of study.   |
| CERTI    | FICATION-To be SIG   | NED by the QUALIFIED SC  | IENTIST or Direct Supervisor   |
|          | ed above. This study ha  |  | orting documentation and acknowledges the accuracy of the information one) $\square$ BSL-1/ $\square$ BSL-2 study, and will be conducted in an appropriate |
| QS/DS F  | Printed Name   | Signature  | Date of review (mm/dd/yy)  |

### **Human and Vertebrate Animal Tissue Form (6B)**

Required for research involving fresh/frozen tissue (including primary cell lines, human and other primate established cell lines and tissue cultures), blood, blood products and body fluids. If the research involves living organisms please ensure that the proper human or animal forms are completed. All projects using any tissue listed above must also complete Form 6A.

| St           | rudent's Name(s)   |  |  |
|--------------|--|--|--|
| Tit          | tle of Project   |  |  |
| То           | be completed by Student Rese   | archer(s):   |  |
| 1.           | What vertebrate animal tissue will be  ☐ Fresh or frozen tissue sample ☐ Fresh organ or other body pa ☐ Blood ☐ Body fluids ☐ Primary cell/tissue cultures ☐ Human or other primate esta | e<br>art   | that apply.  |
| 2.           | Where will the above tissue(s) be o  | obtained? If using an establ   | olished cell line include source and catalog number.   |
| 3.           |  | ame of the research institut   | conducted at a research institution attach a copy of<br>ition, the title of the study, the IACUC approval num-<br>ed, attach a copy of IRB approval. |
|              | him/her by myself or qualified person<br>were euthanized for a purpose othe<br>AND/OR  I certify that the blood, blood produ   | plely with de-identified organs, connel from the laboratory; and the rthan the student's research.  Sucts, tissues or body fluids in the student's research. | s, tissues, cultures or cells that will be supplied to<br>d that if vertebrate animals were euthanized they  |
| F            | Printed Name   | Signature  | Date of Approval (mm/dd/yy) (Must be prior to experimentation.)  |
| <del>-</del> | Title  |  | Phone/Email  |
| Ī            | Institution  |  |  |

### **Continuation/Research Progression Projects Form (7)**

Required for projects that are a continuation/progression in the same field of study as a previous project. This form must be accompanied by the previous year's abstract and Research Plan/Project Summary.

| Components                             | <b>Current Research Project</b>        | Previous Research Project: Year: |
|--|--|----------------------------------|
| . Title                                |  |                                  |
| . Change in goal/<br>purpose/objective |  |                                  |
| 3. Changes in methodology              |  |                                  |
| 1. Variable studied                    |  |                                  |
| 5. Additional<br>changes               |  |                                  |
| ttached are:                           | ract and Research Plan/Project Summary | / Vear                           |

The Regeneron International Science and Engineering Fair encourages students to tackle challenging scientific questions and develop the skills needed to solve the problems of tomorrow.

#### **About Society for Science**

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#### **About Regeneron**

Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents, develops and commercializes life-transforming medicines for people with serious diseases. Founded and led by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to numerous approved treatments and product candidates in development, most of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, neurological diseases, hematologic conditions, infectious diseases, and rare diseases.

Regeneron believes that operating as a good corporate citizen is crucial to delivering on our mission. We approach corporate responsibility with three goals in mind: to improve the lives of people with serious diseases, to foster a culture of integrity and excellence and to build sustainable communities. Regeneron is proud to be included on the Dow Jones Sustainability World Index and the Civic 50 list of the most "community-minded" companies in the U.S. Throughout the year, Regeneron empowers and supports employees to give back through our volunteering, pro bono and matching gift programs. Our most significant philanthropic commitments are in the area of early science education, including the Regeneron Science Talent Search and the Regeneron International Science and Engineering Fair (ISEF).

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