CERTIFICATION FOR REGULATED RESEARCH IN INSTITUTIONAL OR INDUSTRIAL SETTINGS

This form must be completed AFTER experimentation is completed by the adult supervising (e.g. Principal Investigator) the student research conducted in a REGULATED research institution, industrial setting, or any work site other than home, school, or the field. You must submit this form to the OCSEF Scientific Review Committee (SRC) for review AFTER completion of experiments. The student is still responsible for submitting all appropriate completed and signed Certification Forms (e.g. Certifications for Vertebrate Animals, Hazards Control, or Vertebrate Tissues) to the SRC BEFORE research begins.

PLEASE TYPE OR PRINT

Name of Entrant (Last Name, First Name)	School Name
Project Title	

What is a Regulated Research Institution or Industrial Setting?

A Regulated Research Institution within the U.S. is defined as a professional research/teaching institution that is regularly inspected by the USDA and is licensed to use animals covered by the Animal Welfare Act and may also be subject to U.S. Public Health Service Policy. Also included are all federal laboratories such as National Institutes of Health, Veteran's Affairs Medical Centers and the Centers for Disease Control. In addition, pharmaceutical and biotechnology companies and research institutions that utilize research animals that are not covered by the Animal Welfare Act but have an operational Institutional Animal Care and Use Committee and are in compliance with U.S. federal laws are included in this definition. For 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.

In addition to research involving animals, certain areas of research conducted in a regulated research institution or an industrial setting require review and approval by federally mandated regulatory boards that have been established at that institution. These regulatory boards include:

1. Institutional Animal Care and Use Committee (IACUC); Animal Care and Use Committee (ACUC); Animal Ethics Committee
2. Institutional Review Board (IRB); Human Subjects Participant Program (HSPP)
3. Institutional Biosafety Committee (IBC) - for specific Recombinant DNA [rDNA] research studies
4. Embryonic Stem Cell Research Oversight Committee (ESCRO)
5. Safety Review Committee (all studies involving potential chemical, biological or physical hazards)

The student conducting a project in a regulated setting must have the Adult Supervisor/Principal Investigator at that institution complete this Form and provide the applicable regulatory board approvals after experimentation has been completed to the OCSEF Scientific Review Committee in order to participate in the competition.

The student conducting a project in a regulated setting must have the Adult Supervisor/Principal Investigator at that institution complete this Form and provide the applicable regulatory board approvals after experimentation has been completed to the OCSEF Scientific Review Committee in order to participate in the competition.

Rules for Projects Involving Potentially Hazardous Biological Agents, Hazardous Chemicals Activities or Devices conducted in a Registered Research Institution.

If a study is conducted at either a non-regulated site (e.g. school, home or field) or regulated site; the SRC reviews and approves the Certification of Hazards Control provided by the OCSEF and completed by the student, parent or guardian and teacher/supervising scientist.

1. For studies conducted at a Regulated Research Institution, the student must **provide the SRC a copy of the approval document(s) by the appropriate institutional review committee** (e.g. IBC and/or Biosafety Committee) attached to this Certification for Regulated Research Form.
2. If a potentially hazardous biological agents study (microorganisms, rDNA, fresh/frozen tissue, primary cells lines, human and primate cell lines, tissue cultures, blood and blood products and body fluids) was conducted at a Regulated Research Institution but the institution does not require review for this type of study or the review committee does not exist, a letter from an institutional representative documenting either situation must be obtained. The SRC must review and approve the study, assign a Biosafety level, document approval that the student received appropriate training and that the project complies with Intel ISEF rules, before experimentation begins.
3. **Student use or handling of ethidium bromide or gels stained with ethidium bromide is prohibited.** They must be handled only by qualified lab personnel.
4. All studies using U.S. Drug Enforcement Administration (DEA) regulated, controlled substances (CS) must be supervised by a Qualified Scientist who is licensed by the DEA or other international regulatory body. All studies using Schedule 1 DEA CSs must be approved by the DEA before research begins. Schedule 2, 3 and 4 substances do not need DEA approval.

Rules for Projects Involving Human participants conducted in a Registered Research Institution.

Student researchers must follow federal guidelines (Code of Federal Regulations 45 CFR 46) to protect the human research participant and the student researcher. When students conduct research with humans and a Regulated Research Institution, the rights and welfare of the participants must be protected. Most human participant studies will require preapproval from an Institutional Review Board (IRB)/Human Research Protection Program (HRPP) and informed consent/assent from the research participant.

1. The student must **provide the SRC a copy of the IRB Committee approval document attached to this Certification for Regulated Research Form**.
2. Students must **complete the OCSEF Certification of Compliance for Research Involving Human Subjects and obtain approval before research begins.**
3. Students are prohibited from administering prescription drugs to human participants.

Rules for Projects involving Vertebrate Animals.

Projects eligible for competition not done at home/school or the field must be done at Regulated Research Institutions. Some protocols permitted in a Registered Research Institution are not permitted for participation in the Intel ISEF; adherence to RRI rules is necessary but may not be sufficient.

1. The Institutional Animal Care and Use Committee (IACUC) or the comparable animal oversight committee must approve all student research projects before experimentation begins. Such research projects must be conducted under the responsibility of a principal investigator. The local and regional SRC must also review the project to certify that the research project complies with Intel ISEF Rules. This local and regional SRC review should occur before experimentation begins, if possible.
2. Student researchers are prohibited from performing euthanasia. Euthanasia at the end of experimentation for tissue removal and/or pathological analysis is permitted. All methods of euthanasia must adhere to current American Veterinarian Medical Association (AVMA) Guidelines.
3. Research projects that cause more than momentary or slight pain or distress to vertebrate animals are prohibited unless approved anesthetics, analgesics and/or tranquilizers are used.
4. Research in nutritional deficiency or research involving substances or drugs of unknown effect is permitted to the point that any clinical sign of distress is noted. In the case that distress is observed, the project must be suspended and measures must be taken to correct the deficiency or drug effect. A project can only be resumed if appropriate steps are taken to correct the causal factors.
5. **A veterinarian must supervise student administration of prescription drugs to vertebrate animals.**

Rules for Projects involving Embryonic Human Stem Cells.

Studies involving embryonic human stem cells must be conducted in a Registered Research Institution and reviewed and approved by the ESCRO (Embryonic Stem Cell Research Oversight) Committee.

1. The student must **provide the SRC a copy of ESCRO Committee approval document attached to this Certification for Regulated Research Form.**

The student conducting a project in a regulated setting must have the Adult Supervisor/Principal Investigator at that institution complete this Form and provide the applicable regulatory board approvals after experimentation has been completed to the OCSEF Scientific Review Committee in order to participate in the competition.

CERTIFICATION OF PRINCIPAL INVESTIGATOR/ADULT SUPERVISOR AT REGULATED RESEARCH INSTITUTION

To be completed after experimentation by the Supervising Adult in the Regulated Setting (NOT the Student).

1. The student(s) conducted research at my work site:
   a. ☐ to only use equipment
   b. ☐ to perform experiments/conduct research
2. Is the student's research a subset of your work?
   a. ☐ Yes
   b. ☐ No
3. How did the student get the idea for her/his project (e.g. was the project assigned, picked from a list, an original student idea, etc.)?
4. Did the student work on the project as a part of a research group? If yes, how large was the group and what kind of research group was it (students, group of adult researchers, etc.)?
   a. ☐ Yes
   b. ☐ No
5. What specific procedure or equipment did the student(s) actually use for the project? Please list and describe. (Do not list procedures student only observed.)
6. How independent or creative was the student's work?

I certify that I have reviewed the ISEF rules relevant to this project at the website for the International Fair at https://student.societyforscience.org/intel-isef-forms and will attach all applicable approval Forms attesting to the required review by the institutional regulatory board (IRB, IACUC, IBC, Safety Committee, ESCRO). **The student must submit this Form with the attached approvals to the OCSEF Scientific Review Board after the experiments are completed in order to participate in the competition.**

Supervising Adult/Principal Investigator Name (Print)	Signature	
Institution	Title	Date Signed
Address	Email / Phone	